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PONI: An Intelligent Alarm System for Respiratory and Circulatory Management in the Operating Rooms

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A Thesis Deposited for the Degree of Doctor of Philosophy



City University

Department of Systems Science

June 1989

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[REDACTED] I appreciate the help of [REDACTED] [REDACTED] for reading earlier drafts of this thesis. I especially appreciate the patience of each of the physicians mentioned above, who have exposed me to monitoring-equipment.

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ABSTRACT

PONI is an interrelated system of computer hardware and software, which monitors patients in the operating rooms and performs related decision making functions. PONI gathers, analyses and collates physiological data about these patients. Its physiological monitoring function is used to chart the patient's state of ventilation, circulation, and all variables which may alter in life-threatening situations. PONI analyses such parameters as heart rate, blood pressure and respiratory gas content, and provides speedy notice, in the form of cautions and alarms when corrective action is needed. In current practice, the large number of false positive alarms signalling no harm to the patient, is a considerable problem. PONI addresses the problem by comparing and validating instrument readings in this situation involving a knowledge base whose core is a set of 46 rules. This information has been analysed statistically and has suggested the knowledge rules for monitoring of the patient population. The rules were applied to 25,507 warnings (20,471 cautions and 5,036 alarms) from 157 Day Surgery Unit patients undergoing 201 hours of surgery. Most of the cautions were validated by the system analysis, but 2,757 of the 5,036 alarms were invalidated, 1,082 were validated, and 1,197 left indeterminate. From a total of 25,507 alarms, the system validated 19,354, invalidated 3,284 and left in an indeterminate state 2,869. Thus, PONI points up a potential reduction from one alarm every 4 minutes to one every 16 minutes. It is planned to expand the knowledge rules of the prototype expert system seeking to maximise the efficacy of alarm information regarding patient management with the immediate aim of minimising the number of false positive alarms.

KEY FOR SYMBOLS & ABBREVIATIONS

1. INTRODUCTION

1.1 Background

Predicate Calculus

Meaning

$\neg \alpha$

not α

$\alpha \wedge \beta$

α and β

$\alpha \vee \beta$

α or β

$\alpha \supset \beta$

α implies β

$\alpha \equiv \beta$

α is equivalent to β

$\forall v, P$

P is true whatever v stands for.

$\exists v, P$

There is something that v can stand for such that P is true.

1. INTRODUCTION

1.1 Background

Operating room personnel, especially anaesthetists, require pertinent physiological data to be readily available. Quick and accurate decisions must be made in life-threatening situations. In recent years newly-developed instrumentation and computer-aided technology have made an unprecedented amount of physiological data available to clinicians in the operating rooms (ORs). Physiological monitoring originated and was developed based on the premise that more patient data would result in better patient care [172]. Additional data were expected to improve the timeliness and appropriateness of medical decisions, reduce the number of oversights, and facilitate training of those specialising in intensive care [20]. However, so much data are becoming available that it will soon be difficult to assimilate and use them effectively [231]. Important factors may become obscured or forgotten in the midst of numerous less important ones [20]. Devices monitoring additional physiological signals have generated a plethora of new indices and models for patient care and are put in use, evaluated and then replaced. The explosion in the data collection has caused confusion and uncertainty in both the medical community and the instrumentation industry [231][21].

Yet, the idea of using computer technology in the ORs remains irresistible. In this environment the physician and nurse encounter a large amount of information gathered from the patient or from other departments and laboratories. By organising, displaying or manipulating these data, the computer should be able to assist the physician and nurse to improve direct patient care [129]. However, it is very possible to implement a computer system and realise no real benefit; in fact, such systems can become a liability.

The major advantage of computer-based systems is their ability to acquire and store large amounts of data which can be processed for presentation in the clearest manner, thus assisting in overall patient management. In recent years the advent of cheap microcomputers has led to an increase in their use as part of patient monitoring equipment, particularly in Intensive Care Units (ICUs) and Operating Room (OR) suites [62]. These applications acquire and display data by methods which augment or replace more traditional methods of recording such as pen recorders.

One of the drawbacks of using chart recorders when monitoring is that the choice of the paper feed rate can be very important in determining which features show up most clearly. Arterial pressure, pulse waveforms, for instance, will be clearly seen with a fast chart speed, but longer term trend variations will be difficult to recognise [62]. Conversely a very slow feed, although showing up long-term trends, will tend to obscure the more transient features. A computer-based system is flexible enough to overcome these conflicting requirements, and to perform a number of additional functions.

Long-term pressure monitoring (for example arterial pressure and central venous pressure) is an obvious application for such a system and a number of groups have already implemented this idea [1][66]. However, in most examples reported in the literature, expensive computer or constructed specialised electronics or hardware making it difficult for others in the field to adopt the techniques [62].

1.2 Objectives of the thesis

Safe and effective use of anaesthesia equipment continues to be elusive. Users and manufacturers achieve success only after years of experience and serious analysis of positive and negative incidents. Negative incidents result from equipment malfunctions or from user error [230]. Each negative incident should be examined thoroughly to

determine its cause. Results should be made available to the manufacturer, the user who first experienced the problem, and to all others who have such equipment in order to point the way for corrective action and obviate similar problems.

Many detailed reviews of device hazards and incidents have appeared over the years [203]. If the review traces hazards to faulty engineering, the manufacturers usually correct the problem. Industry-wide standard requirements have been generated due to accounts of device failures [230]. Unfortunately, users do not always benefit from the available literature. They may be aware of the failures others experience, but do not incorporate that knowledge into their daily use of the technology even when faced with a similar incident.

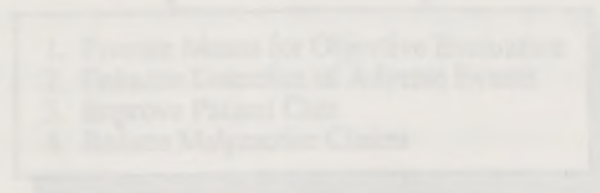


FIGURE 1-1. Research Objectives.

It is the author's intent to provide a common ground for appreciating what makes the work important in this theme, special as a whole. This thesis will also help the understanding of the diverse medical, computer and systems science knowledge and the research emphases of the individual chapters.

The goals of the thesis (Figure 1-1) are:

1. To provide means for objective evaluation.

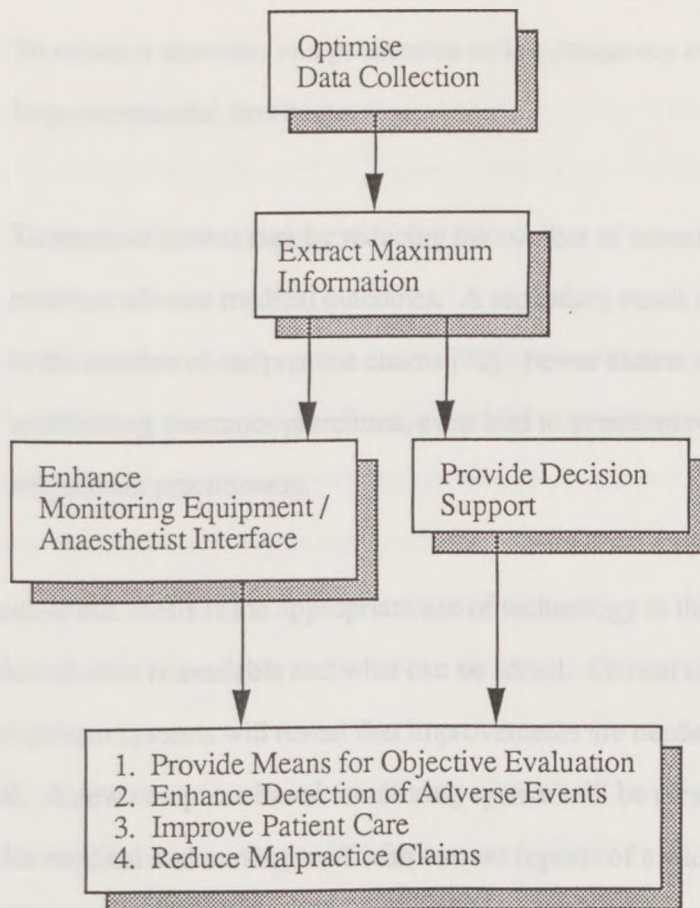


FIGURE 1-1. Research Objectives.

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The goals of this thesis (Figure 1-1) are:

- ◇ To provide means for objective evaluation.

- ◇ To enhance detection and publication of low-frequency events by providing a large experiential data base.
- ◇ To improve patient care by reducing the number of anaesthesia accidents and resultant adverse medical outcomes. A secondary result should be a reduction in the number of malpractice claims [70]. Fewer claims may serve to slow accelerating insurance premiums, even lead to premium reduction for anaesthesia practitioners.

The focus of this thesis is the appropriate use of technology in the ORs, with a discussion of what is available and what can be added. Critical examination of several facets of present systems will reveal that improvements are needed to realise their potential. A new computer-based monitoring system will be presented that is expected to provide medical and nursing staff with current reports of a wide range of measured, observed and derived variables. The new system will aid present technology to realise its potential [129]. It will manipulate, organise and accelerate the availability of data. Plus, it is expected that the computer-based system will improve patient care, provide data for teaching and research, and result in increased staff efficiency.

1.3 Organisation of the thesis

To ensure that the work is understood by the Systems Science, Medical Science and Computer Science reader, continual emphasis has been put on providing reading support in those areas. The basic principles of Anaesthesia and physiological data collection are presented in Chapter 2 as both an introduction to the physiological monitoring and also to the significance of alarms in the clinical setting (the underlying issue of this thesis). This implies a move away from the more traditional static analysis of clinical decision making, towards real-time modelling for decision support in the ORs.

A detailed analysis of the anaesthetist's problem in both respiratory and circulatory environments follows in Chapter 3. Chapter 4 discusses a variety of approaches which have been tried in this area and associated prototypes.

The role of knowledge and data information is discussed in Chapter 5 at a practical level, where data and knowledge collection are the main themes. In contrast, Chapter 6 is detailed in nature, describing the PONI system in a more analytical way. In this context, the objective of Chapter 6 is to consider in some detail the modelling process, by investigating modelling philosophy, methodology and techniques. This has been achieved by considering systems, mathematical and logical approaches.

Although Chapter 6 carries its own validation (statistical analysis and so on) it was found necessary to make an extensive evaluation of PONI, which is reported in Chapter 7.

The overall conclusions of Chapter 8 draw to a close this essentially focussing project by identifying contributions that have been made to systems and medical science, and also by suggesting specific areas where future developments are important, and hence, would enhance the wider research program.

In summary, Chapters 2 through to 4 provide a conceptual introduction, Chapter 5 tackles the knowledge aspect, while Chapter 6 and 7 take a practical and then theoretical look at the research goals.

2. ANAESTHESIA AND PHYSIOLOGICAL DATA COLLECTION

2.1 Introduction

Having in the previous chapter considered the objectives and goals of the PONI research and briefly discussed the chapters presented in this thesis, this chapter will now provide an introduction to the physiological monitoring and also to the significance of alarms in the clinical setting.

Despite all the problems, computerised monitoring systems have nevertheless proliferated in the past two decades. Computers can monitor a myriad of parameters by direct measurement or by derived calculations [55]. Computers can be used as well to manage certain aspects of care, such as intravenous fluid rates, based on concurrent data acquisition and analysis.

The most frequently computer-monitored parameters include the electrocardiogram (ECG), arterial blood pressure, and temperature. Additional variables selected are continuous monitoring of other vital signs (such as respiration, pulmonary artery pressure, central venous pressure, and intracranial pressure, monitoring and analysis of cardiac rhythm), and monitoring of intake and output. Activities may include measuring of respiratory parameters such as tidal volume and peak airway pressure, sampling and analysis of blood gases, and monitoring of intravenous and vasoactive drug therapy [55]. The computer also calculates physiological data such as systemic vascular resistance, pulmonary vascular resistance, left and right cardiac work, left and right ventricular stroke work, oxygen extraction ratio and arteriovenous oxygen difference. It can present a computerised trend analysis, and generate reports of selected parameters (Table 2-3).

Rarely does the opportunity arise to introduce a complete monitoring system, totally new in design and concept, under circumstances in which the user has no alternative to that system. However, monitoring is not merely gadgets [18]. In the development of monitoring devices, much attention is paid to the physics and physiology of the measurements and to the pharmacological needs of patients. The needs of users, which are even more diverse than these of patients, are more difficult to address.

2.2 Historical Background

In 1966 Weil, Shubin and Rand [254] were among the first few to report the utilisation of a digital computer in intensive care. Once such a computer allowed for the study of the interplay of multiple measurements, interest soared [218]. Once problems relating to the collection of physiological information and to the elaboration of parameters were solved, the computer was asked to do more and more: ECG analysis, blood gas analysis processing, record keeping, staff assignment, storage and display of all kinds of data decision making etc. [145]. Eventually, computers were asked for help with delicate therapeutic decisions and applications, thus creating a loop encompassing medical personnel, the machine and the patient.

However, the initial enthusiastic phase was followed by what may be called the ebb phase. Investigators and hospital administrators expressed their concern on the usefulness of computers in medicine and in other fields. This critical attitude was due in part to the economic recession of the 1970s. After a period of free spending, more rational considerations on cost-benefit ratio were being adopted and the cost of computer monitoring was being questioned, then new technological advancements in both hardware and software developed, and a better understanding of computer potential coupled with the advertising from commercial-enterprises promoted a new phase of enthusiastic acceptance. We are still in that stage [145].

Computer science has been able to take advantage of the technological advances which accompany periods of military activity and are associated with challenging and innovative undertakings such as the present space program [14]. Some contributions of this endeavour to world health derive directly from efforts to ensure the health, safety and welfare of astronauts during flight. Other contributions have their origins in portions of the space program unrelated to the life sciences effort. Such discoveries are highly significant and fortuitous for the health industry.

Mercury, Gemini and Apollo bioinstrumentation requirements were generally dictated by weight/volume constraints and by the distance between the crew and their medical monitors. Thus the hardware had to be miniaturised, highly reliable and noninterfering in nature, and the bioelectric signals had to be telemetered back to Earth with maximum fidelity.

In continuing development, signal conditioners have been reduced in size enabling them to be used at or close to the signal source, thereby improving the quality of the signal. Many of the physiological monitoring systems have found widespread application in comprehensive hard-line monitoring of patients in intensive and coronary care units, isolation rooms or OR during surgery and anaesthesia [14]. In time, some of the biotelemetry systems may supersede the hard-line approach for most physiological parameters. They may be applied as well to telestimulation in addition to telemetry as tools of the psychophysicist. In telestimulation, electric stimuli are transmitted by wireless to implanted brain depth electrodes and behavioural responses are elicited via electromagnetic coupling to the stimulus source.

Although use of computerised monitoring systems in critical-care units has increased in the past 10 years, only about 100 such systems currently function in the United States,

supplied by six or seven major vendors, including Hewlett-Packard, Mennen, SpaceLabs, Siemens, and Kontron [55].

Problems with anaesthesia equipment must have appeared with the introduction of anaesthesia. There was little to go wrong with the early drawover inhalers which used sponges to vaporise the volatile agent, yet Dinnick [61] recounts that the second attempt to induce anaesthesia in London in 1846 failed because of a faulty expiratory valve [203].

Early anaesthetists had to rely on simple apparatus, on observation and on a finger against the patient's pulse to guide them, but increasingly complex apparatus to provide anaesthesia and to monitor the patient's condition have been developed [203]. Although, each addition has improved the level of care provided, each addition brought its own problems. The great danger is that the complex technology distracts the anaesthetist from his prime concern: the patient.

2.3 Basic Physiology

2.3.1 Introduction

Hidden behind the operating room doors and cloaked in a cloud of soporific vapours, the anaesthesia environment has remained relatively remote from public attention, medical instrument manufacturers, hospital administrators, insurance companies, and physician groups. Consequently, improved clinical management tools have appeared at the anaesthetising station slowly and piecemeal. Although these improvements have been substantial, significant preventable mortality and morbidity persist. The systematic application of recent advances in technology to enhance and integrate anaesthesia management tools has the potential to reduce the residual morbidity and mortality rates and improve patient care [182]. In this discussion of monitoring, there

will be a limited consideration to issues of patient safety. The selection of an optimal anaesthesia monitoring array is a key step in this direction.

"The anaesthetist is responsible for maintaining the well-being of the patient during surgery. The anaesthetist's goals are to ensure sleep, amnesia (absence of recall of surgery), analgesia (absence of pain), muscle relaxation, and physiologic stability. The drugs used to accomplish these goals are inherently dangerous. They eliminate normal ventilation and depress all organs, including the heart. Anaesthesia can thus be described as continuous resuscitation during on-going administration of lethal drugs. To determine the adequacy of the on-going resuscitation, the anaesthetist continually measures physiologic variables, integrates these data, and initiates or modifies therapy based on them. The process of continuous measurement and data integration defines monitoring. Continuous measurement of physiologic variables can often be accomplished by the human senses (e.g., a finger on the pulse) but is greatly facilitated by transduction with physical devices (e.g., ECG). Data are usually integrated and interpreted by the anaesthetist's intellect. This function, too, can be assisted by the application of technology" [182].

The patient treated in the ORs presents a clinical situation characterised by:

- ◇ Multiple, interrelated derangements, expressed by a continuous shifting of non-linear functions; and
- ◇ Quick generation of a vast number of clinical and laboratory data which have not been weighted.

Thus in such a situation by calculating derivatives, the computer is bound to generate a large number of clinically insignificant data. The proliferation of unweighted information causes confusion, rather than simplifying the processes of applying data analysis to solving diagnostic and therapeutic problems [145].

2.3.2 Oxygen Measurement

Clearly, Cooper's studies [42] and others, as well as the personal experience of most clinicians, indicate that of all the factors that cause morbidity and mortality in anaesthetic practice, hypoxaemia is the most feared [177].

Classic physiology teaches that ventilation and oxygenation are different, i.e., that ventilation effects the levels of CO_2 and that the inspired oxygen tension effects oxygenation. Although this is a convenient rule, it is simplistic. Patients who are not being ventilated get both a rise in their $\text{P}_{\text{et}}\text{CO}_2$ and a decrease in their $\text{P}_{\text{et}}\text{O}_2$ [177].

Paulus [177] explains how oxygen is carried in the blood in both a dissolved form and also in combination with haemoglobin. The equation for total arterial oxygen content (C_aO_2) per 100 ml of blood follows:

$$\text{C}_a\text{O}_2 = 1.39 \times \text{haemoglobin} \times \text{saturation} + 0.003 \times \text{P}_a\text{O}_2 \quad (2.3.2.1)$$

Normal arterial blood with a P_aO_2 of 100 mmHg contains 0.3 ml O_2 /100 ml in solution. With a haemoglobin of 15g/100 ml, the C_aO_2 is 20.8 ml O_2 /100 ml.

Normal mixed venous PO_2 ($\text{P}'_{\text{v}}\text{O}_2$) is 40 mmHg, corresponding to a haemoglobin saturation of 75%. Mixed venous oxygen content (C_vO_2) is determined by the equation

$$1.39 \times 15 \times 0.75 + 0.003 \times 40 = 15.2 \text{ ml O}_2/100 \text{ ml} \quad (2.3.2.2)$$

Thus, for a normal adult, 20.8 ml O₂/100 ml is delivered, while 15.2 ml O₂/100 ml returns to the heart for an oxygen consumption of 5.3 ml O₂/100 ml of blood flow. If cardiac output is 5 L/min, then

$$(5 \text{ l/min}) \times [(5.3 \text{ ml O}_2)/100 \text{ ml}] = 0.27 \text{ l/min oxygen consumption (VO}_2) \quad (2.3.2.3)$$

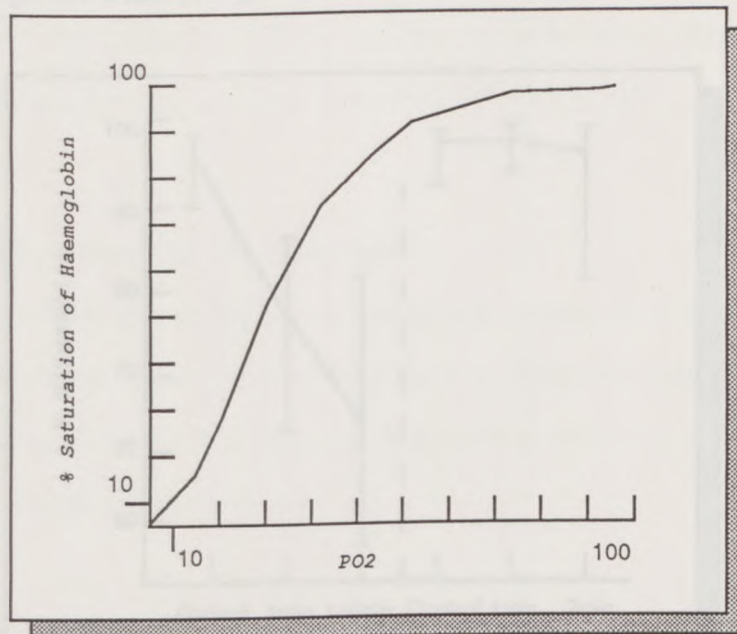


FIGURE 2-1. Oxygen Dissociation Curve.

(Modified from [177])

The oxyhaemoglobin dissociation curve [4] (Figure 2-1) indicates that if oxygen delivery ceases, oxygen tension drops precipitously. Once haemoglobin saturation drops to 75%, tension hits the steep part of the curve. Studies describe what happens to oxygen tension if oxygen delivery ceases to a patient initially breathing room air and

then ceases to a preoxygenated patient [101]. Patients were ventilated at the chosen O_2/N_2O concentration for three minutes and then left apnoeic while their P_aO_2 was measured. Storage of oxygen in the body offers protection for a brief period of time; if gas in the lungs is enriched with oxygen, several more minutes of apnoea will be provided. There are studies that clearly show that after adequate ventilation $\leq 100\%$ O_2 over one hour of apnoea produces no significant fall in S_aO_2 (Figure 2-2) [258]. This causes problems in determining how long the individual patient is safe from hypoxia; makes early warning of decreased oxygen tension and haemoglobin saturation highly desirable. With oximetry, it is no longer assumed that an arbitrarily selected apnoeic period is safe [177].

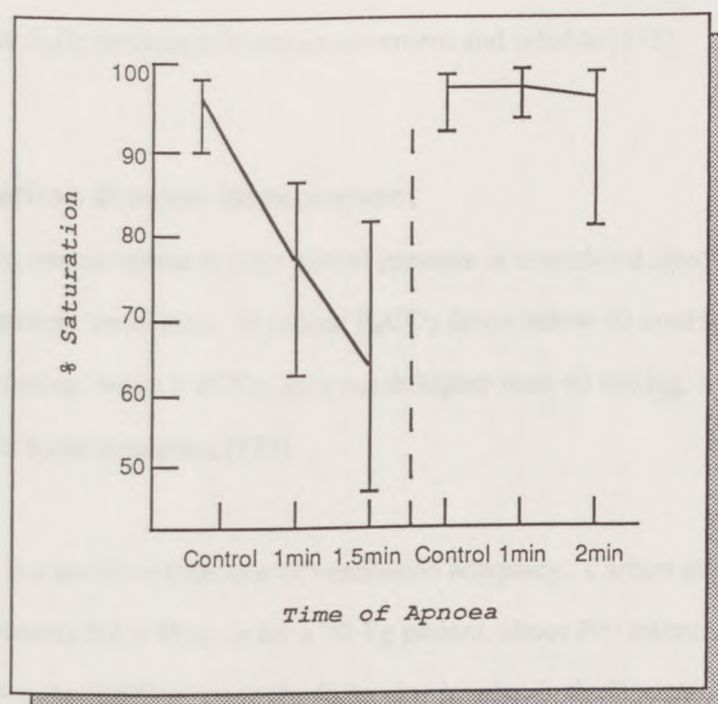


FIGURE 2-2. Arterial Oxygen Saturation During Apnoea.

(Modified from [177])

Without continuous measurement of S_aO_2 , intraoperative periods of inadequate oxygenation will go undetected, as the patient does not become cyanotic until the

saturation is approximately 30% below normal. If ventilation is inadequate, hypoxia ensues, the patient will be desaturated severely before the clinical signs of cyanosis. Also, the patient is now on the steep part of the oxygen dissociation curve, so further denaturation occurs rapidly. To be vigilant against hypoxia, the patient must be observed not only with the senses, but also through instrumentation. Oxygen must be continuously and noninvasively monitored at the cellular level in the brain, heart, and other major organs. Ideally, saturation and partial pressure of oxygen would be measured. At the cellular level (in the end organ cells of the brain, heart, kidney, etc.) P_{aO_2} is the significant value. Availability of O_2 in the blood can be estimated by saturation measurement. In general, because of the shape of the haemoglobin dissociation curve P_{aO_2} is a more sensitive indicator than S_{aO_2} but one can opt for S_{aO_2} because it is more convenient and reliable [177].

2.3.3 Carbon Dioxide Measurement

Classically, measurement of CO_2 partial pressure is considered directly correlated to adequate patient ventilation. If patient P_aCO_2 drops below 40 mmHg, the patient is hyperventilating, while if PCO_2 goes much higher than 40 mmHg, it is considered evidence of hypoventilation [177].

CO_2 level is a sensitive indicator of ventilation adequacy. Carbon dioxide production is approximately $0.8 \times V_{O_2}$, or for a 70-kg patient, about 200 ml/min. If the patient is apnoeic, then the P_aCO_2 rises to the following levels: in the first minute, it rises about 6 mmHg and 3 to 4 mmHg for every ensuing minute. If the patient starts with a P_aCO_2 of 40 mmHg, after one minute of apnoea it will be 46 mmHg; after two minutes, 50 mmHg; and after four minutes, 58 mmHg. While this is not a dangerous range for CO_2 , in most clinical situations the oxygen saturation level will have plummeted at the same time [177].

Measurement of end-tidal CO_2 is used frequently to determine the adequacy of ventilation. End-tidal CO_2 can be measured with the mass spectrometer or an infrared capnometer. Generally, mass spectrometers are used on a shared basis, with patient analysis occurring every one to three minutes [177].

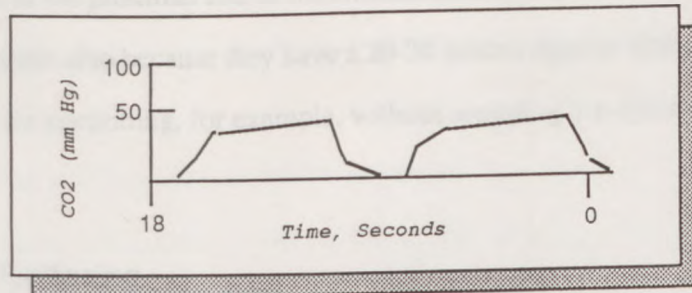


FIGURE 2-3. Real-time Capnogram.

(Modified from [177])

To examine the adequacy of CO_2 measurement as a warning device one has to look at the normal CO_2 waveform of patients who are being ventilated or are slowly, spontaneously breathing. The CO_2 waveform has a plateau (Figure 2-3). The value of this plateau just before exhalation ceases indicates end-tidal CO_2 . The relationship between end-tidal CO_2 and arterial CO_2 is not easy to assess. The differences between the two have been found to be 3 to 8 mmHg [177]. Usually this relationship is relatively stable for a given patient; however, intraoperative changes in shunt may change the relationship substantially.

Other pitfalls plague CO_2 measurement devices. A timelag of up to several seconds can be caused by excessive response time, as in monitoring a breath of interest with the shared mass spectrometer system. Systems that use CO_2 as a measurement are dependent on waveform analysis, and if the waveform is not smooth, with a defined

plateau, the end-tidal-to- $P_a\text{CO}_2$ relationship deteriorates. Aberration in these waveforms can be caused by patient coughing or spontaneous breathing, or oscillations or extremely small tidal volumes with a relatively large dead space. Any aberration leads to inaccuracy. Sampling systems frequently obtain incorrect, mixed gas samples, since alveolar gas is mixed with residual gas in the dead space, particularly if a sample is made at the proximal end of the endotracheal tube [177]. Capnometers are problematic also because they have a 20-30 second apnoea alarm time limit which allows for suctioning, for example, without sounding the alarm.

2.4 Monitoring

2.4.1 Introduction

The bedside physiological monitor is the cornerstone of the modern operating room. All of the estimated 65,000 adult, and paediatric operating rooms in United States (7,500 hospitals times an average of 9 operating rooms) are equipped with some type of physiological monitor. The simplest units display the ECG and heart rate, and have high/low-rate alarms. The most sophisticated monitors also can analyse ECG arrhythmias, monitor intravascular pressures and respiratory status, and measure arterial and mixed venous oxygen saturation. Arterial catheters and pulmonary artery balloon-tipped catheters are frequently used to measure physiological pressures and blood gases. Some monitors even compute cardiac output from thermal dilution curves, a process which formerly required special procedures performed in the cardiac catheterisation laboratory [81].

It should be understood that "measuring" and "monitoring" are different. To "measure" means "to ascertain the extent of quantity" [163]. To "monitor" means "to remind or give warning" or "to maintain regular surveillance over" or "to maintain constant observation and vigilance" [140][63]. Monitoring is not only the process of

measurement or collection of data, but also involves analysis and interpretation of the collected data. As yet, human intervention is needed to complete this step [107].

Since the Second World War, rapid development of medical electronics has led to the development of equipment which can monitor and record without needing the immediate presence of the clinician [107]. Enormous advances in computer technology have further extended the application of instrumental monitoring in clinical practice.

Patient monitoring systems serve three main functions [51]. First, they protect the patient by ensuring that a physiological variable which moves beyond an acceptable range is made apparent immediately to the attending physician. Second, they indicate the pattern of response to therapy so that modifications may be introduced as required. Finally, they provide data to develop advances in treatment modalities [107].

Research has shown that anaesthesia is analogous to continuous resuscitation [182]. The objective is to maintain uninterrupted supply of oxygen to tissue. To accomplish that goal the following are necessary:

- ◇ Gas supply must have an adequate O_2 concentration.
- ◇ Gas supply must traverse the airways of the lung and maintain an adequate alveolar oxygen tension.
- ◇ An adequate volume of blood must traverse the pulmonary circulation (cardiac output must be appropriate).
- ◇ The lungs must transfer oxygen to the blood traversing the alveoli.

- ◇ The blood must be delivered to tissue beds with adequate flow, pressure and must contain adequate haemoglobin concentration.
- ◇ The cellular respiratory organelles must receive the oxygen and utilise it to meet tissue oxygenation demand.
- ◇ The waste products of respiration (CO_2) must exit through the same path in reverse.

OR monitoring equipment can be viewed as devices to warn if any of the above requirements are not being met or are in process of not being met.

The questions of why, what, and how one should monitor are of great importance, but cannot be addressed in this brief review. In the end, the criteria for determining minimum monitoring requirements are the responsible physician's decision to be made in light of accepted professional standards, perhaps with the guidance of the Anesthesia Patient Safety Foundation in the United States, or the Canadian Anaesthetists' Society [107].

Monitors installed in operating rooms provide two kinds of capabilities that help improve patient care [81]:

- ◇ Physiological Monitoring. Computers can acquire, process, store, and display data, and can sound alarms when continuously monitored physiological variables become abnormal in an onset of hypotension or ventricular tachycardia.

- ◇ Integrated Patient Management. Because all data are available, the most advanced systems issue alerts and suggestions based on the total clinical database in the same way that systems give alerts on ECGs or blood pressure.

2.4.2 Physiological Monitoring

Physiological monitoring is a method of quantifying the haemodynamic and respiratory status of the patient [213].

Applications such as routine haemodynamic calculations have been performed with programmable calculators or personal computers. Although useful, these small application packages were accomplished most often at a local level and were not uniform from one institution to the next. Thus, largely, computer technology in the ORs has been introduced and promoted in association with monitoring systems [213].

Monitors formerly were simple signal amplifiers, that is, they accepted an electrical signal from a transducer and displayed a calibrated and amplified version of the signal. The newer generations of monitors are based on digital electronics and microprocessors. They are built with computer electronics. Computers do two things well:

- ◇ Store and retrieve data, and
- ◇ Execute algorithms.

An algorithm is an invariable set of instructions which is used to perform a specific task [129]. Consequently, the emphasis in monitoring technology has been on data acquisition and data management by information systems.

As an adjunct to clinical decision-making the goal of monitoring is to reduce human error. The premise is that unambiguous and accurate information, readily interpretable and available, will help the anaesthetist in deciding and initiating correct therapeutic interventions [252].

Vigilance monitoring attempts to detect and identify a perturbation in the delivery of anaesthesia or the physiological state of the patient and alert the anaesthetist [252]. Ideally, the alert will be early and specific enough to allow the anaesthetist to correct the situation before harm is done to the patient. Although better vigilance monitoring might not prevent anaesthetic mishaps, it has the potential to reduce the sequelae associated with these incidents.

Several areas of technological advancement must be considered in order to realise the potential benefits of better vigilance monitoring and improved clinical decision support. Some of these technologies are being developed; others available have to be widely applied. In anaesthesia monitoring, three areas of active development have led to recent advances. These areas are physical integration, functional integration, and new sensor/instrument development [252].

A combination of both digital and analogue monitoring devices can be used to monitor and manage the critically ill patient effectively [55]. Data acquisition, analysis and calculations based on changing data are used by medical personnel. Other data management systems use a feedback loop that measures, analyses, records, and reports trends in vital signs or other physiological parameters, and then initiates a predetermined therapeutic measure in response.

Finally, some thought is offered on the role of monitoring devices and equipment design as factors in risk management. Such subjects generate countless discussions, arguments, and sales promotions based on medicolegal pressures. Logically, this issue should focus upon the proven cost benefit of producing machines that correct defined inadequacies of human error so that plant production can become profitable. At present anaesthesiology faces an unprofitable situation due to human error [56]. Because human performance has not improved yet and the probability of further progress in this direction is not indicated, a need for improved technology is obvious.

Gardner [81] (Figure 4-1) estimates that 22% of the decision making process in anaesthesia practice involves physiological data from monitoring equipment.

2.4.2.1 Invasive Monitoring

In critically-ill patients, invasive physiological monitoring with the balloon-tip pulmonary artery (PA) catheter supplements the traditional monitored variables arterial BP and heart rate (HR), CVP, temperature, and respiratory rate. Cardiac output, intravascular pressures, and other haemodynamic variables are used frequently in high-risk medical and surgical patients [220].

Although highly effective when used prophylactically, invasive monitoring has major difficulties [219]. They are expensive, time consuming, and not user-friendly.

Derived cardiorespiratory variables must be calculated after the results of haemodynamic measurements and blood gases become available. Finally the standard PA catheter provides a series of snap shots of sequential physiological events rather than a continuous running record of trends and changing patterns.

2.4.2.2 Non-invasive Monitoring

Noninvasive monitoring is preferred because it minimises risks caused by the monitoring process [182]. Levels of noninvasiveness are presented in Table 2-1. Morbidity studies of monitoring tools are used to estimate degrees of noninvasiveness within each level.

•	Absolutely noninvasive
	Observation (e.g., chest motion, pupil size)
•	Very noninvasive
	Airway gas sampling or electrical transmission (e.g., ECG)
•	Moderately noninvasive
	Percutaneous superficial (e.g., intravenous)
•	Moderately invasive
	Percutaneous deep (e.g., systemic artery, pulmonary artery)
•	Very invasive
	Organ invasion (e.g., ICP)
•	Absolutely invasive
	Destructive (e.g., biopsy, autopsy)

TABLE 2-1. Degrees of Noninvasiveness.

At present one study [219] documents the desirability of a noninvasive system over the invasive system. The study shows that the noninvasive system which provides a continuous display of the information allows titration of therapy to defined physiological end-points whereas invasive monitoring provides only a series of static

snap shots. What is lost by lack of directly and, perhaps, more reliably measured physiological variables, may be gained by the continuous real-time nature of the noninvasive measurements that provide physiological criteria for therapeutic goals. Noninvasive bedside monitoring allows therapy to be titrated promptly to optimise treatment goals [239].

A comprehensive noninvasive haemodynamic monitoring system that can provide rapid and continuous, on-line, real-time values in emergency condition is needed [219]. One aim of the present study is to describe such a noninvasive physiological monitoring system as comprised of five commercially available components. The noninvasive instruments were selected after preliminary studies suggested that a certain array of physiological variables could evaluate the central circulation by electrocardiogram (ECG) and noninvasive blood pressure monitor, respiratory function by pulse oximeter, and tissue perfusion by transcutaneous PO_2 (P_tCO_2), P_tCO_2/P_aO_2 ratio, and the mass spectrometer.

The noninvasive heart rate was compared with the simultaneously observed electrocardiogram and pulse oximeter in a series of Day Surgery Unit patients. The study was designed to describe the patterns of abrupt changes in noninvasively monitored variables. An appreciable sudden fall in these variables was considered to be a monitored event. Finally, some of the common interactive responses in cardiac output, pulmonary function, and peripheral perfusion patterns associated with monitored events were explored.

The abundance and sophistication of cardiovascular monitors contrast with the few, less sophisticated respiration monitors available. Given the frequency with which serious life-threatening problems occur with respiration, clearly better technology is needed [102]. As it will be discussed, presently available is capnography analysis for

airway carbon dioxide. It can give rapid early warning about ventilation problems and is, in addition, a useful instrument for setting ventilators. Analysis of carbon dioxide waveforms gives the same type of dynamic display of airway conditions as intraarterial monitoring of blood pressure gives for the cardiovascular system. Correlation of $P_{et}CO_2$ with arterial pressure allows accurate adjustment of ventilation.

2.5 Alarms

2.5.1 Introduction

Quinn [193] states that "alarm" is a particularly confusing word and that it should be restricted to a single meaning,

◇ To alarm (verb): To trigger a state of arousal in which an organism's attention shifts abruptly from its current focus to one designed to deal with danger;

and differentiate it from,

◇ Alarm Mechanism (noun): A device designed to alarm and capable of alarming and disabled when it is not.

During the past 10 to 15 years there has been an increasing trend toward incorporating alarms into medical devices. Many devices used for patient monitoring and life support now include alarms as standard features. Two important reasons are advanced for the cause of this trend: greater sophistication and complexity of medical devices; the increasingly stern view taken by society, expressed through the courts, toward medical misadventures. The primary purpose of an alarm is preventive - to warn of danger [111]. According to the nature of the device and the risks associated with its use, an

alarm is designed to signal either adverse changes in the patient's condition, operator error, including attention lapse, failure or malfunction of the device, or a combination of these elements.

As alarm use has increased, a secondary purpose seems to have evolved - i.e., to serve as a substitute for the operator's attention. For example, alarm systems have been incorporated into some medical devices for the purpose of allowing a single nurse to monitor several patients at one time. This secondary purpose is a result partly of the rising costs of health care and partly of the growing shortage of nurses, and it should be viewed with caution if not concern. Certainly it reflects a fundamental philosophical change in both the design and the use of medical devices. In extreme cases, it reflects irresponsible use of the alarm systems. A nurse or a physician monitoring several patients can respond still to only one emergency at a time [111].

Thus, although alarms can improve the safety and efficacy of equipment use, they do present a number of special challenges to the equipment designer. Some challenges are the selection of the variables that will be provided with alarm outputs, the design of the alarm displays and setting controls, the provision of alarm test procedures, and the preparation of labelling and instructional materials. Most importantly, the designer must be alert to possible adverse effects of the alarm on user performance such as overdependence (an alarm can fail) and diminished vigilance [111].

It should be noted that the primary design goals for the device may conflict with those for the alarm system. For the former, the goal is utility; for the latter, it is safety. Except for certain machine self-monitoring functions, an alarm does little to improve utility, adds to complexity and possibly to cost. Thus the designer of a medical device is challenged to provide a useful, uncomplicated, and cost-effective device that also affords protection against foreseeable hazards [111].

2.5.2 False Positive/Negative Alarms

An alarm which alerts an anaesthetist without any hazard to the patient being indicated is called a false alarm. False alarms do not produce relief in an anaesthetist but rather induce an antagonistic attitude, habituate him to the alarms, or subject the anaesthetist to repetitive stressful reflexes [65]. The anaesthetist becomes likely to stop using alarm devices or ignore their signals, thus posing risk to the patient. Anaesthetists are not alone in this attitude. Operatives at the Three Mile Island nuclear plant found audible warning systems so annoying they expressed desires to rip them off the walls [16].

The following are possible reasons for a false alarm sounding:

- ◇ Alarm malfunction;
- ◇ Alarm activated by an inappropriate device;
- ◇ Alarm variables set inappropriately by the anaesthetist;
- ◇ Alarm variables set by the designer, inappropriately for the prevailing clinical circumstances;
- ◇ Alarm setting by designer inappropriately for the clinical circumstances;
- ◇ Extraneous sounds mistaken by the anaesthetist for an alarm signal;
- ◇ Alarm sounding when the anaesthetist is already alerted to the situation;

- ◇ Inappropriate loudness setting by the anaesthetist, and
- ◇ The greater the number of possible individual alarm signals, the greater the number of possible false alarm signals.

Thus the incidence of false alarms can be reduced by design modifications, by environmental changes, and by education of users regarding settings [153].

The never-achieved goal of all measurements is to eliminate the two types of error. Nonrandom error, or bias, consistently affects the validity, or accuracy, of measurement. On the other hand, random error reduces the reliability or precision of measurement in an unpredictable fashion. The sources of error or imprecision in the measurement of physiological parameters can be grouped into five categories: environment, user, subject, machine, and interpretation [86].

The environment can affect both the machine and the subject. The temperature of the room, for example, has been studied for its effect on spirometer readings [179] and on subject's temperature reading [39]. Cardiac output readings can be affected by the temperature of the solution used in the instrument [3]. Barometric pressure is another environmental factor that affects spirometry values and needs to be noted at the start of the readings. Static electricity in the environment can interfere with the output of an instrument [86]. Instruments need to be tested in the same environment and under the same conditions expected during their intended use.

User error can result from the differences between users (similar to the concept of inter-rater error), within the same user (similar to intra-rater error), or in the supplies or procedures used (administration error) [86]. Machine manipulation or subject interaction may cause different readings to come from different users. For example, if

the user encourages a subject during a pulmonary function test, that subject may expend more effort and obtain a higher reading than the subject who was not encouraged.

Subject error results when either the subject alters the machine or the machine alters the subject. Subject influence over the machine is sometimes used therapeutically, as with biofeedback. However, subjects may alter the readings intentionally such as when a child rubs a thermometer on the sheets [86]. Subjects may alter results unintentionally as well. For example, it has been demonstrated that full subject effort is needed for accurate spirometric determination of pulmonary function [227], and various techniques have been explored to ensure that full effort is achieved [98].

If machine error is random, it is not amenable to control; if systematic it is subject to control with proper calibration procedures. Calibration is the setting of the machine against a standard and should occur on a regular basis. Institutions are provided with a calibration instrument that can be used before any measurement is taken. Essentially, calibration is done by injecting a known quantity into the instrument to ensure that the reading indicates that amount. For a recorder such as an electrocardiograph, an electrical charge (usually 1 mV) is applied and the graph paper observed to be sure that the indicator rises to the appropriate level [86].

Signals transmitted to a display panel can be a potential source of error. Erroneous readings can result from something as simple as improper heating of the element or the use of improper feeding lines for the ink. These problems are easily remedied [86]. Another source of error is the analysis of the readings obtained from the machine. For example, different formulae exist for normative or predicted values for pulmonary function tests [87]. When the Holter monitor tape is read, the only permanently documented arrhythmias are those chosen by the individual scanning the tape [100].

Analysis of aircraft accidents has shown that, during approach to landing, the pilot and crew's attention had been distracted from simple visual observation of the ground by an apparently malfunctioning low-altitude alarm until it was too late. Although most anaesthetic accidents are caused by pilot error careful review of equipment design could reduce hazards posed by inconvenient or poorly designed tools [45]. Historically, anaesthesia equipment have been developed by a process of accretion, feature added upon feature, step by step. At each stage of equipment development, an addition may appear sensible and convenient. Unfortunately the final arrangement of the apparatus may be unsatisfactory from the human engineering or ergonomic point of view [203].

Disconnect monitors should sound an alarm when the pressure within the breathing system fails to reach a preset level within approximately a few seconds [203]. In some units, however, the pressure level can be varied by the user. Often anaesthesia machines have a built-in monitor, but in some ventilators the monitor is a separate extra-cost item which may be omitted when budgets are tight. Even when available, McEwen [152] and colleagues warn that monitors may fail to warn of patient disconnection under certain circumstances.

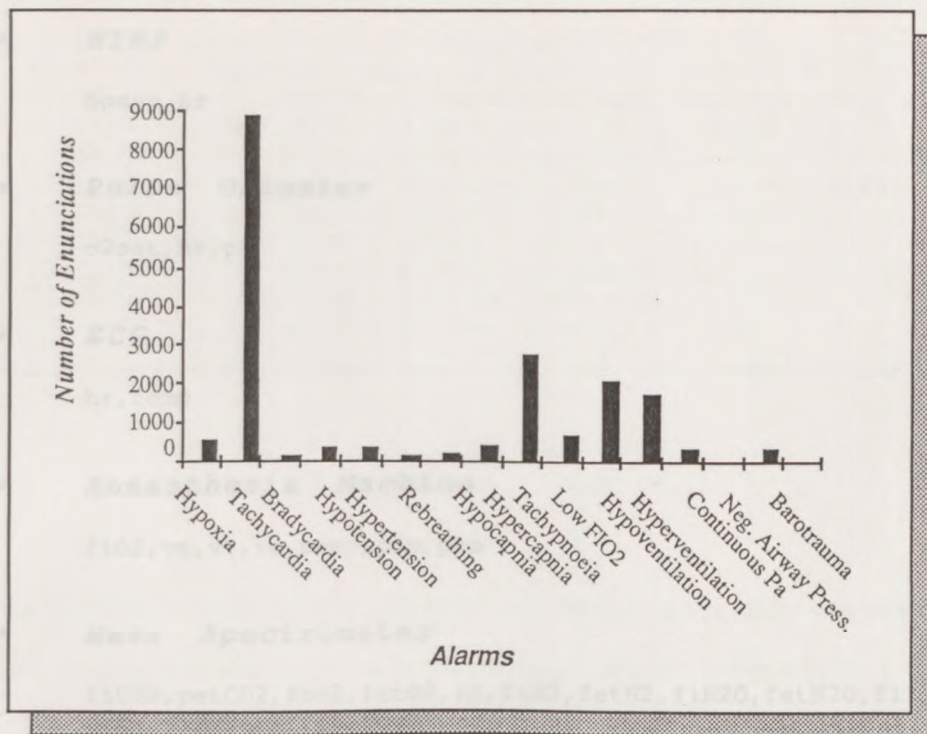


FIGURE 2-4. Sources of Alarms.

A total of 25,507 alarms were recorded; their origins are shown in Figure 2-4. Only eleven alarms indicated potentially serious problems (e.g. laryngospasm or airway obstruction with transient hypoxaemia), four indicated ventilator disconnection and two indicated serious dysrhythmias that require treatment.

•	NIBP
	bpsys,hr
•	Pulse Oximeter
	o2sat,hr,pa
•	ECG
	hr,temp
•	Anaesthesia Machine
	fiO2,ve,vt,rr,peep,pip,pam
•	Mass Spectrometer
	fiCO2,petCO2,fiO2,fetO2,rr,fiN2,fetN2,fiN2O,fetN2O,fiI, fetI,fiE,fetE,fiH,fetH

TABLE 2-2. Data Format.

Ventilator alarms (Table 2-2) were triggered usually during suction or physiotherapy, despite a delay time of less than one second for the Drager anaesthesia machine and 15 seconds for the Perkin Elmer mass spectrometer. A fault of the anaesthesia machine frequently caused the low pressure alarm to sound. The alarms on these ventilators are self-terminating once the problem has been corrected. Only 47% of the monitor alarms indicated tachycardia (0.8% indicated bradycardia), while 50 were false alarms, triggered by the removal of the ECG leads. The infusion devices sounded an alarm to indicate a completed infusion or blockage. The causes of some of the alarms are shown in Table 2-3. The majority of the mass spectrometer alarms were caused either by incorrect alignment or for no traceable reason.

```

12:07:00 -- hypocapnic in mass_spec [11.55] ? r
12:07:00 -- hypoventilation in anesthesia_mach [1.9] ? r
12:08:15 -- barotrauma in anesthesia_mach [40] v(v_pip1) y
12:09:00 -- tachypneic in mass_spec [32.0] v(v_rr6) y
12:09:00 -- hyperventilation in anesthesia_mach [12.5] v(v_ve3) y
12:09:00 -- tachycardic in pulse_oximeter [123] v(v_hr12) y
12:35:00 -- hypertensive in nibp [168] v(v_bpsys2) y
13:11:00 -- tachycardic in ecg [118] v(v_hr12) y
13:11:00 -- tachycardic in pulse_oximeter [118] v(v_hr12) y
13:11:00 -- tachycardic in nibp [119] v(v_hr12) y
13:16:00 -- rebreathing in mass_spec [1.47] ? y

```

TABLE 2-3. Some Individual Alarm Causes.

The distribution of alarms between cases and throughout the study was similar but individual patient alarms showed a wide variation (Figure 2-4 and Table 2-4).

•	hypoxic	:	if the o2sat value is low
•	tachycardic	:	if the hr value is high
•	bradycardic	:	if the hr value is low
•	hypotensive	:	if the bpsys value is low
•	hypertensive	:	if the bpsys value is high
•	rebreathing	:	if the fiCO2 value is high
•	hypocapnic	:	if the petCO2 value is low
•	hypercapnic	:	if the petCO2 value is high
•	tachypnoeic	:	if the rr value is high
•	lowFiO2	:	if the fiO2 value is low
•	hypothermic	:	if the temp value is low
•	hyperthermic	:	if the temp value is high
•	hypoventilation	:	if the ve value is low
•	hyperventilation	:	if the ve value is high
•	continPa	:	if the peep value is high
•	negAirwayPressure	:	if the peep value is low
•	barotrauma	:	if the pip value is high

TABLE 2-4. Sources of Individual Alarms.

2.5.3 The Significance of Alarms in the Clinical Setting

Since a large number of alarms has its source in artifacts, further discussion of this term is needed. When a monitor displays an electromechanical measurement that originates from physiological phenomena and numerous other sources, artifact is the unwanted component of the measurement signal. It may arise from intercurrent physiological processes, from disturbances caused by the monitor, or distortion inherent in the monitoring process, or from extraneous environmental noise [196].

Rapidly advancing technology makes artifact a timely topic despite the dearth of research related to artifact detection and rejection. A bibliographic search of the National Library of Medicine by Rampil [196] for all citations using the key words

"artifact" and "monitoring" or "computers" yielded 118 references published between January 1966 and March 1985. Most of these citations mentioned artifact only transiently, leaving perhaps a total of about 10 papers since 1966 that concentrated on artifacts and their detection. The majority of these concern either long-term ECG monitoring or the particularly noise-sensitive modality of evoked potential monitoring. In contrast, over 24,000 papers on monitoring itself appeared during this interval. A similar search by the author yielded 45,704 papers on monitoring published between January 1986 and April 1989. In these were 38,864 citations using the key words "artifact(s)" and "monitoring" or "computers" and there were 38,879 citations using the key words "alarm(s)" and "monitoring" or "computers."

Artifact detection capability needs to be incorporated into monitoring equipment for three reasons [196]. First, artifacts are responsible for triggering the majority of all false-positive alarms. Second, artifacts contaminate frequently the measurement data in which they occur, thus reducing the amount of information available for patient management. Finally, and most seriously, data corrupted by artifacts may be used unintentionally to alter patient management.

To design for artifact detection optimally requires knowledge of the incidence of the various classes of artifacts in the environment in which the scheme is to function. It is important also to assess the degree and duration of damage inflicted on the measurement by each type of artifact [196].

Doctors and nurses are becoming increasingly reliant upon machines to assist in diagnosis and treatment; this tendency is particularly noticeable in the operating suite and in intensive care areas. As old machines are replaced by more sophisticated and safer models and new ones are added, the number of alarm signals has multiplied and seems likely to multiply further [114].

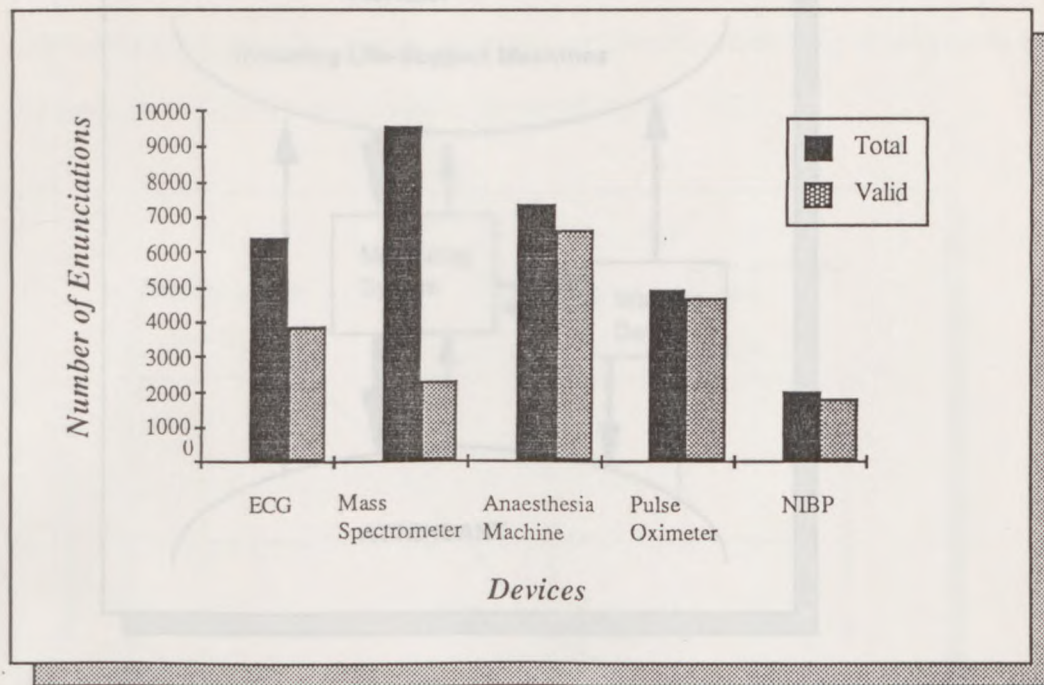


FIGURE 2-5. Distribution of Alarms.

This proliferation of alarm signals (Figure 2-5), particularly auditory alarms, is causing problems [231][123]. In a recent study on breathing system disconnections [42], bedside staff stated that "multiple alarms sound, and the user does not know what happened" and "many ventilator alarms sound like other alarms in the unit." A physician discussing a fatality reported that "the ventilator alarm was confused with the alarm from ECG leads." It is no longer sufficient to consider each warning device as if it were the only one in the environment [122]. A framework is required within which alarm signals can be deployed rationally in conjunction with all other systems to protect the patient effectively.

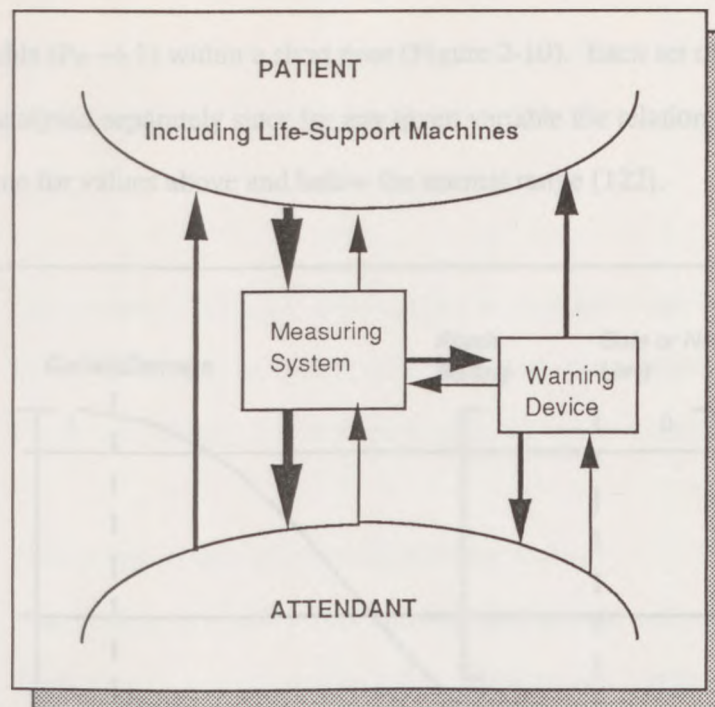


FIGURE 2-6. Inter-relationships Between Patient, the Measuring System with a Warning Device and the Attendant.
(Modified from [122])

A warning device is a mechanism which generates a signal to inform the patient's attendant that a measured variable has moved from an acceptable to an unacceptable level [122]. Clearly the warning device must be considered as a component of a system composed of the patient measuring apparatus, warning device and attendant (Figure 2-6).

According to Kerr [122] for any variable (K), the limits of normal or safe values (K_n) may be considered to be those within which the probability of a damaging event (P_d) is extremely small ($P_d \rightarrow 0$); in other words, the average time interval between damaging events is infinitely long. As the variable moves away from this safe range, the probability of a damaging even increases, and the average period between damaging events shortens, until a value (K_d) is reached at which damage becomes

inevitable ($P_d \rightarrow 1$) within a short time (Figure 2-10). Each set of circumstances needs to be analysed separately since for any given variable the relationship is unlikely to be the same for values above and below the normal range [122].

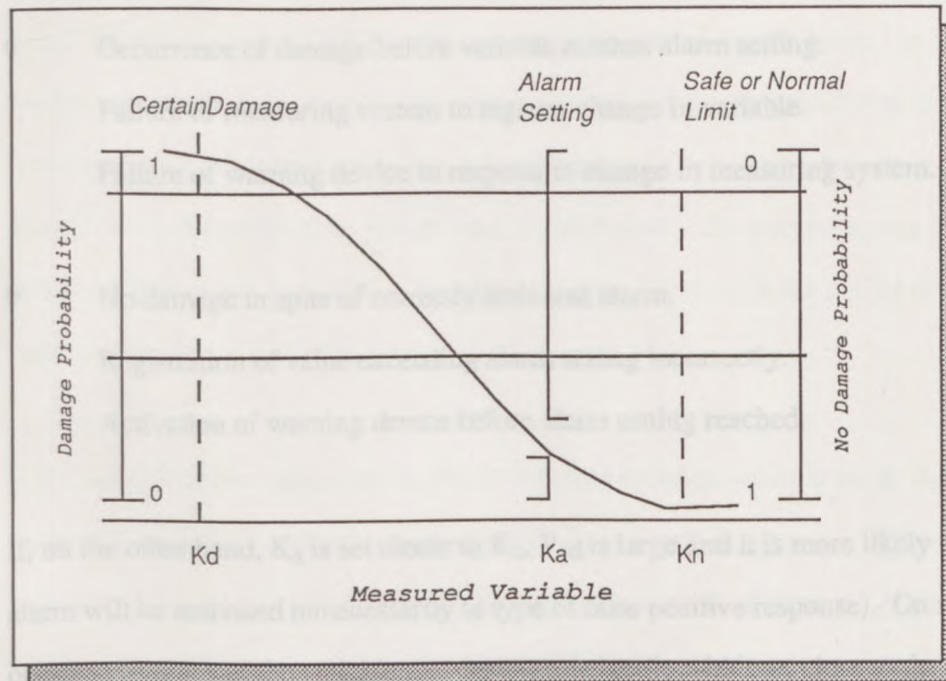


FIGURE 2-7. Probability that Damage Will, or Will Not Occur.

(Modified from [122])

The value of the variable at which the alarm is activated (K_a) lies between these two limits. At this point P_d will have a value between 0 and 1 (Figure 2-7). It should be noted that, as the probability of damage increases, the probability of damage not occurring (P_{nd}) decreases in a complementary manner:

$$(P_d + P_{nd} = 1)$$

The closer to K_d that K_a is set, the greater the possibility that a damaging event can occur without activation of the alarm. Such false negative responses may be clinically

disastrous and undermine the attendant's confidence in the alarm as a predictor of damage. Other causes of false negative and false positive responses are:

- ◇ Occurrence of damage before variable reaches alarm setting.
- Failure of measuring system to register change in variable.
- Failure of warning device to respond to change in measuring system.
- ◇ No damage in spite of correctly activated alarm.
- Registration of value exceeding alarm setting incorrectly.
- Activation of warning device before alarm setting reached.

If, on the other hand, K_a is set closer to K_n , P_{nd} is large and it is more likely that the alarm will be activated unnecessarily (a type of false positive response). On most occasions, values of the variable may be expected to lie within or close to the normal range. Thus, the alarm will be activated more frequently as the difference between K_a and K_n diminishes. The clinical instinct is to set K_a close to, or even at, K_n but user acceptance will be affected adversely if the inevitably false positive signal is generated frequently [122]. Hence, the overall effectiveness of system will be affected negatively [268][210].

A system in which P_d increases from 0 to 1 at a particular value of the variable ($K_n = K_d$) (e.g. one measuring a variation in the shape of an ECG waveform) has the advantage that no false positive or negative responses are generated but it will not predict damage, only signal it. The predictive value of the warning device will be affected also by the sensitivity of the measuring system, its ability to detect changes between K_a and the value of K at which the steeper increase in P_d occurs. In an insensitive system, K_a may have to be set within the normal range so that the alarm will

be activated more frequently than would be the case if a more discriminatory system were used to measure K [122].

Matters are complicated further because the probability of damage is related also to the period of time that the variable remains outside its normal or safe range. In general, the longer that variable stays outside its safe limits, the greater the probability of damage. Since no living creature is immortal, it could be argued that a safe limit does not exist. It is possible, therefore, to envisage a set of iso-temporal lines representing the relationship between P_d and $K_a - K_n$ where the time involved is the period that the variable remains at K_a [122].

If the variable is changing rapidly, the time before damage occurs may be shortened because K will reach quickly values at which P_d is increasing steeply. Most monitoring devices, however, are not able to measure rates of change. A crude indication may be obtained if the time interval between the signals produced by two warning devices set at different values of K is noted [122].

An alarm is triggered only when the measurement has been outside the set limits for a period which will be determined by the response time of the measurement system (T_m) plus that of the warning device (T_w) [122].

Once the alarm has been activated, or period of time passes before corrective action restores the variable to its normal range. In some instances, this correction time (T_c) is a few seconds (e.g. turning on a cylinder to restore the oxygen supply, or re-connecting a ventilator), but in others it may be minutes, even hours (e.g. administering fluids to increase arterial pressure or digitalis to slow the heart rate. Damage probability may be underestimated if it is calculated at the time when the

warning device is activated particularly if T_c is long. On the other hand, the estimation of damage probability becomes more difficult as time passes [122].

Part of the difficulty in correcting an alarming variable is that there are many possible reasons for the deleterious change. This situation applies particularly to physiological variables close to damaging events (e.g. brain PO_2); warning device on this type of variable may present the attendant with a wide range of possible corrective actions of varying effectiveness. T_c is likely to be long and difficult to predict unless supplementary information is available to guide the attendant. Intelligent systems which are able to utilise data from a number of measuring systems can provide such guidance and thereby reduce T_c [92]. Other warning devices, notably those which are attached to variables with relatively long alarm-damage pathways, present the attendant with a clear-cut corrective action so that T_c can be predicted more accurately [122].

Therefore, to find the alarm limit with a particular probability of damage in mind, the iso-temporal line used must be one such that $T > T_m + T_w + T_c$. The clinical value of a warning device that does not meet this condition will be minimal. Wherever the alarm limits are set, note that the smaller the possibility of damage, the more likely it is that the alarm will signal a no-risk condition. Since these false alarms are inevitable [225], the design and construction of the measuring system and warning device should minimise the number of incorrect responses for other reasons [122].

The second part of the anaesthesia monitoring system concerns devices (including certain monitoring devices) to inform the anaesthetist that a potentially critical deterioration of physiological parameters has occurred, or that a situation exists which, if uncorrected, will lead to such a deterioration. Tachycardia, followed by bradycardia, which may lead to serious hypoxaemia, and the warning sound of a disconnect alarm are examples. These warnings may not allow the physiological parameters to fail

safely, but they do allow the anaesthetist to realise that continuation of the anaesthetic as originally planned is not indicated by the feedback of physiological parameters. The lack of feedback necessary to continue the anaesthetic is analogous to the military concept of fail-safe [65]. Of course, it is preferable to have a monitoring system that includes an automatic failure-preventing device; the present monitoring system that warns of a potential critical deterioration of physiological parameters depends on the ability of the anaesthetist to assimilate and act upon this information. This system, often the only one available, is limited but extremely useful.

2.6 Patient Management

2.6.1 The Patient Population

An increased incidence of anaesthesia disasters in healthy patients undergoing minor procedures is alleged incorrectly. The error stems from a misinterpretation of studies in which cases of mishap or disaster are collected from several sources. For example, in a series of 41 malpractice cases of cardiac arrests during anaesthesia, reported in 1976, the majority were young, healthy patients undergoing low-risk surgical procedures [242]. But the appropriate denominator for the incidence equation is missing, a lack acknowledged by the authors. Without knowing the size and type of population from which individual cases are drawn, it is inappropriate and misleading to infer increasing incidences.

Good evidence exists now that healthy patients undergoing minor procedures in an ambulatory setting are less likely to suffer anaesthetic deaths than healthy patients in a hospital setting [118].

2.6.2 Immediate Management Problems

Recently medical and lay persons have expressed suspicions that the risks of anaesthesia are too high. Available statistics neither confirm nor deny this suspicion, nor can correctable factors be precisely identified. In some medical specialties, morbidity and mortality rates are used as indices of therapeutic effectiveness and quality of care, but attempts to assess the risks of anaesthesiology using such data have been inconclusive. Risk assessment is difficult due to the lack of any dependable reporting system, the difficulty of separating the consequences of surgery from those of anaesthesia, and the inherent difficulties of retrospective analysis of rapidly occurring and poorly documented events [56]. Thus, methods other than morbidity and mortality studies need to be developed in order to estimate even crudely the current patient risk factor.

Historically, instruments used in the operating room monitored only one or two variables per device. As new monitors were created they were added on to rather than integrated into the existing system. As the numbers of devices proliferated, several problems arose [252]. First, it became difficult to find space for the new monitors. This problem has been compounded by the variety of shapes and configurations employed by the manufacturers; they are difficult to stack in the limited available horizontal space. If the devices are stacked too high, they are endangered by hoses, lights, IV poles, and gravity. Second, the cables needed for power, patient input, or device interconnection proliferated and intertwined in a confusing fashion. Third, visibility of individual displays were compromised by crowding and it became difficult to scan all the different monitors.

Increasingly, technical expertise is needed to cope with the explosion of technology. Any moderate-to-large-sized anaesthesia department probably has sufficient technology

to justify a clinical engineer to supervise the use of the equipment. Such technical guidance is required to implement sound policies for assuring equipment performance and controlling the anaesthesia delivery and monitoring technology. The right individual, with appropriate training skills, hospital knowledge, and patient care-oriented interests will do more than repair and service equipment; he should also manage materials and supplies, conduct in-service education programs, act as liaison between manufacturers and suppliers, assure conformance to standards, and investigate device-related mishaps. While it is difficult for an anaesthesia service to receive adequate support from a centralised medical engineering group, the effort should be made. Anaesthesia technology will become more complicated, not less, so that the sooner clinical engineering support is established for an anaesthesia department, the better the chances of avoiding equipment failure and incidents of patient damage [43].

Should an incident take place, the control and alarm settings on all equipment must be recorded as accurately as possible, even though changes may have taken place for interventions. Any measured or monitored variables such as peak respiratory pressure, tidal volume, and oxygen concentration should be listed. To anticipate and prevent an incident, record such ventilation variables periodically, together with blood pressure, heart rate, and other physiological assessments that appear on the anaesthesia record. Such a record has been established as one of the best ways to recognise a trend leading to trouble.

After an anaesthesia-related incident, the following questions should be answered:

- ◇ At the time of the incident, what changes were observed to attract attention?
- ◇ What alarms were activated?

2.3 Summary

◊ Was something altered just before the incident?

◊ If the scavenger or patient circuit is involved, how were they connected?

2.7 Systems Science and Medicine

Patient care can be regarded as a special case of the management of a complex system.

A system is a comprise of a number of elements or components which are interconnected to form the whole. The whole system's then behaviour depends not only upon the behaviour of the elements individually, but also upon the the nature and manner of their interconnection. As an example, the structure and processes associated with circulation can be referred to as the circulatory system. This is because its functioning depends not only upon the nature and behaviour of the components, such as the heart, arteries or veins, but also the precise manner of their interconnection. Therefore, the elements of the system function together giving rise to the behaviour of the whole [74].

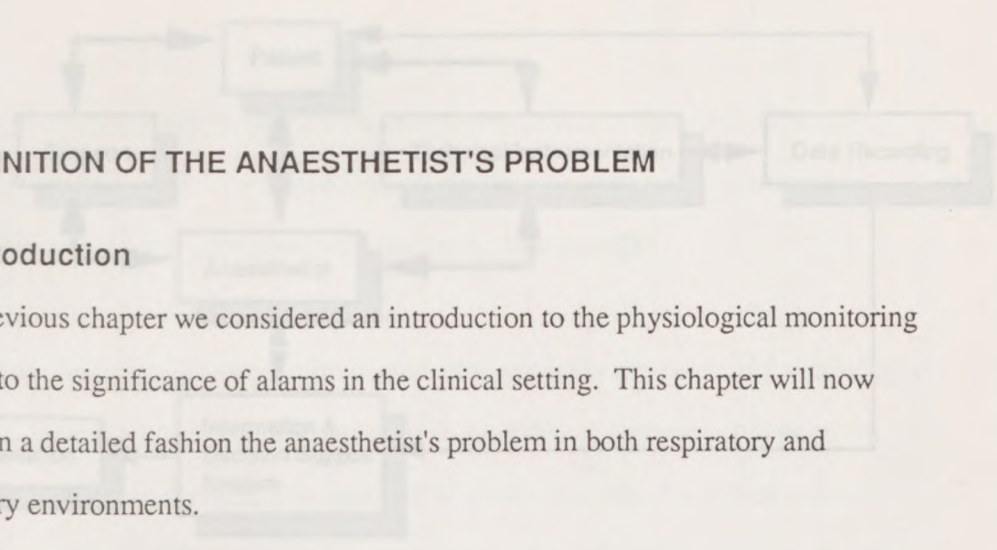
The major importance of adopting a systems approach in the analysis of the behaviour of a physiological system is that all factors are considered simultaneously. Application of a systems approach involves functional description, systems analysis and mathematical modelling. A mathematical model of a system is a set of equations relating system variables [74]. For a large system the equations can be complex and the nature of the relations difficult to visualize and understand. Graphic representation of the equations is possible for intuitive understanding.

2.8 Summary

Computerised monitoring systems facilitate the acquisition, storage, and retrieval of multiple vital parameters which allow for rapid clinical decision making and timely patient management. However, computerised monitoring systems augment not replace direct patient observation by anaesthesia personnel [55]. To provide the most effective care for patients, anaesthetists must become proficient in the use of computerised monitoring systems but also retain a humanistic caring quality. As anaesthesia practice becomes more technological and as scientific knowledge becomes more available, human error will become the dominant factor in mishap [43].

A description of the conception, design, implementation and redesign of a large computerised monitoring system follows, enumerating the problems encountered and the lessons learned. It relates a unique experience and, as such, should be valuable to designers and manufacturers of monitoring systems and equipment for the operating room, intensive care unit, and recovery room [18]. It should also be useful to users of monitoring equipment aiding them to understand the difficulty of producing a perfect monitor.

Having addressed a brief historical and physiological introduction, the next chapter will examine the anaesthetist's problem of false positive alarms.



3. DEFINITION OF THE ANAESTHETIST'S PROBLEM

3.1 Introduction

In the previous chapter we considered an introduction to the physiological monitoring and also to the significance of alarms in the clinical setting. This chapter will now analyze in a detailed fashion the anaesthetist's problem in both respiratory and circulatory environments.

Physicians and nurses collect a great deal of data through frequent observation, regular testing, and continuous monitoring of critically-ill patients. Physicians generally prescribe complicated therapy regimens for such patients. Unless the mass of accumulated data is presented in a compact, well organised form the physicians can miss important events and trends [70]. Economic pressures to reduce the use of therapeutic and diagnostic resources compound the physician's difficulties [81]. Table 5-1 presents the Harvard monitoring standards.

As surgical and anaesthetic techniques grow in complexity, anaesthetists are reaching the limits of their ability to handle the roles of controller, decision maker, data gatherer, and performer of various technical procedures [125]. Saunders [212] proposes that the functions of the anaesthetist be classified and strengthened by integrating the monitoring, display, and gas delivery equipment into a cohesive system better suited to the anaesthetist's needs. Figure 3-1 shows the anaesthetist's field of activity and communication after an information and decision support system has been added.

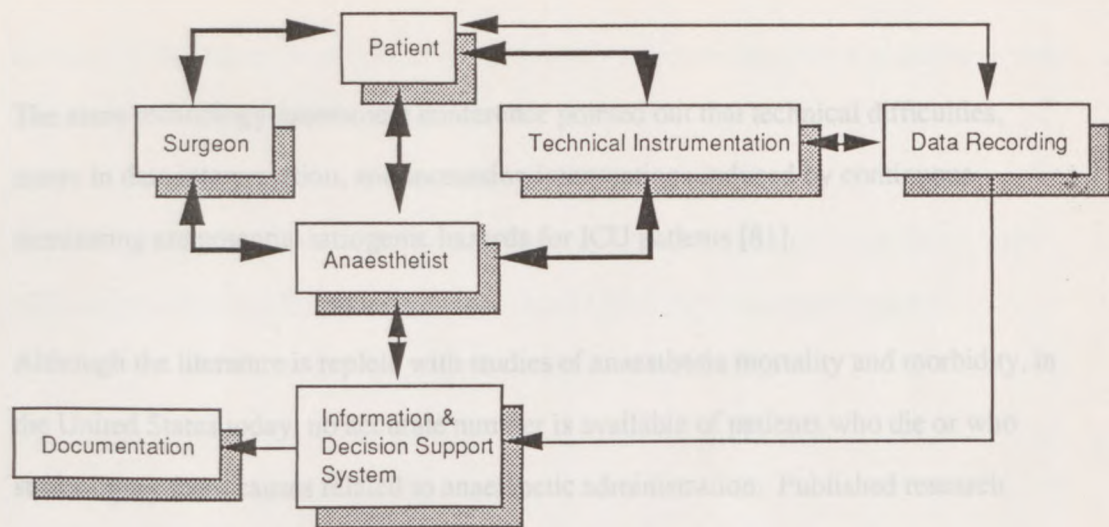


FIGURE 3-1. The Anaesthetist's Field of Activity.

(Modified from [125])

The successful development of such a complex system depends on the design and evaluation of an appropriate anaesthetist-computer interface to support the integration of monitoring, record keeping, and decision making [125]. Furthermore, the interface must be adaptable to typical situations and to individual user behaviour. The ergonomic systems design must cope with the process, the user, and the complex interfacing system, and it must result in interactive modes that are adapted appropriately.

A recent consensus conference on Critical Care Medicine, sponsored by the National Institute of Health, provided insight into the application of technology to the problems of the critically ill [49]. The conferees found evidence that ICU care can be life-saving to patients with acute reversible diseases such as respiratory failure from drug overdose, or cardiac conduction disturbances amenable to pacemaker therapy. Patients with septic or cardiogenic shock, and patients who have just recovered from major surgery or who suffer from acute myocardial infarction can benefit as well [81].

The same technology-assessment conference pointed out that technical difficulties, errors in data interpretation, and increasing interventions induced by continuous monitoring are potential iatrogenic hazards for ICU patients [81].

Although the literature is replete with studies of anaesthesia mortality and morbidity, in the United States today, no accurate number is available of patients who die or who suffer injury from causes related to anaesthetic administration. Published research estimates annual mortality rates from anaesthesia in the U.S. to range between 1 per 2,000 and 1 per 10,000 [43].

The inadequacy of the traditional method gathering information in the ORs has been stressed many times. The difficulties of using the available information for diagnosis and therapeutic intervention stem from:

- ◇ The number of data required to identify a symptom;
- ◇ The number of redundant information received from equipment;
- ◇ The need for continuous data base up-dating;
- ◇ The real time needed for providing the information; and, usually,
- ◇ The fragmentary availability of basic data for the identification of the necessary information.

The complex problem of information handling in the OR seems ideally suited to computation. A number of investigators have attempted to implement prototype

systems [145]. Most have found it necessary to implement the system in stages so that clinicians would not be intimidated.

3.2.1 Introduction

Following will be a discussion of the development of an anaesthesia monitoring array designed to optimise effectiveness. Important to the concept is improving the effectiveness of the monitoring system to assist the anaesthetist in:

- ◇ Identifying the changed patient state;
- ◇ Recognising the pathways that lead to this state; and
- ◇ Selecting an appropriate management method to return the patient to an acceptable state.

Analysis of current mortality estimates in light of safety monitoring expenditures suggests that the current standard of practice does not provide reasonable care [182]. An educated guess as to a monitoring array for healthy patient care forwards the idea that a skilled, vigilant anaesthetist aided by the proper tools is the optimal situation. These tools must be selected to minimise unexpected occurrences leading to adverse outcomes.

The criteria used to evaluate measurement systems for clinical variables include: accuracy, specificity, reliability, simplicity, ruggedness, calibration requirements, cost, availability of permanent record and compatibility with the least intrusive environment for the patient [67].

3.2 Respiratory Complications

3.2.1 Introduction

Trends in assessing respiratory status are leading to continuous monitoring of pulmonary function and adequacy of ventilation by continuous measurement of mechanical variables, as well as direct measurement of blood gas tensions or indirect measurement by respiratory and transcutaneous gas analysis, including arterial oxygen saturation with oximetry [252].

During anaesthesia, respiration rates can be determined by simply watching and counting inspiration and expiration. The more elaborate techniques measure chest wall movement. One such technique is impedance plethysmography, electronic measurement of electrical impedance caused by chest motion during breathing. With this device, no additional patient connections are required since interfacing is accomplished via the ECG electrodes. Other techniques using magnetometers are being reported also [252].

Pulmonary variables such as tidal volume, minute ventilation, and inspiratory force will be obtained easily and routinely with improved fluidic, sonic, or other electronic mechanical methodologies. Due to these newer sensing units, the additional capabilities of measuring and calculating variables continuously such as compliance, resistance, and work of breathing will be possible [252].

3.2.2 Data Set that Defines Respiratory Complications

Although the effectiveness of ventilation can be assessed by discrete sample blood gas analysis, new developments in solid-state electronics and electrodes are leading to the development of improved oximeters, transconjunctival oxygen and transcutaneous

oxygen and carbon dioxide monitors. Indwelling catheters and electrodes having multivariable capability, including continuous analysis of blood gas tensions and pH, are also under development [252]. As discussed, new instruments for respiratory and anaesthetic gas analysis are available to anaesthetists due to recent advances in infrared and Raman spectroscopy, mass spectrometry, and fluidic technology .

Currently, the use of alarms which indicate malfunction of patient-breathing circuits during mechanical ventilation of the lungs (ventilator alarms) are being touted. If such alarms are to be generated, however, they must be relevant, accurate and reliable [128].

Most ventilator alarms are based on monitoring of breathing system pressures. Changes in the dimension of the chest and abdomen, changes in transthoracic impedance, changes in the concentration of end-tidal carbon dioxide, changes in expired gas temperature, and direct measurements of gas flow may also be used, but these may remain normal in the presence of dangerously abnormal pressures. Alarms based on monitoring pressures should be capable of detecting simultaneously a number of different abnormal conditions in the patient breathing system [165].

Safeguards against failure or operation in a dangerous mode should be built into ventilator alarms. Protection against accidental inactivation by using a key-operated or a pressure-activated on/off switch should be included. Devices should be immune from interference by diathermy, and from damage by exposure to excessive positive or negative pressure. Devices which detect the failure of the pressure in the breathing system to be regularly raised to a certain level have been designated as disconnect alarms, and those which, in addition, detect excessive pressure instantaneously are called ventilator alarms. To avoid operation in a dangerous mode the device should protect against inappropriate time delays or pressure thresholds by using preset fixed values, or by having controls which cannot be accidentally changed (i.e. protected

controls). Low pressure alarms with unprotected controls which permit the setting of a delay of greater than 25 seconds, and the setting of pressure thresholds of less than 7.5 cm H₂O were considered unacceptable for such a device should not be recommended for general use [165].

Ventilator alarms present a particularly difficult design problem because they should be reliable, safe and simple, while at the same time they should be capable of detecting a variety of abnormal condition. Ventilator alarms are likely to be used from time to time by inexperienced personnel, yet failure or malfunction can lead to direct consequences [165]. Thus, it is felt that a ventilator alarm should satisfy these basic requirements before it should be recommended for general use: adequate power failure precautions; controls fixed at predetermined known values, accurately calibrated, correctly labeled, and protected from accidental adjustment.

Long time delays before alarms sound may be dangerous; fifteen seconds was chosen as the safe limit. Perhaps alarms with excessively long time delays were designed for patients being weaned from using intermittent mandatory ventilation (IMV) at slow mandatory rates [89]. For such patients who are not at great risk from disconnection, alternative types of monitoring are more appropriate, the monitoring of expired minute volume or end-tidal carbon dioxide for example. Devices with excessively long time delays and with unprotected time-delay controls should not be recommended for general use [165].

Arterial oxygen saturation has been chosen for detecting hypoxaemia, a reversible morbid state (Figure 7-1). Detection of hypoxaemia is high priority since it is among the most common states leading to anaesthesia-related death and severe morbidity [182]. Oxygen saturation can be monitored by pulse oximetry. Next two major pathways likely to lead to the hypoxaemic state are monitored. Continuous monitoring

of ventilation is necessary, since inadequate ventilation is the most common cause of hypoxaemia. A set of variable - CO₂ waveform, and ventilatory flow - has been chosen to differentiate among most of the known processes that can produce inadequate ventilation. Partial or complete breathing circuit disconnection or occlusion, oesophageal or bronchial intubation, ventilator failure, and bronchospasm are some of the processes. The set of variables can be monitored optimally with a qualitative CO₂ monitor, and an electronic flowmeter. An oxygen monitor in the breathing circuit is included because delivery of an inadequate gas mixture is a less common, but serious, process that can produce hypoxaemia and lead to death.

Halothane hepatitis, malignant hyperthermia, and embolic phenomena are dramatic causes of disaster [118]. They constitute but a small group in collections of anaesthetic mishaps because they are so rare that they appear in even large studies of anaesthetic mortality.

3.2.3 Justification

It is believed that the incidence of unintentional introduction of anaesthetic to patients could be reduced if modifications were made to new machines and retrofitted to existing machines [263]. The modifications would include a colour-coded computer screen (CRT) triggered by a switch activated by a vaporiser. Many currently-used vaporisers have a cam-projection on the concentration setting dial that could be retrofitted with a cam-activated light switch. Vaporisers that do not have cam-projections would be fitted with other types of switches. The CRT could be mounted in a conspicuous place on the anaesthesia machine, preferably near the rotameter display module.

Improvements in design that reduce chances for error should be pursued always. The design change described could significantly improve patient safety in anaesthesia.

3.3 Circulatory Complications

3.3.1 Introduction

Recently it has been suggested that momentary levels of arterial pressure are greatly influenced by such factors as psychophysiological and environmental conditions and physical activity [266]. Thus pressure may fluctuate considerably during short or long periods. Currently, researchers attempt to devise non-invasive instruments for pressure measurement which allow long-term ambulatory measurement and continuous measurement on a beat-to-beat basis. Conventional sphygmomanometric techniques based on Riva-Rocci's principle, using an upper arm, are not always suitable for these measurements [217].

Since adverse outcomes are caused by circulatory insufficiency, the array of variables contains a subset for the detection of this state. Several types of circulatory insufficiency may be encountered: fluid volume imbalance or anaemia, cardiac compromise, and vascular impairment. It is difficult to differentiate among these states and the processes that lead to them in a timely fashion. ECG waveform, heart sounds, peripheral pulse amplitude, intermittent arterial blood pressure, and CO₂ waveform may be used to identify circulatory insufficiency and differentiate among these states. The development of monitoring tools that identify these states, especially fluid volume imbalance, is a high priority [182].

3.3.2 Data Set that Defines Circulatory Complications

Since assessment of tissue homeostasis may be the primary function in monitoring, technological research is being directed toward measurement of tissue perfusion and the effects of the surgical and anaesthetic processes upon the myocardium [252].

Although no clear cut techniques of assessing tissue perfusion are currently available, physiology has taught that tissue perfusion can be inferred indirectly by assessing the integrity of the electrical and mechanical activity of the heart in producing an adequate cardiac output.

Assessment of electrical activity comes directly from the ECG. Currently, small reliable battery-operated integrated units with multilead capability are used for monitoring. These units have an oscilloscope with digital rate display and strip chart recorder. Results from the unit are and will continue to be integrated into monitors containing automatic blood pressure measurements and into various haemodynamic computer algorithms for data processing. Newer technologies of ECG data processing integrated with older concepts to provide an AM/FM modulated acoustic signal are being considered. Arrhythmia detection is being considered also [252].

Hypoxaemia (i.e., insufficient oxygen in the arterial blood to sustain life) is unquestionably the commonest cause of anaesthetic disasters, as every study of anaesthetic mortality proves. Collections of anaesthetic mishaps, including those involving litigation, indicate that from one third to two thirds of those that end in death or severe brain damage were the result of hypoxaemia. Hypoxaemia has many cases but the most commonly reported has been failure to ventilate. Certainly the early and famous study of Beecher and Todd of 1954 suggested that the use of curare led increased anaesthetic mortality [7]. Controversy surrounded this publication because respiratory depression as a cause of the excess mortality was not acknowledged by the

authors; it was recognised by only a few anaesthetists at the time. Subsequently the need for augmented or controlled ventilation with muscle relaxants has been universally accepted, and the anaesthetic mortality rate has fallen. However, still occurring is inadvertent failure to provide adequate ventilation [118]. Increasingly, noninvasive pulse oximetry is the preferred method of monitoring oxygen saturation (S_aO_2) of haemoglobin in arterial blood. The proliferating number of commercially-available pulse oximeters, their reliability, their ease of operation, and the advantage of continuous S_aO_2 monitoring makes pulse oximetry particularly useful in anaesthesia and intensive care [157].

Currently, blood pressure is measured by auscultation with the cuff and stethoscope, but more elaborate noninvasive techniques utilising microphone, oscillotonometry, doppler, or other technologies will appear. Remaining standard will be indwelling arterial blood catheters containing newer disposable solid state intravascular sensors or ones that are connected directly to external transducers [252]. Measurement of cardiac output is another means of assessing cardiac function. This measurement will be simplified due to new and improved developments in microelectronics.

Thermodilution is the most convenient accepted technique especially since routine use has been simplified cold injection solutions are no longer required; specific-sized catheters and injected volume are no longer necessary. A display of the thermal curve and constant rate injection techniques provide consistent data which assist in interpretation of the results. Noninvasive techniques for measuring cardiac output utilising Fick's principle, chest impedance plethysmography, and other theories are being developed [252].

Transoesophageal echocardiography and similar techniques to provide continuous real time assessment of cardiac function are being developed. Although technologically

cumbersome, their potential adds an existing dimension to anaesthesia delivery [30][252].

Improved stethoscopes with better acoustic properties are appearing also. Such electronic amplification of the acoustic signals allows better phonocardiographic and chest sound data to be gathered.

Integrated instrument designs will continue to lead designers to generate multiparameter cardiovascular monitoring systems [252]. These systems will contain both multilead ECG and multiple blood pressure capability and cardiac output. This output will provide increased inputs for microcomputer-based data processing, including haemodynamic calculations. With improved data processing, newer systems will have greater alphanumeric and colour graphic display capability.

In basic and clinical medicine, non-invasive and accurate measurement of arterial blood pressure could provide important information with which to evaluate cardiovascular haemodynamics.

3.3.3 Justification

Arrhythmia monitoring of the ECG is the most complicated of the bedside monitor's tasks. Romhilt reports that people-based arrhythmia monitoring is expensive and unreliable, and that monitors find the job tedious and stressful [208]. A large central computer-based system to monitor rhythm may come to replace human monitor watchers [81].

3.4 The Problem of False Positive Alarms

Due to the recently complexity of OR monitoring, the use of a computer has become more desirable, not only to assist in routine tasks but also to act in alarm functions.

Some sophisticated statistical monitoring techniques have been reviewed by investigators [137][241][108] and have been found to have the potential for forecasting adverse conditions before they occur, unfortunately, they have the disadvantage of complexity and thus, are not widely used [12].

Conversely, notoriously prone to false alarms are the most rudimentary alarm systems, ones that are activated when upper or lower limits of a variable are exceeded. Raison [194] found that alarms on the limits of heart rate (ECG signal) and arterial pressure were mostly spurious. They concluded that it was more practical to trigger the alarm only when changes in both heart rate and arterial pressure occurred coincidentally [12].

Studies of anaesthetists' behaviour while at work in the operating room reveal they spend a significant portion of time looking at the patient and the surgical field [64][154][150]. Frequently the anaesthesia delivery system and displays from monitoring devices are behind them [154]. In addition, at times they may be several meters away performing other tasks. Thus there are occasions when they cannot scan instruments vital to the patient's welfare. Even when free they cannot predict with certainty when they should look deliberately. Experiments have shown most subjects perform vigilance tasks with approximately 90% accuracy [175]; vigilance is relaxed under a variety of circumstances that have been the subject of major reviews [115][40][144]. Neurophysical and behavioural theories agree with conventional wisdom that task performance suffers when the operator is over- or under-stimulated. The stimulations under consideration may be conscientiously arranged but even this endeavour may not be completely successful. Indeed these efforts are likely to be

rendered useless by the mental and physical deterioration caused by the length of time the person has been working [88]. This negative effect of fatigue on performance has been demonstrated in anaesthetists [6], residents [78][2] and other health workers [52].

These studies suggest that monitor information about hazards to the patient should be presented to the anaesthetist in an auditory mode as well as a visual one. Reviews of anaesthetic deaths [228] and recent critical incident studies [42] prove that human error and imperfections in many operating room environments are related to anaesthetic deaths. To improve the quality of patient care studies cite the need for improved instrumentation and better care by personnel [153]. The processes of data acquisition and ensuing action are illustrated in Figure 3-2.

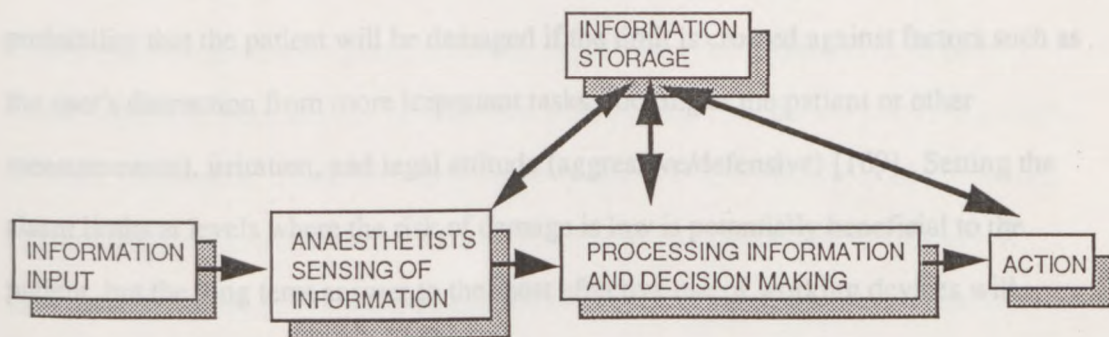


FIGURE 3-2. Data Acquisition and Ensuing Action.

(Modified from [153])

Many medical accidents are caused by the failure of doctors and nurses to observe a change in a patient's condition. In an attempt to improve safety, systems were developed which measure variable in the patient or in machines attached to them, but the attendant's attention was divided then between patient and variable display. Next, warning devices were added to the measurement systems creating monitors [169]. So many monitors are being employed, however, that the multiplicity of alarm signals generated by their warning devices is causing problems.

many monitors are being employed, however, that the multiplicity of alarm signals generated by their warning devices is causing problems.

Appreciate that when a warning device is set properly, it may be activated on many occasions when the actual danger is slight [169]. On each occasion when the variable being measured crosses the alarm limit, the patient either will or will not be damaged. It would be irresponsible to set the alarm limit at a level at which the probability of damage was high, in clinical practice, it is set where the probability of damage is low. This decision has two inevitable consequences: first, at this level, the probability that damage will not occur is high (false alarms will be common), and secondly, the frequency with which the limit will be crossed will be higher than if it were set further from the normal range. Setting the alarm limits on a monitor, implicitly balances the probability that the patient will be damaged if the limit is crossed against factors such as the user's distraction from more important tasks (looking at the patient or other measurements), irritation, and legal attitude (aggressive/defensive) [169]. Setting the alarm limits at levels where the risk of damage is low is potentially beneficial to the patient, but the long term answer to the most effective use of working devices will require several approaches.

One is the physiological considerations. If the chain of consequences between the event that activates each warning device and that which produces damage in the patient is analysed. The relative importance of alarms will be appreciated more readily. If intelligent, or smart, alarm systems are being devised, temporal factors must be considered and, in particular, the time taken by the attendant to correct the alarm condition in order to set priorities for the alarms. Warning devices on variables measured on the patient (e.g. heart rate or oxygen saturation) indicate that a physiological derangement already exists and that the time before damage occurs may be short. Unfortunately the time required to correct the problem may be relatively long

because of the time needed to analyse the large number of possible causes [121]. In contrast, measurements made on machines attached to the patient (e.g. loss of oxygen pressure) have a short correction time because the cause of physical derangement is clear.

Looking at the engineering side reveals that warning devices could feed their signals to common outlet which would indicate both the existence and nature of the problem.

This approach is being pursued actively in the United States, where several companies are producing anaesthetic machines with central alarm systems which incorporate alarm signals from devices measuring ventilator variables, gas pressures and composition from the machine, plus signals from other patient monitors [121].

From a psychological view point, the alarm signals themselves should be improved. Visual signals, of course, must be observed to be effective yet the attendants' reliability has been questioned. Therefore many warning devices were made to produce sounds. Unfortunately these are loud, continuous or intermittent high pitched noises which wound continuously, annoying the user and causing a common initial response to be to silence the alarm and only then to tackle the problem that has activated the alarm [121]. Another common response is to disable the alarm altogether [237].

The purpose of the present study was to develop an alarm system of intermediate complexity that would detect adverse trends in respiration and circulation of Day Surgery Unit surgical patients with a minimal incidence of false alarms. These two categories were chosen because, they form the primary database for the diagnosis of adverse alterations in intravascular volume and respiratory gases [12].

The problem of developing an automated alarm detection system was chosen for several reasons:

- ◇ As the variety of equipment used in the ORs has increased, so has the incidence of alarms, posing difficulties for all staff [169].
- ◇ Another goal of this study was to provide data on the frequency and origins of alarm calls in a general purpose OR.
- ◇ It was possible that such a system would enhance the effectiveness of patient care and the anaesthetist's monitoring efficiency.

Although little variation was discovered in the overall frequency of alarms throughout the 45 weeks of the study, the number of alarms per patient varied considerably, similarly to other studies [169]. The level of dependency of each patient and the ability of the medical staff to anticipate alarms are reflected in the study.

Note that alarms can be reset only when the fault is corrected. The anaesthesia machines' pumps had to be switched off to silence the alarm. Hence, the warning devices on the ventilators, monitoring systems and volumetric infusion pumps may be muted, and continue to display only a visual warning. Note, also, that if an alarm signal is silenced without correction of the original fault, the possibility of harm to the patient still remained [169].

From the early evaluation of results, ECG monitoring is unreliable and the immediate alarm and the electrode connections should be improved. The drip rate pumps perform as well as the other infusion devices, but generate many unnecessary alarms [169]. A high false alarm rate distracts the attendant's attention from an important alarm and makes unnecessary noise close to the patient.

In a recent comprehensive review on warning devices, Kerr [122] suggests several ways in which alarm sounds might be allocated, but stresses that there is insufficient evidence to provide support for any particular system [169]. The majority of alarms in this study signalled minor malfunctions, rather than events which threatened patient safety. This study illustrates the need for a rational alarm system and suggests that the risk and response approach would best safeguard patients.

3.5 Summary

A computerised monitoring system should be capable of universal application to all types of patients; it should present an unbiased clinical picture to both the patient and the third-party payer [261].

Studies of monitor design have shown that when uninterrupted monitoring is required, the machine is more reliable at detecting problems than the person [115]. For example, electrocardiographic monitoring, for all its weaknesses, will remain standard in the OR. Automated blood pressure monitoring devices are beginning to enter anaesthesia practice and in some instances may perform better than the human. Still, two classes of devices that can detect serious errors or other failures before physiological changes or injury occur are not included universally in anaesthesia practice; these are oxygen analysers and airway pressure (disconnect) alarms. In almost every study of mishaps or deaths, incidents and management errors could have been detected by appropriate use of these two devices. At one time well-designed oxygen analysers and ventilation alarms did not exist, but that situation has been corrected. Still, a careful selection process, user education, daily calibration, and periodic maintenance are required if the full benefits of these anaesthesia seatbelts are to be realised. Their potential is great if neither misused nor misinterpreted. No doubt where it has not occurred, soon both will be considered standard monitoring equipment [43].

Having addressed in this chapter the anaesthetist's problem, the next chapter will now examine some systems concerned primarily with physiological monitoring and artificial intelligence.

Having in the previous chapter considered the anaesthetist's problem in both respiratory and circulatory environments, this chapter will now discuss a variety of approaches in the area of monitoring and associated prototypes.

Most commercially-available integrated data management systems have not been successful for either user or vendor. The vendors tend to underestimate the diversity of situations found in intensive care medical practice and in hospital OEs. Expensive customisation has been required at each new location. Products tend to focus on the acquisition and processing of physiological data and not to take into account the need for linkage to other sources of data in the hospital (Figure 4-1). Generally, the systems do not include user-programmable functionality so that each user could tailor the system to serve his particular needs [81].

4. CRITICAL REVIEW OF EXISTING WORK

4.1 Introduction

Having in the previous chapter considered the anaesthetist's problem in both respiratory and circulatory environments, this chapter will now discuss a variety of approaches in the area of monitoring and associated prototypes.

Most commercially-available integrated data management systems have not been successful for either users or vendors. The vendors tend to underestimate the diversity of situations found in intensive care medical practice and in hospital ORs. Expensive customisation has been required at each new location. Products tend to focus on the acquisition and processing of physiological data and not to take into account the need for linkage to other sources of data in the hospital (Figure 4-1). Generally, the systems do not include user-programmable functionality so that each user could tailor the system to serve his particular needs [81].

In a few institutions, the systems have been deemed successful [81]. The systems were considered successful because:

1. The medical staff recognized the need for computers and were committed to making them work.
2. A powerful physician/advocate of the computer system served as its manager.

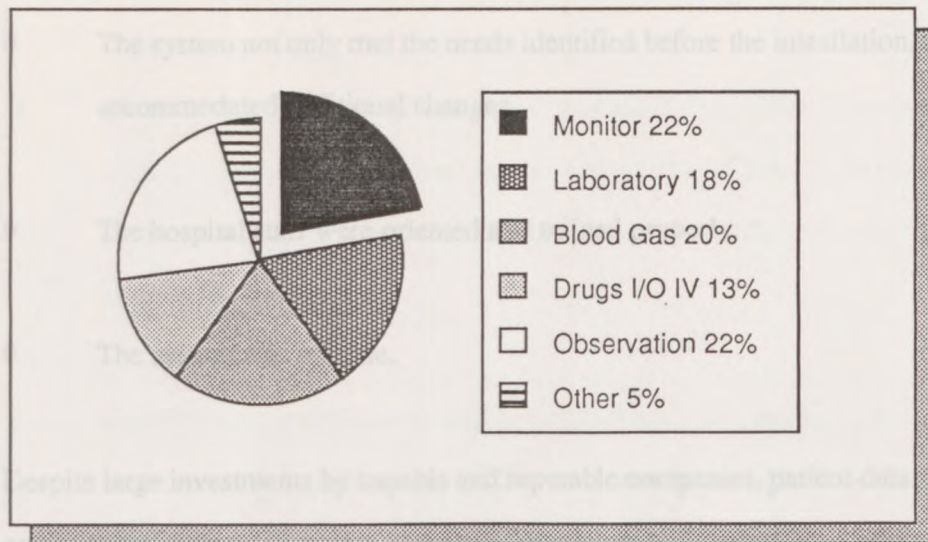


FIGURE 4-1. Data Used for Decision Making.

(Modified from [81])

The systems available have other short comings. rarely have they been integrated with administrative or clinical data procedures. Thus, in most operational systems, duplicate charting is required. Most of the systems have not resolved the difficulties of manual data entry into a computer. For a good system to compete with a ballpoint pen and a piece of paper, it must be simple, fast, and reliable. Finally, most of the systems have not provided integrated databases or decision-making capabilities.

In a few institutions, the systems have been deemed successful [81]. The systems were considered successful because:

- ◇ The medical staff recognised the need for computers and were committed to making them work.
- ◇ A powerful physician/advocate of the computer system served as its manager.

- ◇ The system not only met the needs identified before the installation, but also accommodated additional changes.
- ◇ The hospital staff were oriented and trained properly.
- ◇ The system was reliable.

Despite large investments by capable and reputable companies, patient data management systems have not sold well. Several manufacturers are stepping back now to take a broader look at the needs of the entire hospital before investing further in OR patient management systems. From the experience [84, 85] in applying computers to OR patient management, it is clear that a certain critical mass of data is required before a system will be successful.

4.2 Evolution of Prototypes

The use of multiple microprocessors in bedside monitors has revolutionised the acquisition, display, and processing of physiological signals. The new monitors have more computer power than earlier systems that could fill a room, and they require less space than their predecessors' cooling fans. A discussion of how these signals are acquired may be found in related literature.

Monitoring instruments with built-in microcomputers have many advantages other than size over their analogue predecessors:

- ◇ Systems can be upgraded easily by changing software programs in read-only memory (upgrading older systems necessitated replacing the hardware, because the logic was wired in).

- ◇ Because the digital computer's can store patient data information (such as the ECG), it permits sophisticated pattern recognition. Older systems built with analogue computer technology did their work on the fly with only a small peek at the patient waveform.
- ◇ Signal quality can be monitored and maintained. For example, the computer can watch for degradation of ECG skin/electrode contact. If the contact is not good, the monitor can alert the physician to change a specific electrode, thus assuring good signal transmission from skin to sensor.
- ◇ Physiological signals can be acquired more efficiently by converting them to digital form early in the processing cycle, and handling waveform processing functions (such as calibration and filtering) in the microcomputer. Local computer power also simplifies the physician's task of operating the monitor.
- ◇ Pattern recognition and waveform feature extraction can also be done in microcomputer-based monitors. The computer can use waveform templates to identify abnormal waveform pattern and to classify ECG arrhythmias.
- ◇ Selected data can be retained easily. For example, strips of interesting physiological sequences such as periods of arrhythmias or marked changes in hear rate can be stored in the bedside monitor easily for later review. Measured variables, such as heart rate and blood pressure, can be graphed for detection of life-threatening time-oriented trends.
- ◇ Simpler, more reliable, signal transmission makes possible a bedside monitor that transmits its signal to a central display for review by nurses or physicians.

- ◇ Smarter bedside monitor alarms signal fewer false alarms. In the past, alarm systems used only high/low-threshold limits, and could signal only artifacts. Now, the computers and bedside monitors can distinguish between artifacts and disasters, and can alert physicians and nurses about serious problems. The bedside monitor processes different signals using information from one signal to verify another for example, comparing the heart rate derived from the ECG tracing with that derived from the arterial pressure. Thus, the system is more like a human observer who analyses various inputs [81].

4.3 The Prototypes

It is important to emphasise that the computer systems described here are research prototype systems. None are in clinical operation. The systems have been tested partly on retrospective data from a small number of patients, and partly on a limited basis in the OR. Their ultimate goal is the development of a practical system; the immediate goal is to explore the AI research problems involved in giving computer-based clinical advice and to begin to develop solutions. Major problems remain at both the research and practical level, some of which are untouched still. These problems include:

- ◇ Linking the systems to real-world data collection where practical issues as dealing with artifacts are extremely important [196].
- ◇ Dealing comprehensively with the need for sophisticated, intelligent alarms [11].

- ◇ Tailoring the systems to the demands of the clinical environment, so the systems are human-engineered to maximise their efficacy.
- ◇ Dealing fully with the variability of medicine, so the systems will deal appropriately with coexisting disease, concurrent treatment, etc., that will be encountered.
- ◇ Testing and validating decision rules and algorithms; and
- ◇ Accommodating practice variation to the different experts and institutions.

Researchers in the field of medical AI believe that much research is necessary before many of these issues can be confronted satisfactorily. Below are described several on-going research projects dealing with these fundamental issues in the anaesthesia and OR settings.

4.3.1 The Ventilator Manager System

Ventilator manager (VM) is a prototype system designed to assist physicians and nurses to monitor respiratory and related cardiovascular variables in real time [72].

VM assists physicians and nurses managing patients receiving mechanical ventilatory support. VM attempts to identify equipment malfunctions and to suggest therapeutic interventions. It was developed between 1978 and 1980, before the current generation of ventilators were used widely.

VM uses if-then rules that were developed in collaboration with intensive care specialists and that fall into four categories:

◇ Status Rules. Status rules make judgements about the patient's cardiovascular and respiratory status, for example, it says whether the patient's respiratory rate is acceptable.

◇ Transition Rules. Transition rules attempt to recognise when the patient has been changed to a different ventilator setting or different device. VM cannot assume that physicians will always inform the system when this occurs.

◇ Instrument Rules. Instrument rules attempt to identify artifactual readings, an important concern in the intensive care unit; for example, ventilator tubing can become reversed or disconnected.

◇ Therapy Rules. Therapy rules recommend action based on the conclusions drawn from the first three categories of rules. VM is "deterministic" in making its recommendation; it makes no attempt to weight the pros and cons of competing options. Types of therapy recommendations include:

- change ventilator settings,
- change ventilator modes, and
- check equipment that may be malfunctioning.

At all times the system considers the patient to be in one of the therapy states. When VM finds conditions that signal transition from one state to another, it prints a recommendation that the patient might be started on the therapy corresponding to the destination state. For example, the system can move from the controlled mandatory ventilation (CMV) state to the assist mode state if certain conditions are met, such as:

◇ The patient has been on CMV for at least 30 minutes;

◇ Hypoventilation is absent; and

◇ The haemodynamics are stable.

Similarly, state transition in the reverse direction, from the assist mode to CMV, is possible if other conditions are met, such as:

◇ Respiratory rate is acceptable; and

◇ The tidal-volume-out (TVOT) is not acceptable.

VM was one of the first medical AI systems designed to help manage a patient over time. In addition, qualitative values for variables were developed. This was a novel attempt to address the fact that numeric values can be interpreted meaningfully only within the wider clinical context [204].

4.3.3 The DUKE Automatic Monitoring Equipment (DAME) System

From 1972 to 1983 the Duke University Department of Anesthesiology designed,

4.3.2 The Smart Respiratory Alarm System

Scientists at Pacific Medical Center in San Francisco have developed a smart respiratory alarm system. Using if-then rules, this system's knowledge monitors the signals generated by a bedside ventilator. The program is designed to recognise twenty three separate alarms, each belonging to one of three categories [204]:

◇ Monitoring equipment malfunctions;

◇ Ventilator related alarms; and

◇ Patient related alarms.

A gas sampling system placed between the Y of the ventilator tubing and the patient generates the ventilator signals. Primary data gathered include flow, pressure, and oxygen and carbon dioxide tensions at the outlet of the endotracheal tube. These primary data elements are processed to determine secondary monitoring variables, such as tidal volume inspired, tidal volume expired, respiratory rate, PEEP, even the effort expended by the patient in fighting the ventilator.

Performance of the smart alarm system was tested in 157 post-cardiac surgery patients over a six-month period. The nurses caring for those patients were interviewed to determine their opinions of the 476 alarms. The nurses considered most useful those which occurred infrequently (fewer than six times per month). The smart alarm was viewed as a useful back-up for them.

4.3.3 The DUKE Automatic Monitoring Equipment (DAME) System

From 1972 to 1983 the Duke University Department of Anaesthesiology designed, built, and maintained most of its own OR patient monitoring equipment. The Duke Automatic Monitoring Equipment (DAME) System was able to be designed and tested when a new hospital facility was constructed in 1980. The system consists of microcomputer-based instrumentation on monitoring carts; they communicate with a central minicomputer which allows selection of different software monitoring packages based on the needs of the patient [18]. Multiple problems, including frequent total monitoring failures during surgery, plagued the DAME System in its first year of operation. Even when some problems were solved, user acceptance was poor because of the large size and weight of the monitoring carts, the inadequate quality of displayed physiological data, and the difficult man-machine interface. Because the remaining problems could not be rectified with the existing monitoring carts, a new generation of

monitors was designed. The smaller, multiprocessor microDAME was designed to be automatic and user friendly. The microDAME eliminated much that had proved undesirable in the DAME system; however, when the microDAME was near completion departmental research ceased.

4.3.7 The AIS System

4.3.5 The Leicester System

The Leicester System is a clinical monitoring system which uses a computer and an analogue-to-digital converter connected to standard fluid pressure and transcutaneous blood gas measurement equipment. It collects and stores information from up to four channels as trend data points, as waveform samples or as both. Monitoring and waveform recording roles have not been combined before in comparable systems [62]. The trend data from any of the channels may be displayed on the computer screen as required as either a short-term (up to 3 h) or long-term (up to 99 h) graph. All these data may be retrieved from disk at the conclusion of monitoring to produce hard-copy for patient records. The pressure waveforms, in particular, have been used as the basis for subsequent research.

4.3.6 The Unibed System

Unibed is a computerised ICU patient monitoring system. The bedside module is a general-purpose unit designed to replace all the traditional monitoring devices. A microcomputer controls all user-interaction, signal processing, and data presentation in this unit. The nurse-station module, containing a microcomputer is responsible for information routing, controlling nurse-desk equipment, data and signal presentation. The system has been in use since 1978 in an 8-bed surgical ICU and since 1980 in a 8-bed coronary care unit [191]. The system makes use of application programs for ECG, blood pressures, temperature, thermodilution cardiac output, and fluid balance. Programs for monitoring controlled ventilation are as well present. The system currently has a feedback control of mechanical ventilation.

4.3.7 The AIS System

The Anaesthesia Information System (AIS) aids the anaesthetists to monitor and record physiological data during a surgical operation. The developmental impetus was to provide an anaesthetist-computer interface that can be adapted during the anaesthesia process to typical situations and to individual user behaviour. One main feature of this interface is the integration of the input and output of information. The device for interaction between the anaesthetist and the AIS is a touch-sensitive, high-resolution colour display screen. Information is entered when the anaesthetist touches the virtual function keys on the screen. A data window displays data generated over time, such as automatically recorded vital signs, including blood pressure, heart rate, and rectal and oesophageal temperatures; it displays manually entered variables as well, such as administered drugs, and ventilator settings [125]. The information gathered by the AIS is presented on the cathode ray tube in several pages. An overall view of the content of every work page is given on a main distributor page. A one-page record of the anaesthesia is plotted automatically on a multicolour digital plotter during the operation.

Medical staff who used the AIS imitated the anaesthetist's recording and information search behaviour but did not have responsibility for the conduct of the anaesthetic.

development problems in the areas of monitoring and clinical care. The next chapter will examine the underlying issues of knowledge and data base management.

4.3.8 The Zentralkrankenhaus Links der Weser System

A microcomputer-assisted monitoring system was developed for the continuous measuring and processing of cardiorespiratory variable, including systemic and pulmonary arterial pressures, CVP, minute ventilation, inspired and expired O₂ and CO₂ concentrations, temperature and heart rate. The primary data were converted to digital form, processed, displayed on a CRT monitor, and also stored for later evaluation. This system automatically calculated and displayed on-line and in real-time both primary measurements and derived cardiorespiratory variables, including oxygen consumption, CO₂ production, left and right ventricular stroke work, pulmonary venous admixture, and systemic and pulmonary vascular resistance [96]. Printouts of the variables and trend graphs could be obtained for any specified time period. During its development, the monitoring system was tested on 30 critically ill patients. It was discovered that the real-time calculation of cardiorespiratory variable was a great advantage during monitoring and treatment.

4.4 General Overview

Medicine is a complex and demanding world in which to introduce computer-based advisers. A broad range of information can be brought to bear on medical problems, including fundamental biomedical principles, clinical observations linking disease states to clinical findings anecdotal case-based knowledge, and critical interpretation of the clinical literature [204]. Due to the complexity and diversity of medical knowledge, it is challenging to develop robust, sophisticated computer-based adviser.

This chapter was an outline of some research projects that are beginning to confront development problems in the areas of monitoring and clinical care. The next chapter will examine the underlying issues of knowledge and data base management.

In the previous chapter a variety of approaches and associated prototypes in the area of monitoring was considered. This chapter will now deal with the role of knowledge and data information. This chapter will also present a view of data models and their development. It outlines data model concepts and terminology and those issues of particular interest to current research.

One active AI research area concerns the problems of integrating information from multiple sources for assessment [26]. For example, in the ORs are available:

1. Real-time physiological data from a host of monitors;
2. Intermittent laboratory data;
3. Diverse clinical observations made by inspecting the patient; and
4. Patient history that might be relevant to a particular clinical question.

Examples are seen in some of the systems discussed earlier. The problem of how to design a computer system to integrate and take full advantage of all the information and its interrelationships is an important area for basic AI research.

Another major area for basic research is validation of the knowledge in an expert system to ensure that it is accurate, complete, and consistent, and evaluation of the system's clinical efficacy [27]. In addition, a number of projects are exploring how the

5. KNOWLEDGE AND THE DATA BASE SYSTEM

5.1 Introduction

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Another major area for basic research is validation of the knowledge in an expert system to ensure that it is accurate, complete, and consistent, and evaluation of the system's clinical efficacy [27]. In addition, a number of projects are exploring how the

computer can assist actively in the validation process. Researchers have touched upon only a few of the issues that might be addressed when validating and evaluating medical expert systems [204].

Care of the critically-ill patient places rigorous demands on the practising physician. As a result of their illness or injury, these patients are subjected to a wide variety of operations. They are connected to sophisticated physiological monitoring equipment, their therapy is complex, its timing is critical, and careful documentation is essential. The large volume of resulting data must be stored, processed, and used for clinical decision making. The tremendous growth of medical information, the demand for cost-effective care, and the need to justify clinical decisions for patients, utilisation review committees, third-party payers, and health care policy makers have placed even more demands on physicians caring for the critically ill [82].

Twenty-five years ago, when large main-frame computers and cumbersome storage devices were required, it appeared inconceivable that an automated patient system would become readily and economically available for even a few bed locations [107].

With the advent of micro-computer technology, and in particular the Large Scale and Very Large Scale Integrated Circuit (LSI, VLSI) technology, micro-processor and micro-computer techniques are not utilised at all levels of data acquisition and processing. Compact high speed devices which store enormous amounts of information have proliferated making it practical, and cost-effective to create patient data management systems capable of accepting all electronically measured variables and laboratory data, reports, and demographic data, and also interpreting and analysing the information. Through database, spreadsheet, and mathematical and statistical transformations, critical events can be identified and various diagnoses suggested [107]. Calculations required for detailed and complex therapeutic regimes involving

antibiotics, fluid and electrolyte balance, and vasoactive drug manipulations can be done automatically.

5.2.1 Introduction

Many hospitals are developing computer-based management information systems whose patient database technology replicates, if not replaces, the traditional hospital chart [107]. The interested and informed physician can use these systems to the advantage of both himself and his patients. All he needs is equipment that measures physiological variables in areas such as the OR and the intensive care unit and can link up with wider database systems.

The technology exists to permit monitoring systems to interact with other biomedical equipment such as automatic lung ventilators and infusion pumps in a manner which would permit these devices to respond to physiological changes outside a given pre-set range [107]. However, discussion of these exciting possibilities is beyond the scope of this chapter.

The five basic components of a patient monitoring process dealt with in the previous chapters are: signal generation, data acquisition, data transmission, data processing, and data presentation or display.

In patient monitoring systems the patient, who is the source of all monitored information has to be connected safely and reversibly to a piece of equipment. In order to design the system, it is essential that the factors which affect the functional integrity and safety of the man-machine interface are appreciated [107]. Regardless of the sophistication of transducer technology, each system has its advantages, its disadvantages and its limitations.

5.2 Monitoring Devices and Data Collection

5.2.1 Introduction

Recently, infrared absorption, mass spectrometry, optics, and transcutaneous technologies have progressed rapidly. These technologies are the basis of the capnography, oximetry, spectrometry, vaporimetry, nitrousimetry, and transcutaneous oxygen ($P_t\text{CO}_2$) monitoring systems. These systems are capable of continuous and noninvasive monitoring of the following:

- ◇ The gas supply to the anaesthetic machine and ventilator;
- ◇ The integrity of the entire breathing circuit;
- ◇ The state of the patient's oxygenation and CO_2 concentration;
- ◇ Changes in the patient's metabolism, circulation, and ventilation; and
- ◇ The concentration of anaesthetic agent being delivered [255].

- Anaesthetist or Nurse Anaesthetist should be present in the operating room.
- Every patient receiving anaesthesia shall have arterial blood pressure and heart rate measured every 5 minutes.
- Every patient receiving anaesthesia shall have the electrocardiogram continuously displayed during the operation.
- Continuous monitoring of the patient's ventilation and circulation during general anaesthesia.
- Continuous breathing system disconnection monitoring.
- Measurement of oxygen concentration in the patient breathing system with an oxygen analyser during every administration of general anaesthesia.
- During every administration of general anaesthesia there should be readily available a means to measure the patient's temperature.

TABLE 5-1. Harvard Minimal Monitoring Standard.

- Qualified anaesthesia person present at all times
- Continuous evaluation of:
 - Oxygenation (inspired oxygen concentration, blood oxygenation).
 - Ventilation (continuous evaluation of the adequacy of ventilation, with controlled ventilation).
 - Circulation (continuous display of ECG waveform, arterial blood pressure, heart rate determined, continuous evaluation of oximetry).
 - Body temperature.

TABLE 5-2. Summary of ASA Standard for Basic Intraoperative Monitoring.

Currently standard practice appears to include the use of an electrocardiographic (ECG) monitor, blood pressure device, and a monitor of delivered oxygen concentration,

although this is difficult to document [260]. A stricter standard was adopted by the House of Delegates of the ASA on October 21, 1986 [69]. A discussion of the reasons the Harvard standard was adopted is contained in Table 5-1 [70]. The minimum requirements of the ASA standard are summarised in Table 5-2.

MONITORS	ALARMS													
	Hypoxic	Tachycardic	Bradycardic	Hypotensive	Hypertensive	Rebreathing	Hypocapnic	Hypercapnic	Tachypnoeic	Low FIO ₂	Hypothermic	Hyperthermic	Hypoventilation	Continuous Pa
Pulse Oximeter	Existing Variable	Heart Rate	Heart Rate											
ECG		Heart Rate	Heart Rate							Existing Variable				
Non-invasive Blood Pressure Monitor		Heart Rate	Heart Rate	Existing Variable	Existing Variable									
Anaesthesia Machine							Respiratory Rate	Respiratory Rate			Existing Variable	Existing Variable	Existing Variable	Existing Variable
Mass Spectrometer				Existing Variable	Existing Variable	Existing Variable	Respiratory Rate	Respiratory Rate						
	Existing Variable	Heart Rate	Heart Rate	Respiratory Rate	FIO ₂ Value									

FIGURE 5-1. Matrix of Monitors vs. Alarms.

It is believed that stricter standards, requiring additional monitoring equipment, will further reduce the incidence of patient injury and be cost-effective [260]. The monitoring array is summarised in Table 5-3. In the following paragraphs a detailed description is provided. In the Figure 5-1 the effectiveness is estimated of each instrument identifying conditions leading to the specific injuries associate with the categories listed in Table 5-4. The matrix represents an opinion based partly on a review of the literature and partly on gained experience.

•	Noninvasive blood pressure monitor
•	Pulse oximeter
•	Electrocardiogram
•	Anaesthesia machine
•	Mass spectrometer

TABLE 5-3. PONI Monitoring Array.

•	o2sat,	low:	hypoxic
•	hr,	high:	tachycardic
•	hr,	low:	bradycardic
•	bpsys,	high:	hypertensive
•	bpsys,	low:	hypotensive
•	fiCO2,	high:	rebreathing
•	petCO2,	high:	hypercapnic
•	petCO2,	low:	hypocapnic
•	rr,	high:	tachypnoeic
•	fiO2,	low:	lowFiO2
•	temp,	high:	hyperthermic
•	temp,	low:	hypothermic
•	ve,	high:	hyperventilation
•	ve,	low:	hypoventilation
•	peep,	high:	continPa
•	peep,	low:	negAirwayPressure
•	pip,	high:	barotrauma

TABLE 5-4. Individual Alarms.

5.2.2 Completeness and Consistency of Collected Information

Most likely, a mention of operating room monitoring would conjure up in physicians' minds equipment monitoring blood-pressure or ECG, pulse oximetry and anaesthesia gases. These were certainly the focus of systems introduced 20 years ago; but newer systems dealing with a much broader class of information are becoming available [81].

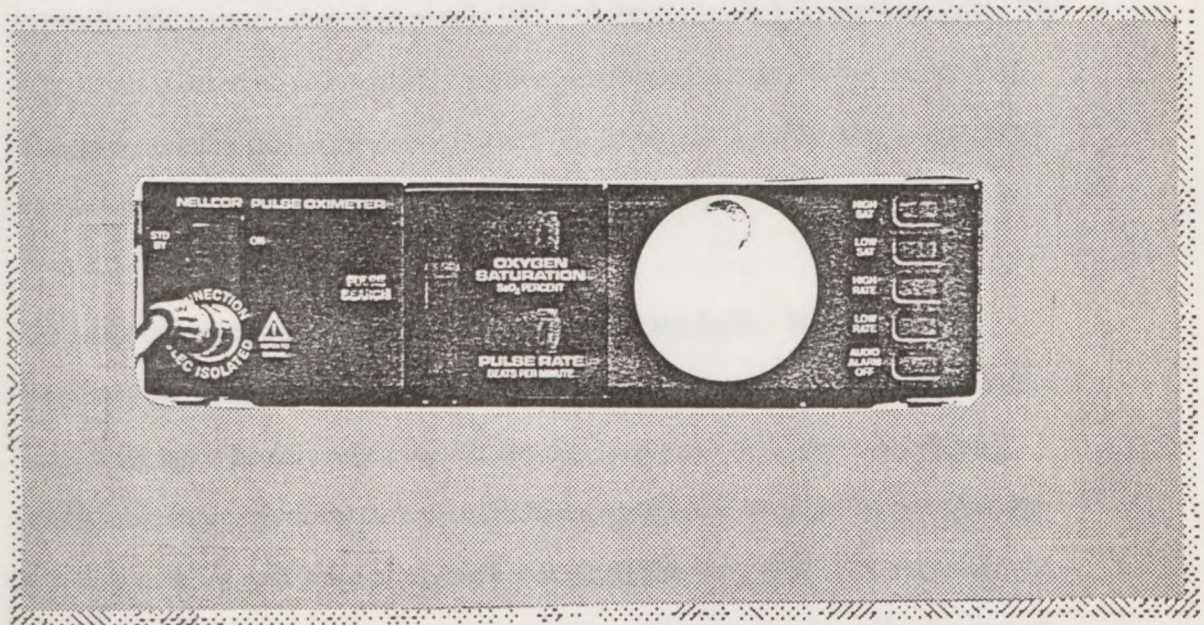


FIGURE 5-2. Pulse Oximeter.

PULSE OXIMETER. The pulse oximeter (Figure 5-2) measures oxygen saturation of arterial blood, as well as heart rate and qualitative arterial pressure waveform. The waveform permits a qualitative estimate of the perfusion of that limited area. Ear or finger oximetry reliably and continuously monitors the oxyhaemoglobin saturation and the pumping action of the heart. Pulse oximeters utilise a solid state, dual wavelength, optical sensor to detect changes in light transmitted through tissue (usually a fingertip) due to blood-volume fluctuation in a vascular bed [267]. When the arterial vascular bed expands during systole, the path length of light transmitted through the tissue increases correspondingly; the light corresponding increase in the path length of light

transmitted through the tissue produces a photoplethysmographic waveform. The amount of blood entering the vascular bed with each heart beat, the wavelength of the incident light, and S_aO_2 determine the amplitude of the waveform. The transmitted light intensity is composed of a pulsatile component created by arterial pulsation, and a fixed component due to light absorption by tissue, bone, venous blood, and diastolic arterial blood. The pulsatile component is filtered and amplified and the ratio of the red (typically 660 nm) to infrared (typically 940 nm) signals is used to calculate S_aO_2 . The calculation is based on an empirical equation whose coefficients are determined from clinical calibration studies. Pulse oximeters do not require tissue heating to arterialise the blood and thus eliminate the risk of burn to the patient [157].

The pulse oximeter was always successful in measuring S_aO_2 . The ability to accurately and continuously monitor S_aO_2 is no longer just a desirable ideal method of monitoring but is heavily relied upon in the day-to-day care of patients undergoing anaesthesia, those in critical care units, those being tested in exercise laboratories and sleep laboratories, and those receiving home oxygen therapy [33]. Consequently, the oximeter monitors the oxygenation of the patient and can provide an early warning of otherwise undetected hypoxic events. A continuous reading of the percent of oxyhaemoglobin saturation at the finger tip by finger oximetry provides concrete evidence of pulsatile flow, a direct and useful measure of cardiac pumping and circulation. Certain oximeters sound an audible tone with pitch directly linked to the level of saturation. This feature is valuable in case of difficulty with oxygenation, it enables the anaesthetist to appraise the direction of saturation change without visual observation of the monitor. The disadvantages of pulse oximeters is its sensitivity to movement artifact and low perfusion states. Several models are sensitive to electrocautery interference.

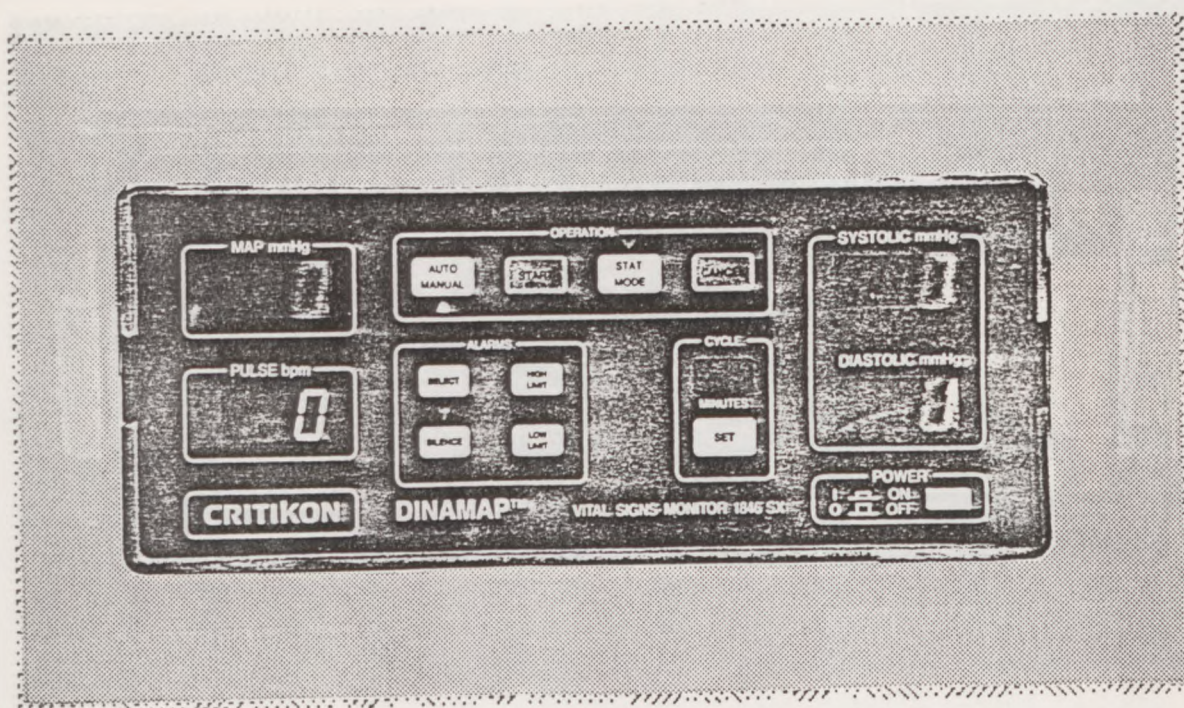


FIGURE 5-3. Noninvasive Blood Pressure Monitor.

AUTOMATIC NONINVASIVE BLOOD PRESSURE MONITOR. Advances in technology have made new instruments available to free the hands of the anaesthetist. The noninvasive automatic blood pressure (NIBP) monitor (Figure 5-3) has already found widespread acceptance in replacing intermittent manual sphygmomanometry [131]. This device presents distraction of the anaesthetist by periodic blood pressure measuring. Unfortunately it has slight to moderate sensitivity to movement; however this has not discouraged widespread use [259].

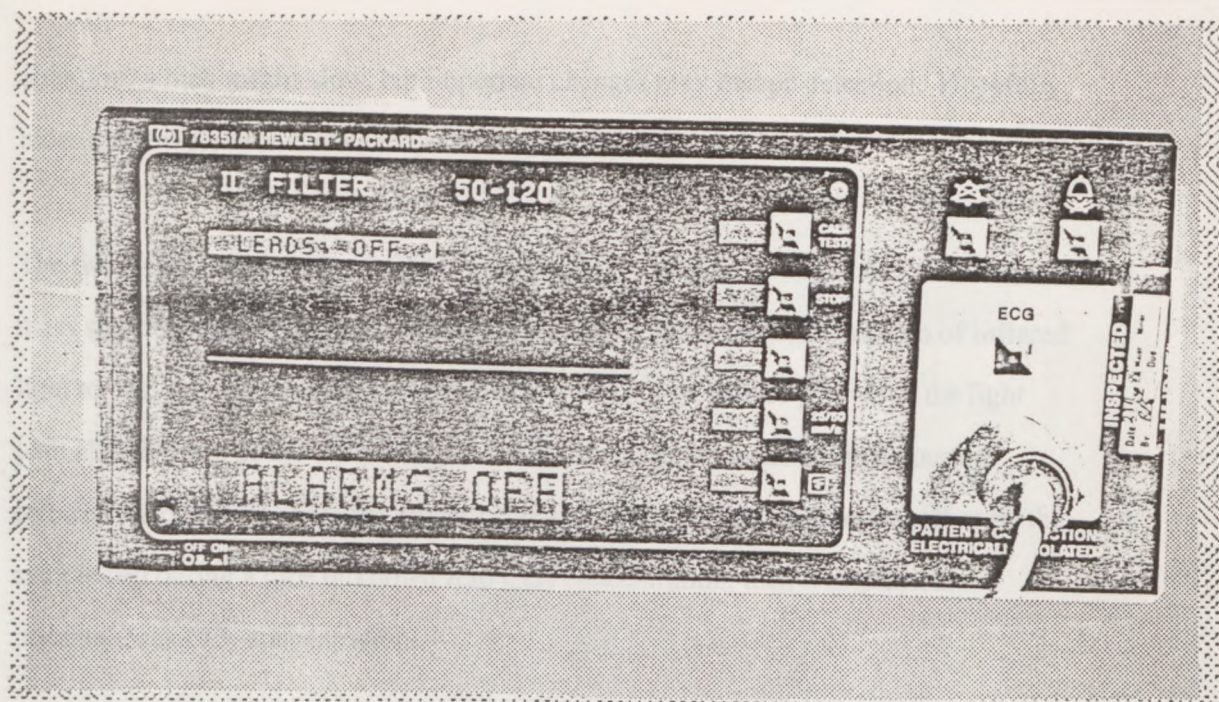


FIGURE 5-4. Electrocardiogram.

ECG MONITOR. This device (Figure 5-4) measures the electrical activity of the heart and displays it. Newer systems require five leads and can display all diagnostic axes. ST segment monitoring increases the opportunity to identify cardiac ischaemia and is also a useful source of heart rate. It is gaining acceptance increasingly. One of the primary uses of the ECG for healthy patients is to provide an additional audible pulse rate signal and direct rate read-out. It provides a valuable alerting function to the anaesthetist and/or other OR personnel during a cardiac arrest; however, under normal circumstances it is a poor early warning of potential problems [102]. Other traditional monitors of circulatory functions such as blood pressure, heart sounds, and palpation of the pulse are not as sensitive as the ECG in distinguishing between arrest and hypotension.

STETHOSCOPE. The stethoscope monitors both the respiratory and cardiovascular systems and airway disconnection. Its effectiveness depends on vigilance (sustained

attention) which means slow, but important changes may escape detection. Hopefully, more modern electronic units may enhance performance.

The two widely used devices of CO₂ measurement today are infrared analysers and mass spectrometers (Figure 5-5) [239]. An infrared analyser causes a beam of infrared light to pass through the sampled gas. Carbon dioxide molecules present in the light path absorb some of the infrared light. Thus, the system compares the amount of infrared energy absorbed to the amount absorbed by a CO₂-free reference cell or by the sample cell during a time of known zero CO₂ concentration; then it displays the instantaneous CO₂ concentration.



Figure 5-5. Mass Spectrometer.

MASS SPECTROMETER. This is one of the available single monitors that measures all anesthetic gases and vapors, breath by breath. Nitrogen measurement detects air embolism and air leakage into breathing circuits. Specific halothane measurement identifies and quantifies unwanted mixtures of agents. The mass spectrometer continuously measures in detail the inspired and expired concentrations of six gases: oxygen, nitrogen, N₂O, halogenated anesthetic agents, and CO₂. Any deviation from their normal values is detected within seconds. By displaying delivered gas and end-tidal concentrations, the spectrometer focuses on variables which deviate from the expected values. It often pin-points the nature of a mishap [255]. Several manufacturers have made reliable mass spectrometer systems available for use in

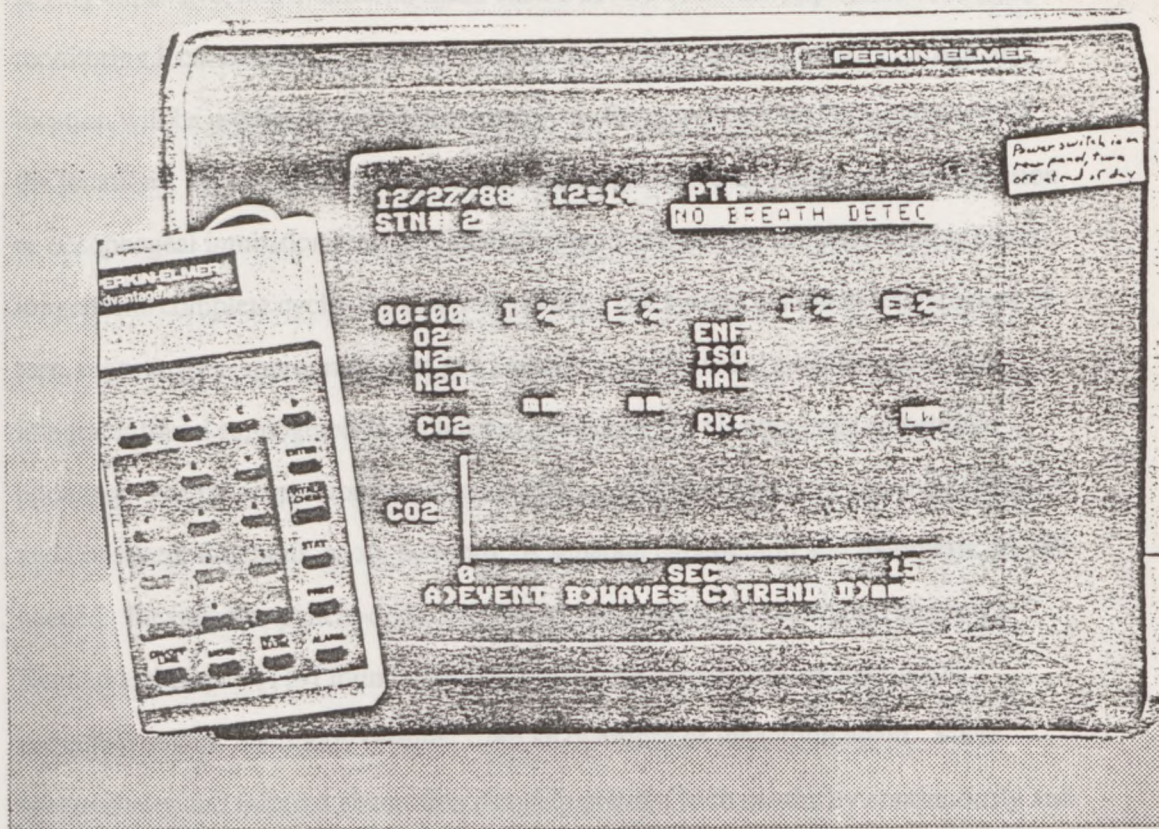


FIGURE 5-5. Mass Spectrometer.

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anaesthesia monitoring. The major problem with a mass spectrometer is that the device is very expensive, and in order to make such a device economically feasible, several monitoring locations share it. Sharing the central system means that any particular location will be monitored only intermittently as the system makes its rounds among the locations. Thus, sudden and possible catastrophic events as airway disconnection or oesophageal intubation may go undetected by the mass spectrometer system for as long as one complete cycle of monitoring [239]. The system examines each patient in turn, reporting the appropriate data to a cathode ray terminal at each location. An integral infrared capnograph in each room minimises the disadvantage of periodic updating. The mass spectrometer system offers centralised maintenance and calibration and consistent functions, room by room. A separate capnograph and halometer are not needed. Inexpensive patient-dedicated mass spectrometers are available currently. Keenan and Boyan [119] found that one-third of the anaesthesia-related deaths occurring at their institution resulted from an overdose of inhalation agent. Mass spectrometry and infrared absorption can help prevent such deaths by continuously and reliably measuring inspired and/or expired concentrations of nitrous oxide (N_2O) and halogenated anaesthetic agents. Gathered information alerts the anaesthetists to any delivery of excessive N_2O and volatile agents and also the accuracy of the vaporiser and flowmeters.

CAPNOGRAPH. The most rapid, reliable, and positive detector of oesophageal intubation and airway disconnection is the capnograph. The capnograph indicates inhaled and exhaled carbon dioxide concentrations and assesses variables such as ventilation, cardiac output, distribution of blood flow, and metabolic activity (e.g. malignant hyperthermia). Modern capnographs measure nitrous oxide, also. Its waveform display capability is desirable; it reduces the risk of misinterpretation which increases the utility of the device. Capnography measures continuously the changing concentration of CO_2 during each respiratory cycle, thus furnishing information on

metabolism, circulation, ventilation, and circuit integrity [224]. Any significant deviations in these variables are discernible immediately on the capnogram. Usually, endotracheal tube misplacement results in a loss of the capnogram. Kinking increases the slope of the ascending limb of the capnogram. Failure to ventilate, hypo- and hyper- ventilation will produce changes in the capnogram in a few breaths. Any disconnection returns the capnographic waveform to baseline instantly. If a misconnection occurs, the CO₂ concentration shows a straight line reading of CO₂ since the patient can neither inspire nor expire. A major overdose of anaesthetic agent will impair cardiac output, which will prevent the circulation from transporting CO₂ to the lungs. A progressively continuous fall in the height of the capnograph parallels an increasing circulatory impairment or a progressively diminishing circulatory blood volume. Because there is only one normal capnographic waveform, any deviation must be interpreted and corrected. Capnography will detect most significant respiratory, haemodynamic, and equipment aberrations as they occur, often before the patient's oxygenation and CO₂ levels change [255].

HALOMETER. This device detects over- and underdosage of halocarbons (e.g. halothane) and warns of airway disconnection. Rapidly responding models measure inhaled and end-tidal concentrations; the latter correlates with anaesthetic depth. The halometer does not usually identify a specific agent except for the mass spectrometer. The agent in use must be manually entered. Halometry facilitates the use of economical low-flow-rate techniques.

SPIROMETER. The spirometer monitors ventilatory volumes and detects airway disconnection and obstruction.

BREATHING CIRCUIT OXYGEN ANALYSER. A recent addition to the monitoring of gas transport is the transcutaneous oxygen analyser. This oximeter monitors

oxygen tension of gases delivered to the patient and warns of disconnection of the gas supply and miscalibrated flow meters. From a theoretical stand-point, instantaneous awareness of P_aO_2 is most important in averting serious patient injury. Since current transcutaneous monitors respond to changes in the skin circulation as well as to P_aO_2 they give additional information about the circulation. Failure of skin blood flow appears to provide valuable warning of impending shock. However, this has not proven to be as easy to use as capnography [102].

THERMOMETER. Euthermia favours normal cardiovascular function and clotting. Hyperthermia is a late indicator of malignant hyperthermia.

AUTOMATED RECORD KEEPER. This device offers objectivity in record-keeping, continuous recording of data, great accuracy, and consistent, legible records. It reduces anaesthetist distraction due to record keeping. Unfortunately, it records artifacts the anaesthetist would not accept [156][260].

5.2.3 Data Acquisition

Data acquisition includes the collection of data and may involve both data transduction and data conditioning [107].

For convenience and because of space limitations, reference will be made in this review primarily to the measurement and monitoring of the electrocardiogram (ECG) and blood pressure (BP). These commonly monitored variables are excellent examples of the two general classes of monitored variables.

The first class, represented by the ECG, is that which generates bio-electric potentials, and can be detected directly, usually by electrodes applied to the skin which are then

attached to amplifiers. The second class, represented by the non-invasive blood pressure monitor, does not generate bio-electric potentials; but it requires specialised transducers in order to generate an electronic signal.

Measurements must be prepared or conditioned before they can be analysed and interpret. This is done usually with amplifiers or filters or conversion for a digital format. Data conditioning may be considered in two stages, namely, pre-conditioning and conditioning.

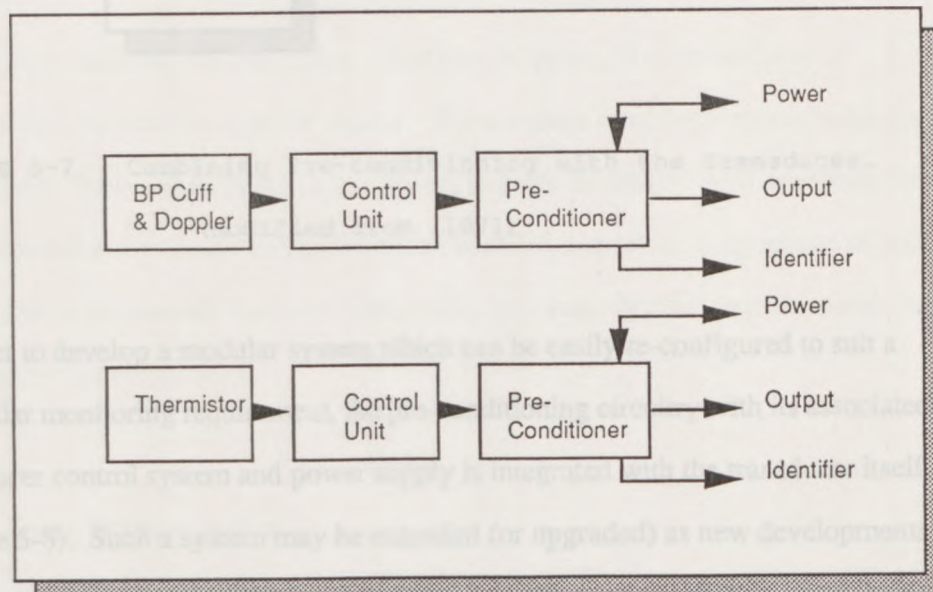


FIGURE 5-6. Output Conversion of Dissimilar Transducers.

(Modified from [107])

A source signal is converted by pre-conditioning into a standardised format suitable for a common conditioning process (Figure 5-6). This process is similar to the pre-amplification of signals in an audio amplifier. However, in the case of audio, signal may be in either analogue or digital form. The component parts of the circuitry for different transducer systems are similar but not interchangeable. If the preconditioning

circuitry is integrated with the main monitoring chassis, the device will remain dedicated and rather inflexible or at least inconvenient to use (Figure 5-7). Many stand-alone monitors follow this approach [107].

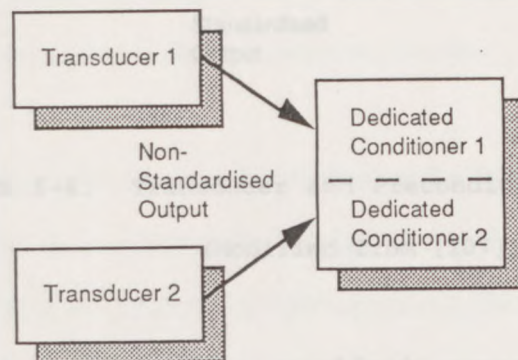


FIGURE 5-7. Combining Pre-conditioning with the Transducer.

(Modified from [107])

In order to develop a modular system which can be easily re-configured to suit a particular monitoring requirement, the pre-conditioning circuitry with its associated transducer control system and power supply is integrated with the transducer itself (Figure 5-8). Such a system may be extended (or upgraded) as new developments occur without the need for major reorganisation and expense [107].

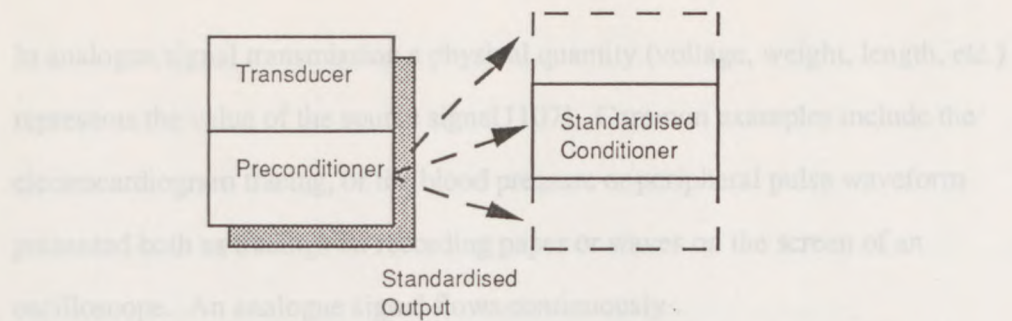


FIGURE 5-8. Transducer and Preconditioner Integration.
(Modified from [107])

During conditioning, a signal is processed for the purposes of transmission, processing (analysis), storage or display. If the signals have been appropriately preconditioned, they will have the same format, and will be labeled with an internally coded identifier [107]. Such signals can be handled in a uniform, generalised fashion by the rest of the monitor system. This results in a more flexible overall system with reduced design complexity.

5.2.4 Data Transmission

Before the data collected from the patient can be used, it must be transmitted to the next part of the system. This can take place at several points, as the input to, within, or as the output from the monitor. The descriptions which follow apply equally to data transmission locally within the traditional bedside monitoring unit and to larger integrated systems including those with remote analogue and digital processing equipment for data processing and display [107]. Whether the data transmission should be in analogue or digital form is beyond the scope of this review. However, the reader should have a clear understanding of what is meant by analogue and digital and be aware of the limitations of each.

In analogue signal transmission a physical quantity (voltage, weight, length, etc.) represents the value of the source signal [107]. Common examples include the electrocardiogram tracing, or the blood pressure or peripheral pulse waveform presented both as tracings on recording paper or waves on the screen of an oscilloscope. An analogue signal flows continuously.

Digital transmission, on the other hand, involves the transmission of codes which are used to represent the numbers or the value of the signal. The digital representations of the source variable are presented at regular intervals [107]. Thus, signals transmitted in digital form are made up of discrete data points.

Current technology favours the digital format because it prevents noise and digital distortion. In addition, with digital data it is possible to correct errors more easily. The digital format isolates and protects patients from electrical hazards, a plus for physicians. Thus, increasingly, the physician is being supplied with devices and equipment which use digital technology and logic [107].

5.2.5 Rationale for Choice of Data

During 1986 the common physiological measurements reported in literature were those most often used in the clinical setting, such as blood pressure, heart rate, weight, and temperature. Occasionally chart review determined the measurements without discussion of the accuracy of the particular laboratory involved or the recording procedure [86].

The validity of physiological measures is described specifically as criterion-related validity the degree to which scores on an instrument are correlated with an external criterion measured either in the future or concurrently [86]. For example, to assess the

concurrent validity of physiological measures blood pressure measurements obtained through intraarterial lines may be used as the criterion to establish the validity of auscultatory blood pressure readings. Predictive validity can be established by evaluating a measures strength as a predictive clinical tool [240]. For example, peak expiratory low rate has been demonstrated to predict asthma episodes.

The types of validity identified for physiological measures and those needed for physiological measures are not always comparable because of inherent differences in the nature of the different measures. Although the notion of construct validity is probably more relevant for physiological measures, the counterpart for physiological measures entails an understanding of human physiology and the mechanics or engineering of the physiological equipment [86]. Comparison of a new measure with standards set by the National Bureau of Standards, as reported by Cashion and by Shanks in establishing the validity of electronic thermometers, is an example of this type of assessment [32][216].

Comparing results obtained from a small portable device with those from a larger and more complete instrument may be a method of assessing whether the instrument taps the domain of the variable being measured, a counterpart to content validity [86]. Eichenhorn et al., for example, compared the results of a portable peak expiratory flow meter with those of a spirometer [68].

Using physiological measures is difficult because of the similarities and interrelationships among all body systems [50]. It is important to choose an instrument that has selectivity, the ability to identify correctly the signal under study and to distinguish it from other signals. For example, the selectivity of electrocardiographic signals permits detection of electrical signals generated by the myocardium from those generated by skeletal muscles. In controlling for the interrelationships among body

systems, it is difficult at times to decide what is affecting the variable being measured. For example, are changes in intracranial pressure the result of position changes or the result of the touch involved in turning the person? Making this determination requires careful planning of the research protocol to control or monitor the other, possibly unknown, factors [86].

Since hypoxia (and not usually hypercapnia) causes damage and that hypoxia generally precedes hypercapnia, a tool is needed that will monitor tissue oxygenation continuously and reliably. Monitoring brain oxygen saturation and heart oxygen saturation is essential also, as both organs consume oxygen and do not store it [177]. However, that is not possible at present, so the use a pulse oximeter in addition to capnography to monitor the adequacy of ventilation and oxygenation is necessary. It may be believed that one or the other method is adequate, but it has been found otherwise in the surgical environment. To amplify, consider some clinical situations encountered during pre-induction evaluation and in the OR, intensive care unit, and recovery room.

Anaesthetic induction and endotracheal intubation are especially risky procedures in which both capnography and pulse oximetry are helpful; they assure adequate ventilation and oxygenation by giving an early warning of problems. In addition, by attaching the pulse oximeter probe to the finger prior to preoxygenation, the proper function of the pulse oximeter is assured, as is its appropriate placement. Adjustments to its location are made at the clinician's leisure, without the distraction from the patient, that would occur during intraoperative placement. A thick layer of nail polish, a poorly perfused digit, an inoperative or defective probe, as well as an inappropriately directed light may be discovered before anaesthetic induction begins. Occasionally a patient has lower than expected oxygen saturation, and a quickly obtained arterial blood gas and a change in anaesthetic plan may be indicated by this piece of data [177].

Once preoxygenation is initiated, a capnograph is obtained usually through a mass spectrometer. Although the capnograph with a face mask may be of poor quality, it provides some assurance that ventilation is taking place and the system is working properly. If a gas sampling tube is disconnected, inappropriate oxygen concentration is indicated, and a lack of carbon dioxide is shown. The mass spectrometer provides information about other respired gases, it displays, for example, inspired gas and expired oxygen concentration and it indicates when a patient is denitrogenated [177]. Shortly after initiation of preoxygenation, a rise in arterial oxygen saturation is expected which denotes that all is well with patient and instrument.

The following example of oesophageal intubation concerns highlights the multiple physiological problems facing us and will provide a better understanding of the reasoning needed to select proper devices and data.

Although useful in many situation pulse oximetry may be a late indicator of oesophageal intubation. Authors [188][139] have noted normal functioning of a ventilator when connected to an oesophageal tube. With the vocal cords relaxed, mechanical (or manual) ventilation into the oesophagus can cause alveolar gas exchange. After deliberate intubation of both oesophagus and trachea, ventilation into the oesophagus also caused ventilation of the lungs, evidenced by carbon dioxide recording obtained from the open endotracheal tube in 18 of the 20 patients studied by Linko et al. [139]. Because ventilation of the lungs with room air will considerably slow the onset of haemoglobin desaturation and cyanosis after oesophageal intubation, this can delay recognition of tube misplacement until surgery is in progress or distractions such as record keeping are taking place. Therefore detection of haemoglobin desaturation with pulse oximetry may provide a relatively late sign of tube malposition [15].

Perhaps the most reliable and simple determination of proper tube placement involves capnometry, the measurement of carbon dioxide concentration during the respiratory cycle, and/or capnography, the display of this concentration in a wave form on a screen or paper graph [15]. Carbon dioxide is reliable because CO₂ can be detected in monitoring patients with an intact pulmonary circulation whose trachea is intubated, whereas no CO₂ is present in gases exiting from an oesophageal tube.

Easily identifiable CO₂ curves are obtained with ventilation through the trachea [139]. Initially, carbon dioxide can be detected with oesophageal intubation when expired CO₂ has been forced into the stomach during prior mask ventilation [15]. End-tidal CO₂ is low in such cases and the wave pattern irregular. Since CO₂ levels diminish rapidly with repeated ventilation, it is easy to distinguish between intratracheal and intraoesophageal tracings [139].

Finally, the mass spectrometer can produce a continuous CO₂ waveform, as well as a digital value, which allows for rapid diagnosis of accidental intraoperative disconnection of the breathing circuit between ventilator and endotracheal tube. This event is identified by Cooper et al. as the most frequent "preventable anaesthetic mishap" [45]. Intraoperative tube obstruction from secretions or kinking also may be diagnosed. Even inadvertent movement of the tube tip from the trachea into the retropharynx can be detected by the distinctly different end-tidal CO₂ waveforms produced [15]. The noninvasiveness of such monitoring has been a factor, researchers [181] stressing that no other parameter can so readily evaluate the status of both ventilatory and metabolic systems. Duberman and Bendixen [65] state, "The capnometer is the best device for warning of an undetected oesophageal intubation." A non-profit biomedical engineering research firm concluded that combined with blood pressure and heart rate measurement, carbon dioxide monitoring "comes closest to

being a fail-safe monitor for most problems that can cause anoxia and death" after an assessment of human and technology related errors [60].

In summary, end-tidal carbon dioxide measurement is perhaps the most reliable means of determining proper tube position and should be employed routinely whenever possible [15].

In another example, concerns on anaesthetic ventilation are highlighted and the related physiological problems. The patient looks a little dusky, his blood looks dark and the heart rate is slowing. These observations alert key operators to evaluate the patient for problems. The first step is to determine the adequacy of ventilation. Monitoring ventilation requires observation, auscultation, instrumentation, and occasionally, palpation. A decision is based on past experience [177].

A study of cardiac arrest [119] due to anaesthesia determined 449 cardiac arrests recorded during 163,240 administrations of anaesthesia were "due to anaesthesia and/or the anaesthetic management." Twelve of the 27 were due to a failure to provide adequate ventilation. Hypoxaemia was cited as "obviously the direct cause of cardiac arrest in each of these patients in the 'failure to ventilate' group" [177]. Since in most instances, early recognition of hypoxaemia would have prevented the mishap, this study suggests that the routine monitoring of arterial oxygenation would significantly reduce the incidence of anaesthetic cardiac arrest.

Cooper and colleagues [42] analysed major errors and equipment failures in anaesthesia management with significant results. By studying near-misses and negative outcomes to patients they discovered that failure to detect inappropriate ventilation, wrong airway management technique, breathing circuit disconnection or misconnection, and oesophageal intubation caused 23 of the 70 substantive negative

outcomes. Approximately half of the equipment failures were airway device-, ventilator-, or breathing circuit-related. The authors concluded that "no fewer than 14 of the 70 substantive negative outcome incidents probably would have been detected much more promptly had some combination of monitoring based on oxygen sensing and surveillance of ventilation been in use." For the purpose of discussion, note that three fourths of the substantive negative outcomes involved moderately or severely ill patients. As today's patients are older, and sicker, less margin for error is critical [177]. There is a feeling, that the above results prove a serious need to monitor oxygenation and ventilation with more accuracy, rapidity, and specificity.

With induction of anaesthesia and its attendant alterations in gas exchange, the anaesthetist needs lung function monitoring instruments that not only measure but also warn. Measurement and warning are not necessarily synonymous; after the anaesthetist assumes the function of risk assessment. Thus, all mechanical and electronic methods are supplemental to physical examination, i.e., inspection, palpation, percussion and auscultation. Anaesthetists always use a precordial or oesophageal stethoscope; the risks are nil, the benefits enormous. However, just as the presence of electric cardiac activity does not guarantee systemic perfusion, neither does the presence of breath guarantee adequate alveolar gas exchange [29]. To monitor both carbon dioxide and oxygen exchange, ancillary techniques and instrumentation have been developed.

Inspection of the reservoir bag permits an estimate of minute volume (V_E) of CO_2 in spontaneously breathing subjects. However, anaesthetic circuits or faulty valves which permit rebreathing can mislead the clinician. Because anaesthesia can produce respiratory depression and rebreathing of CO_2 can be highly variable, qualitative monitors of spontaneous ventilation, such as respiratory rate, tidal volume, movement of reservoir, chest-abdominal movement, the stethoscope, and transthoracic electrical

impedance measurements, are not as reliable as devices measuring alveolar or arterial PCO_2 [209]. End-tidal CO_2 can be monitored using an infra-red capnograph or mass spectrometer, except in the high-risk group of pulmonary disease patients where the end-tidal CO_2 to arterial PCO_2 gradient increases. Transcutaneous CO_2 monitoring (TcPCO_2) has limitations, but may be useful in some cases [29].

The last three causes of hypoxaemia can be detected only by monitoring arterial or venous PO_2 . For oxygen, minor alterations of PaCO_2 do not denote serious problems; however, this is not true for PaO_2 . Potential causes of hypoxaemia are:

- Transcutaneous oxygen analyzers (TcPO_2).
- ◊ Decreased $\text{F}_\text{I}\text{O}_2$.
- Intra-arterial PO_2 sensors.
- ◊ Decreased alveolar ventilation (V_A).
- Oximetry.
- ◊ Increased V/Q mismatching.
- TcPO_2 detects capillary PO_2 but needs a 30-45 minute warm up and has limited usefulness in low flow states [22]. Intra-arterial PO_2 sensors are expensive, invasive and are altered by temperature, blood flow rate and N_2O .
- ◊ Decreased $\text{P}_\text{V}\text{O}_2$ in:
 - Anaemic states;
 - Low cardiac output states; and
 - Increased VO_2 conditions.

In conclusion, current technology provides reliable, versatile techniques to monitor $\text{F}_\text{I}\text{O}_2$ should be monitored always with a properly calibrated oxygen analyser in the inspiratory limb of the breathing circuit. Improvements in design are underway to reduce the incidence of hypoxic gas delivery due to human error or machine malfunction during $\text{F}_\text{I}\text{O}_2$ monitoring [29].

Decreased- V_A -induced hypoxaemia is caused most frequently by a disconnection during mechanical ventilation [45]. Anaesthetic ventilators should be used only in conjunction with low pressure disconnect alarms, although such threshold alarms are not fail-safe [152] [29].

The last three causes of hypoxaemia can be detected only by monitoring arterial or tissue PO_2 . Three techniques are available:

- ◇ Transcutaneous oxygen analysers (T_CPO_2).
- ◇ Intra-arterial PO_2 sensors.
- ◇ Oximetry.

T_CPO_2 detects capillary PO_2 but needs a 30-45 minute warm up and has limited usefulness in underperfusion and obese states [221]. Intra-arterial PO_2 sensors are expensive, invasive and are altered by temperature, blood flow rate and N_2O concentration [94]. Pulse oximetry, a non-invasive routine monitor of oxyhaemoglobin saturation, is the most likely of the three techniques to be used routinely [267][29].

In conclusion, current technology provides reliable, versatile techniques to monitor lung function [29]. Note that inspired oxygen concentration, airway pressure and disconnect alarms should be monitored at all times because vital to patient survival.

- **ECG**

Full multi-lead selection.
Arrhythmia detection.

- **Gases**

End-tidal carbon dioxide should give accurate information.
Inspired oxygen analysis should be available.
Pulse oximetry should be available.
Anaesthesia gas concentrations.

- **Haemodynamic monitoring**

Pressures, measurement of cardiac output, blood temperature
and blood gas saturation data.

- **Pressure**

Pulmonary, intracranial, or other pressure measurement.

- **Temperature**

TABLE 5-5. General Monitoring Selection Criteria.

Selection criteria for monitors can be observed in Table 5-5 [107].

In gas exchange it is the heart's job to transfer oxygen through the lungs and to the tissues-gas transport. Cardiac output measurements will alert monitor of failure of this organ. Adequate cardiac output is indicated by the presence of metabolic acidosis and by arteriovenous oxygen. Adequacy of gas transfer in the lungs is best monitored by measuring the P_aO_2 , lung mechanics. Spirometry indicates function of the ventilatory pump and the lungs. Monitoring P_aCO_2 denotes adequacy of ventilation and thus of the effectiveness of the ventilatory pump. Inspiratory and expiratory force measure its strength but not its endurance [180]. Ventilatory pump failure is assessed still today by elevation of P_aCO_2 . A better predictor of impending fatigue is needed.

Often focused upon are the ventilator and its control. A ventilator substitutes only for the ventilatory pump. The type of dysfunction of the pump and the disorder of lungs and heart will delineate the requirements of the ventilator and monitors needed [180].

When the patient is pulled from a motor vehicle with multiple injuries with complicated lung infection or postoperative course - the modern OR patient - the most sophisticated ventilator is inadequate. A system is needed that is able to facilitate control of all these elements of the gas exchange system and most important, the interaction between the three [180]. Then the physician includes in the decision process the effects of the patient's primary disorder- chest injury and/or multiple fractures and/or head injury and/or sepsis.

Present systems need improvements to manage such complex cases. Currently they fail to collect and monitor critical data and to aid the nurses and physicians in the enormous task of recording and synthesizing data which is essential in decision making.

When patients develop ventilatory failure, is the proper information available? When no agreement has been reached on criteria for setting levels of positive end-expiratory pressure (PEEP) and for settling the difference between continuous positive airway pressure (PAP), the importance of mean airway pressure, the effect of pleural pressure on cardiac afterload and preload, clearly there is much to learn. Unfortunately, available knowledge has not been used fully [180]. Ventilators and their management should not require a complex bank of unnecessary dials. Analysis of ventilatory mechanics and functional residual volume is feasible and relatively simple. As such technology is used for decision making, new questions will arise and should be explored.

5.3 Data Representation and Utilisation

Data presentation and display deals with the machine-man interface. The main interface relies on auditory and visual sensory clues. Visual display is accomplished either by presentation of the measured variables on a display screen (oscilloscope, cathode ray tube, etc.) or as a paper recording or print-out, hardcopy.

In the early days of monitoring, source waveforms and any initial techniques were displayed by analogue techniques. Oscilloscopes used either bouncing-ball or prolonged intensity or storage display techniques; meters (voltmeters, ammeters) were fitted with appropriate scales to permit direct read-out rates, pressures, and temperatures. Current varying in intensity with the variable being monitored set off flashing lights, thus permitting an analogous visual presentation. More recently, the emphasis has been on the use of digital technology whether the presentation is in analogue or digital form [107].

The medical record is the principal instrument for ensuring continuity of care for patients [200]. Continuity is especially important for critically ill patients, served by a team of physicians, nurses, and therapists who rely on the medical record in turn [81].

The data base consists of a detailed procedure file, which references many master files.

The procedure file has a three part key:

- ◇ HUPID (patient history number);
- ◇ Procedure date; and

◇ OR number.

The data that is loaded into the database is collected from several sources:

◇ Hospital Admission Discharge-Transfer and Billing Systems (ADT).

◇ The Anaesthesia Data Record (AR) - to determine which data elements should be included in the system [5]. Sample forms for anaesthetists to fill out in addition to the standard AR have been created, which would include the new data elements required by the system.

Data are sampled serially, the sampling intervals dictated by the monitoring device used. Serial measurements of vital parameters reveal trends in the patient's clinical status and allow for quick evaluation of current therapies [55]. For example, Hewlett-Packard's ECG monitor samples data every 3 minutes.

5.3.1 Objective Data Elements

PATIENT DEMOGRAPHIC INFORMATION: Patient age, sex, and race.

PHYSICAL MEASUREMENTS: Height, weight, pre-procedure medications, and vital signs [5].

PROCEDURE INFORMATION: Included are pre-procedure diagnosis, scheduled ICD-9 codes, attending surgeon, the anaesthesia team, type of airway management, ventilation, monitoring and heating devices employed, anaesthetic agents, haemodynamic information, the length of the various phases of the case including Start of Anaesthesia Induction time, and the disposition to Recovery Room, SICU, or elsewhere.

POST-DISCHARGE INFORMATION: Included are admission and discharge diagnosis codes (ICD-9 and Blue-Cross/Blue-Shield) and length-of-stay.

5.3.2 Subjective Data Elements

For the purposes of this thesis subjective data elements are treated as events; these events may be clinical or non-clinical (e.g. violations of established procedures). In most cases, clinical events are not singular objective observations. Rather than defining hypertension as blood pressures exceeding an arbitrary set of values, hypertension as a perioperative event can be expressed as "Did one or more episodes of hypertension that required management occur during the case?"

The research is based on the belief that the anaesthetist's judgement about the significance of the clinical events which occur throughout the case should be added for the notation of events. Part of the system's Quality Assurance mission is to monitor the accuracy and honesty of the anaesthetist in recording these events.

Each event that is noted consists of these associated data elements:

- ◇ The actual date that the event took place.
- ◇ The operating room that the event took place.

◇ Who noted the event.

◇ The major ICD9 code of the event.

- ◇ The time period during which the event was noted. Several episodes of a specific event during a specific time period can be combined with an explanation in the comment field below.
- ◇ Any therapeutic agents used to manage the event, including a free text description of the success of the treatment.
- ◇ A free-text comment field, used to describe the course of management of the event.

Each procedure can have any number of accompanying events, including medical history findings and extending through (and potentially after) discharge. The Quality Assurance coordinators cross-check the integrity of the event data. They record all events which meet predetermined screening criteria, whether or not those events were recorded by anyone else involved with the case. This allows for listing of events that were recorded by the system but not noted by the anaesthetists.

Associating events with specific procedures makes, possible correlating the occurrence of events with other procedure information [5]. The data problem of multiple procedures taking place during a patient's hospital stay, was one of the issues that had to be solved.

5.4 Knowledge Acquisition and Representation

The dramatic influx of new instrumentation for monitoring all types of patient and equipment variables during anaesthesia has placed an overwhelming burden on anaesthetists who must choose the equipment appropriate for their practices. Much of the instrumentation is more complicated than the relatively simple ECG, pressure, and

temperature monitoring devices in general use. Providing additional information to anaesthetists who have few free hours to study the complex technological issues may have limited usefulness [41]. As it is known too well, there are many ways to make poor choices in device selection.

A vigilance task has been defined by Olmedo and Kirk [171] as one "which requires the detection of changes in a stimulus during long monitoring periods when the subject (i.e. the observer) has little or no prior knowledge of the sequence of the changes." An anaesthetist performs many vigilance tasks, some concurrently [226]; several are for the monitoring of the patient's physiological responses to anaesthesia and surgery. The information about the patient's welfare is presented to the anaesthetist in almost as many different ways as there are parameters to monitor. The anaesthetist makes decisions about the conduct of the anaesthesia by integrating and analysing this information [130].

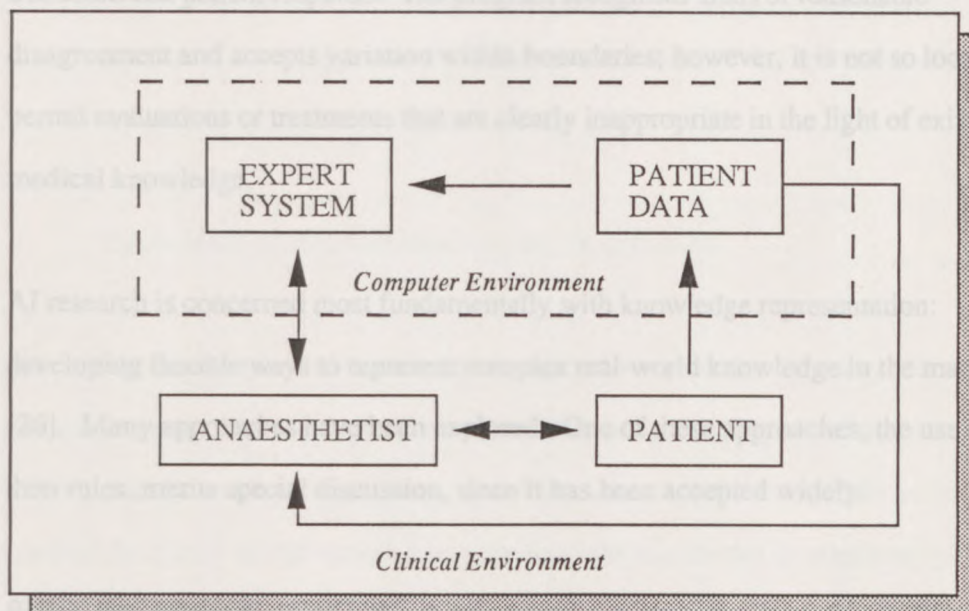


FIGURE 5-9. PONI's System Structure.

In general, knowledge bases are incomplete, approximate and biased models of the world. The incompleteness of medical knowledge bases requires that they be built incrementally. The above method both allows, building of a complete model at any time and also making improvements to the knowledge base as human experts learn from the change of social judgments [36].

A consistent clinical approach that can be employed by different physicians is the basis for a successful monitoring program. An algorithm has been developed that specifies sequences for diagnostic evaluation, treatment modalities, and expected patient responses (Figure 5-9). This algorithm, "a set of rules for solving a particular problem in a finite number of steps," [261]: may be computerised and used to monitor medical problems. The computer is not meant to influence physician judgement on an individual case or suggest that all physicians agree on all aspects of management of any one patient. Rather, it is intended to present generally accepted outer boundaries of treatment and patient response. The program recognises areas of reasonable disagreement and accepts variation within boundaries; however, it is not so loose as to permit evaluations or treatments that are clearly inappropriate in the light of existing medical knowledge.

AI research is concerned most fundamentally with knowledge representation: developing flexible ways to represent complex real-world knowledge in the machine [26]. Many approaches have been explored. One of these approaches, the use of if-then rules, merits special discussion, since it has been accepted widely.

RULE-BASED EXPLANATION. A rule-based explanation allows the machine to make its internal logic more transparent to the physician user, but may not address all of the physician's questions. Researchers in the MYCIN project concluded that adequate explanations for the MYCIN system could not be derived from the existing

MYCIN program [37]. Computer-based explanation, it was argued, often requires that the computer system have a higher level, more strategic view of the medical task than necessary for the computer to achieve good performance [204].

An if-then rule is a simple programming construct consisting of two parts. The first part is an if clause, which contains a test; the second part is a then clause, which contains one or more actions the computer is to perform if that test is true. The use of if-then rules makes the computer's logic accessible to the medical expert. In contrast programs written in programming languages such as FORTRAN or BASIC are difficult even for experienced programmers to understand. Several potential benefits arise when representing the knowledge in if-then rules:

- ◇ Knowledge can be inspected, potential errors identified and changes suggested.

- ◇ Each rule may be seen as a small chunk of knowledge. In theory, these small chunks of knowledge may be added to a system, thereby incrementally enhancing its performance.

- ◇ Explanation of recommendations may be enhanced.

The rule-based approach to knowledge representation provides the computer with a set of decision rules, but provides only a superficial understanding of the medical domain. Other AI projects are exploring how a more profound appreciation of the underlying medical field may be incorporated into the machine to enhance its reasoning [204].

QUALITATIVE CAUSAL MODELLING. A qualitative causal model is one in which the various system variables are expressed in qualitative terms [204]. For example, the

value of a variable, such as blood pressure, may be very low, low, normal, high, or very high, rather than a numeric value.

Many AI researchers believe that this qualitative approach allows the program to approximate better the character of expert clinical reasoning as medical problems often may be conceptualised in qualitative terms by physicians [204]. For example, a physician may believe that "low" cardiac output and "high" blood volume are consistent with a certain type of heart failure. Additionally, researchers stated that the same variable value may be viewed as high in one clinical setting but normal in another. For example, a heart rate of 120 beats/min may be considered normal if blood pressure has recently fallen to abnormally low values, but considered abnormal in other clinical settings.

5.5 Summary

The ultimate goal of a medical computer system is to assist physicians in making medical decisions not to deprive them of choice. However, more integrated information as rule-based logic can provide is still to be valued as input to these decisions. Computers can be set up to apply rule-based logic to patient care. Early work [83] in this field has led to some simple but helpful data interpretation and alarm protocols. In a sense, generating alerts from the integrated data is at the same stage as alert generation with physiological data twenty years ago [81]. The computer filled that need and it seems probable that automated decision-making will become indispensable also in data integration alert technology.

Computer software tools and strategies are emerging for use with decision-making or intelligent systems. As many medical mistakes appear to be due to errors associated with simple clinical events it is apparent mistakes could be avoided with computer-

aided decision making. Data indicate that application of clinically relevant medical knowledge frequently does not take place properly due to the physician's ignorance or inability to process all patient data [149]. The computer should be able to assist physicians by noting actions consistent with accepted medical practice. The challenge, of course, is to develop medical logic applicable more than the demonstration situations. This requirement parallels the improved robustness that has developed in the arena of physiological monitoring [81].

In this chapter techniques were examined for data management. The next chapter will now discuss the importance of the methodological assumptions and research design of PONI.

After defining the objectives that the system should satisfy, the available literature was reviewed. The only documented system that seemed directly comparable to the one defined was the VM system (Chapter 4.3.1). No reference to the successful implementation of another information system with similar requirements was found nor was a satisfactory turnkey system discovered to be in production.

Several articles that dealt with the development of objective screening criteria for evaluation of anesthesia risk were available [5]. The set of criteria based on these articles was refined, specifically including the suspected hypoxia risk factors identified by several authors.

It was decided to develop the PONI system internally with the assistance of the anaesthesia staff.

6. PONI: DESIGN & IMPLEMENTATION OF A PROTOTYPE SYSTEM FOR RESPIRATORY AND CIRCULATORY MANAGEMENT

The system described here runs on a popular, readily available, and relatively

6.1 Introduction

Having in the previous chapter considered the role of knowledge and data information, this chapter will now describe the methods of representation developed while building PONI. In the course of describing these methods, specific solutions to some of the issues raised above are offered.

The Hospital of the University of Pennsylvania is a teaching hospital with 704 acute care beds and 30 operating rooms. The clinical role of the Hospital's Department of Anaesthesiology is to provide anaesthesia care for surgery and diagnostic procedures, staff the Hospital's day surgery unit, recovery rooms, and intensive care units, and provide Respiratory Therapy. The Department performs about 3,567 procedures a year in DSU.

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It was decided to develop the PONI system internally with the assistance of the anaesthesia staff.

The system described here runs on a popular, readily available, and relatively inexpensive microcomputer which derives its signals via RS-232 cables from standard respiratory and circulatory monitoring equipment. The two main objectives of the project were to provide an on-line display of the trend in any of the measured parameters giving the unit medical staff clear up-to-date information; and secondly, to store these data for subsequent analysis. The equipment acts both as a trend data monitor and the equivalent of a sampling tape-recorder. Currently this dual function is not available on comparably priced commercial equipment [62].

A computer's flexibility is particularly useful in a research program because new on-line data processing features may be built into the system as more understanding of the importance of the various parameters has been gained [62]. The computer is used for preparing hard-copy of the information and subsequent off-line analysis of the signals, as well.

6.2 Description of the Methodology

Due to proliferation of new monitoring equipment the anaesthetist is required to scan several different analogue and digital readouts on various monitors [145]. A proposition to unify the monitoring process by providing all monitoring data in the same location was made. The new monitor should include not only the measurements of units as ECG, finger pulse oximeter, and arterial pressure but also temperature and electronic, noninvasively measured blood pressure. Data from carbon dioxide, oxygen, and anaesthetic gas analysis, as well as capability for monitoring fresh gas

flows and respiratory variables has been added. It was preferred to have on-screen digital data displayed close to the appropriate waveforms.

At present the anaesthetist must also periodically copy all physiological data on to an anaesthetic record during a check. These tasks could, however, be done automatically and objectively by the monitor, allowing the anaesthetist to give complete attention to the patient. A monitor was sought that included limit alarms for all monitoring variables, display of trend graphs, and the capability for automated production of an on-line anaesthesia record. Such a complete, accurate, computer-produced anaesthesia record would aid in quality assurance, data acquisition for research, and medicolegal purposes [145].

There was a requirement for the new monitor to have a front end unit similar to that of existing units, a minimum of buttons and keys, a simplified procedure for calibrating the multiple devices, and less interference from electrocautery [145].

Osborn [172] defines today's computer-based monitoring correctly as "a science in transition" with vague purposes, variable technology and no clear utility evaluation protest. He indicated a useful way to reach the stage of a coherent patient care system by breaking down the general problems into components. Once it is decided what to measure, monitor and compute in the complex field of ORs, work on the subcomponents begins [145]. His suggestions were adapted in this work, applying informatic techniques to single problems, then trying to make them work in an integrated system.

Such a fragmentary approach is dictated to researchers here and at many other institutions by the different nature of the problems confronted; each required a unique approach and different equipment [145]. Within HUP there are two distinct areas: the

Day Surgery Unit (DSU) and the HORNET Group. Each area has its own environment which resulted in using different types of computers: In the DSU environment a microcomputer, interfaced with analytic instruments and equipped with a Write Once Read Many (WORM) laser-disk, was needed to store a large number of data and to perform complex elaboration. In the HORNET Group, a personal computer with sufficient calculation potentiality, equipped with a number of language compilers and interpreters for software development was needed.

To assist in the majority of critical-care management decisions, the computer must deal with a large and varied flow of data into a patient's computerised record [81]. Relevant data come from diverse locations such as the admissions desk and bedside physiological monitors.

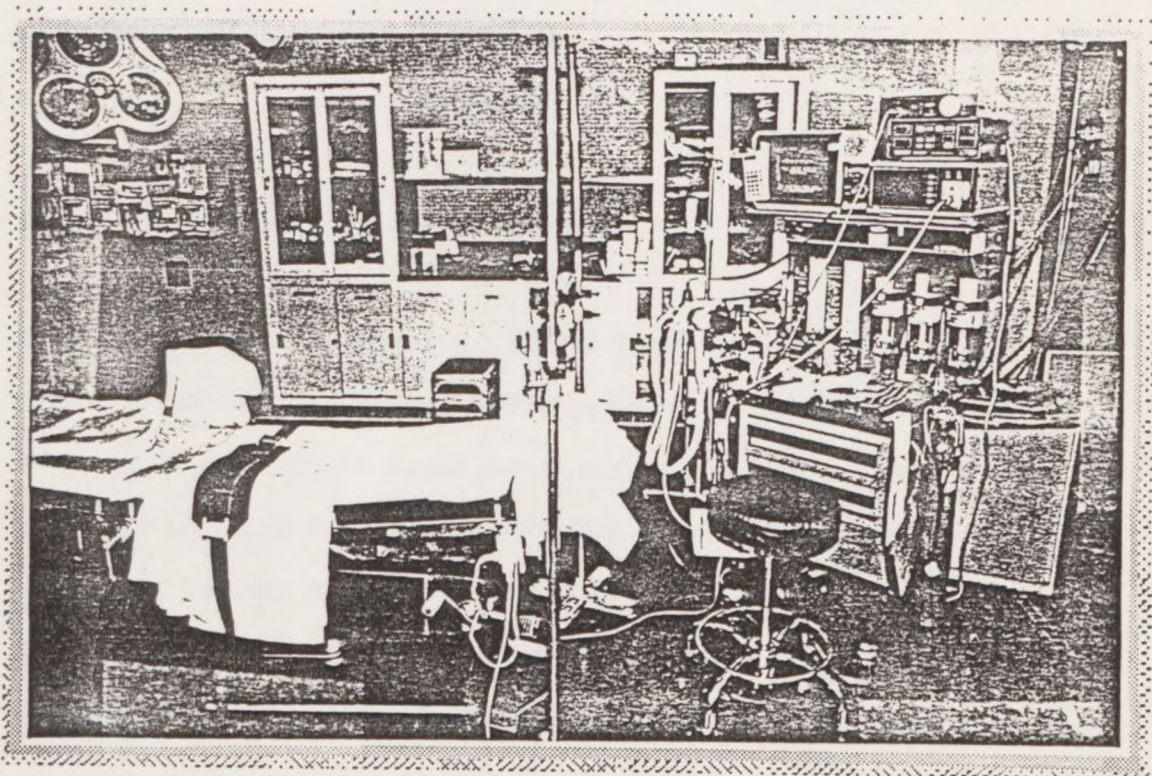


FIGURE 6-1. The PONI Hardware.

Evaluation of available commercial monitors revealed that most of the features an anaesthetist wants were not assembled together on commercial monitors [18]. Multiple wires and cables from each monitor were connected to the patient and a single, convenient front end unit connected to the patient was needed. Display of the finger pulse and ECG data and temperature data were seldom available on these monitors. Calibration procedures for intraarterial pressure monitoring were slow and cumbersome. No integrated monitor that processed and displayed all the important variable was being manufactured. On-screen digital displays, trending, and automatic record keeping were not available. It was decided therefore to design and build a state-of-the-art monitor, better than any on the market. Due to the proposal, approval from hospital administration was obtained to use the funds allocated for research for the design and construction of the monitoring system (Figure 6-1). Planning, development, and implementation of the system were based on the results of a survey of the senior staff anaesthetists (Figure 6-2).

FIGURE 6-2 PONT'S STAGES OF METHODOLOGY.

In order to design PONT, cataloguing of the various classes of alarms that may be present in a particular measurement was first necessary. Then identification of the features of the alarms that distinguish them from the desired variable. These features may be observed in either the time or frequency domain. Before actually scanning for alarms, the measuring system self-tests and then checks to see if it is properly connected to the patient. The observer and intelligent monitor strive to maintain optimal monitoring conditions and signal quality.

To evaluate the alarm system, a study was carried out in the Anaesthesia Department with the cooperation of the senior staff anaesthetists (Appendices I & II). Initially

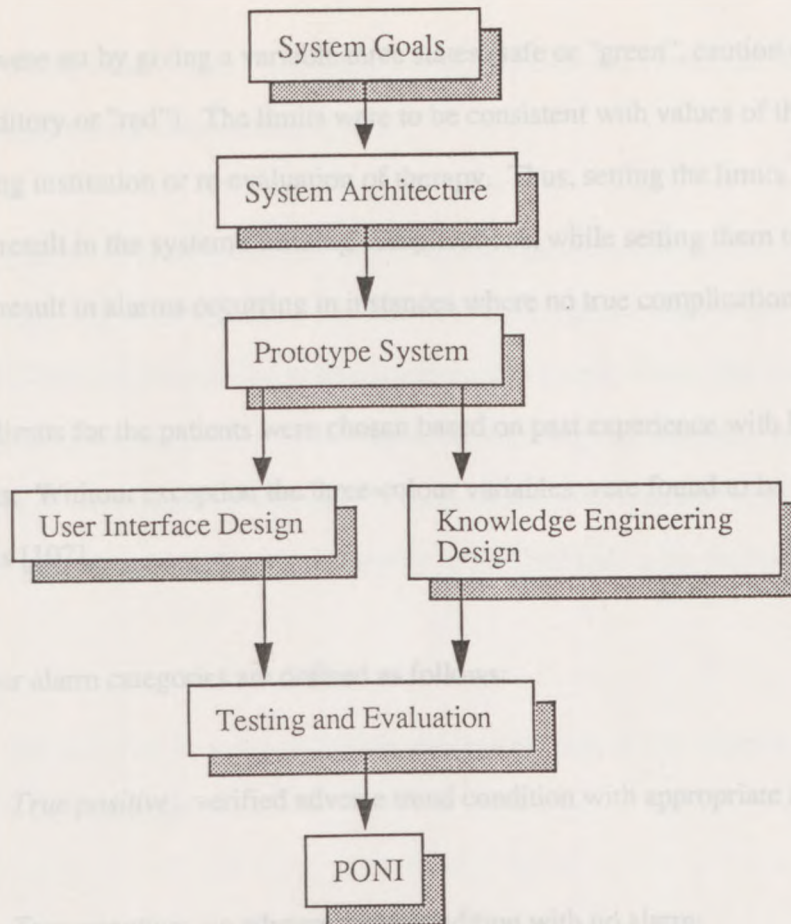


FIGURE 6-2. PONI's Phases of Methodology.

In order to design PONI, cataloguing of the various classes of alarms that may be present in a particular measurement was first necessary. Then identification of the features of the alarms that distinguish them from the desired variable. These features may be observed in either the time or frequency domain. Before actually scanning for alarms, the measuring system self-tests and then checks to see if it is properly connected to the patient. The observer and intelligent monitor strive to maintain optimal monitoring conditions and signal quality.

To evaluate the alarm system, a study was carried out in the Anaesthesia Department with the cooperation of the senior staff anaesthetists (Appendices I & II). Initially

limits were set by giving a variable three states (safe or "green", caution or "yellow" and auditory or "red"). The limits were to be consistent with values of the variables requiring institution or re-evaluation of therapy. Thus, setting the limits too wide would result in the system's missing complications, while setting them too narrow would result in alarms occurring in instances where no true complication existed.

Trend limits for the patients were chosen based on past experience with Day Surgery Patients. Without exception the three-colour variables were found to be appropriate for patients [107].

The four alarm categories are defined as follows:

- ◇ *True positive:* verified adverse trend condition with appropriate alarm;
- ◇ *True negative:* no adverse trend condition with no alarm;
- ◇ *False positive:* no adverse trend condition with inappropriate alarm;
- ◇ *False negative:* verified adverse trend condition with no alarm.

The present system was developed for a Day Surgery Unit employing computer monitoring, where the majority of the patients were healthy and undergoing minor surgery.

Often, alarm detection schemes target the time domain, with observations of the change in measurement new time as the starting point in alarm detection schemes. Observing whether the measurement exceeds a set of amplitude bounds for a period of time is a

simple test for alarm needs. Allowable limits for the time derivative of the measurement are built into the program.

Along with the bedside monitors of BP/sys, a central computer process routinely samples, among other variables, the heart rate and respiratory rate every 15 s. If the value of BP/sys is determined to be outside present (trend) limits, the computer activates an alarm sequence. In this sequence, the computer initiates a repeat mode of sampling of BP/sys at 15 s intervals. If three consecutive repeated values of either variable remain outside the preset upper or lower limits, then the following events occur:

- ◇ An alarm of the trend of BP/sys over the preceding 15 s appears on the bedside video monitor.
- ◇ A computer window screen displays coloured light; and
- ◇ The bedside keyboard is locked out to other functions until the alarm is reset by the physician at the bedside. If a value of BP/sys outside of limits falls within limits, then the computer continues its 15 second sampling until three successive values are outside the limits or three successive values are within limits. At this point, regular analysis every 15 seconds resumes. The developed algorithm allows monitoring of any variable in the same fashion. As presently programmed, after an alarm is triggered and reset, it is inhibited for a period of 20 s to allow appropriate action by the staff.

The statistics of a time domain measurement are examined also to identify changes in the pattern of individual physiological signals. If a system has relatively stable

characteristics or derived parameters as is the case for the systolic blood pressure and heart rate then a statistical test such as mean is applied to detect changes in the signal.

Next frequency domain analysis is built in to describe the frequency content of a signal for a given block of time. Frequency analysis is useful because an alarm may be composed of frequencies in a range different from the signal of interest. Because of this, frequency analysis may be used to distinguish alarms difficult to appreciate in the time domain and also frequency analysis may separate and dispose of offending frequencies, thus cleaning up the measurement signal [196].

The algorithm allows an alarm to be activated when a variable within preset acceptable upper and lower limits is found on repeated sampling to be outside these limits. Using Webster's definition of "trend" [250] as "the general movement in the course of time of a statistically detectable change," it was felt appropriate to call the system a "trend detection alarm" and the limits "trend limits" [213].

The mean age for the monitored group was 34, the occurrence of preoperative risk factor was 6% and the average operating time was 1.28 h. The condition of each patient was optimised before surgery: congestive heart failure was treated with diuretics and inotropic agents. Pneumonia was treated with IV antibiotics and chest physiotherapy. Renal failure was treated with haemodialysis. The incidence of postoperative morbidity was 1.2% (e.g. persistent nausea and vomiting, excessive fluid or blood loss, excessive pain requiring I.V. narcotics, or other surgical complications).

8.3.2 Theoretical Background

Limitations exist in routine methods of assessment. Central venous pressure (CVP) has been used to determine fluid balance, but it gives little indication of the state of hydration in elderly patients. A more accurate measure of fluid balance is the

pulmonary artery wedge. Cardiac output (CO) has been estimated by measurement of central venous blood gases, but the relationship between the saturation of venous oxygen (SVO_2) and CO is uncertain. The best method of assessing CO is by direct measurement using the Swan-Ganz catheter and thermodilution technique [213].

Using right arterial pressure is deceptive in assessing left ventricular function. The cardiac index, pulmonary artery wedge pressure, or right arterial pressure may be normal when the left ventricular function is abnormal. Left ventricular function is reliably determined by measurement of the cardiac index, left ventricular stroke work, and the pulmonary artery wedge pressure with construction of the Sarnoff curve [213].

6.3 Methodological Assumptions

6.3.1 Introduction

As computer technology is applied more widely to the patient, monitoring safety is critical. Failure may involve grave danger to human life. Although the computer's ability to deal with complexity has been increasing, the complexity of the systems being build has increased as well. Unfortunately, the ability to eliminate or handle errors has not kept up with the increasing possibilities for introducing them. Large real-time safety-critical systems are perhaps the most complex systems man has ever tried to build. Large numbers of instructions are involved; the space shuttle has 40,000,000 instructions in support software. Timing requirements not usually found in data processing systems add additional design problems [132].

6.3.2 Theoretical Background

This section presents an approach to the development of sophisticated alarms to be used during anaesthesia. The principles of this approach may be applied to other

monitoring situations. Ideas from systems engineering were borrowed and applied to patient monitoring. In particular, the methodology chosen essentially passes through four basic stages: systems analysis, systems design, implementation and operation [76].

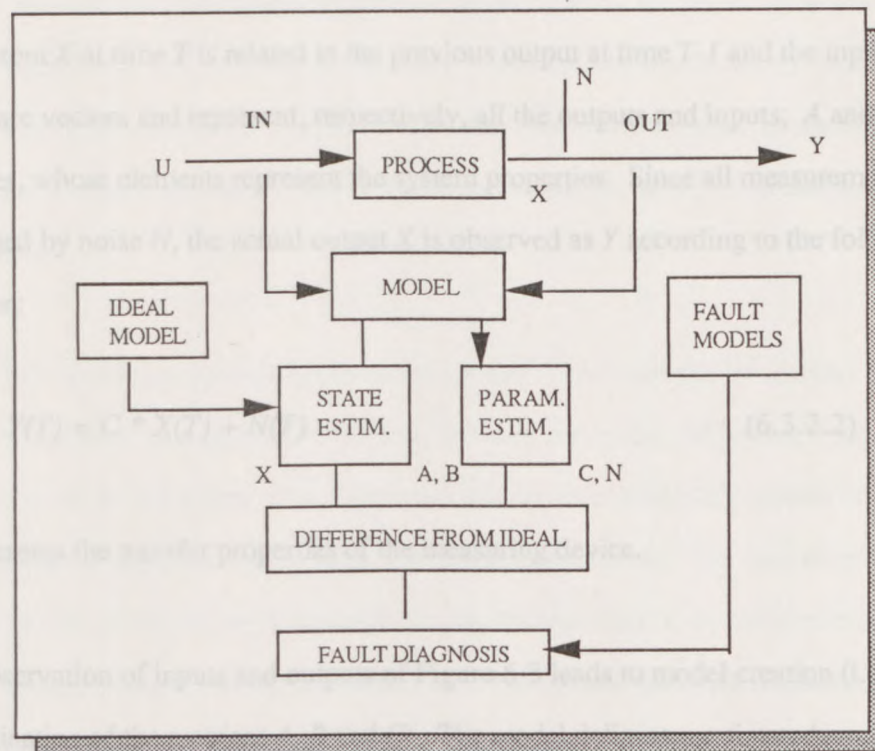


FIGURE 6-3. Structure for Fault Detection.

(Modified from [10])

For the monitoring purposes according to Beneken [10] the physiological data are divided into three levels based on the criteria listed in table 5-4 and Appendix I: low, normal and high. Table 2-3 charts alarm messages during a typical computer-monitored operation. Figure 6-3 is a modified version of the structure of fault detection methods. It is based on process models and accommodating nonmeasurable quantities as described by Isermann [113]. The process is represented as a block with

inputs U , actual outputs X , measured outputs Y and an unpredictable noise component N . A mathematical representation of such a process is:

$$X(T) = A * X(T - 1) + B * U(T) \quad (6.3.2.1)$$

The output X at time T is related to the previous output at time $T-1$ and the input U . X and U are vectors and represent, respectively, all the outputs and inputs; A and B are matrices, whose elements represent the system properties. Since all measurements are corrupted by noise N , the actual output X is observed as Y according to the following equation:

$$Y(T) = C * X(T) + N(T) \quad (6.3.2.2)$$

C represents the transfer properties of the measuring device.

The observation of inputs and outputs of Figure 6-3 leads to model creation (i.e., the determination of the matrices A , B and C). The model delineates estimated parameter and state variables. Thus, estimated state variables and parameters may be compared with the ideal or normal process. If the estimated variables deviate from the normal detection of a fault either in the process or in the measuring part is possible. To diagnose a fault with respect to location, size, and time, the process must be well understood; the effect of the different fault conditions on the parameters and state variables must be known in advance. Fault models provide this information [10].

The technique of model parameter estimation and of state estimation was developed to tackle engineering problems. Its use in the medical and biological fields, however, has been limited to the identification of subsystems of the human body [8].

The model suggested in Figure 6-3 can be applied to patient monitoring but in a limited fashion. OR monitoring systems monitor ventilation, electrocardiogram (ECG), blood pressures, skin perfusion, muscle relaxation, oxygen saturation and derived information, anaesthetic concentrations, drug delivery, fluid balances, and blood gas values. However this information exceeds human capacity for quantitative analysis. On the other hand, it is probably unnecessary to estimate all the necessary parameter values to establish a complete model. Technical, man-made systems are understood more easily, equipped with sensors or transducers and, therefore, modelled more easily [10].

Figure 6-3 cannot be applied directly to monitoring. The anaesthetist assesses the patient's condition in a qualitative manner, as when observing the patient's pupils during a surgical procedure. Yet, Figure 6-3 can be used to identify aspects of the anaesthetist's thought process in relation to patient monitoring. The anaesthetist has a mental picture of the patient, a model, based on the reactions of the outputs to certain inputs (drugs) or input variations (ventilation). He corrects for expected inaccuracies of the measurements (N) and estimates the actual outputs (X) from the patient. Planning anaesthesia furnishes an ideal patient model, with which to compare the observed behaviour. The human monitor uses training and experience to compare patient condition with known fault conditions (fault models) [10]. In establishing the fault diagnosis, the anaesthetist will also take into account probabilities of incidents learned through experience to decide if an action must be initiated.

Therefore, in order to design sophisticated alarm generators along these lines, it is necessary to have:

- ◇ A model of the normal, or ideal patient.

- ◇ Models of the possible alarm or fault conditions.

- ◇ A model of the patient under observation.

Because it is not feasible to build a model of the patient in terms of all its parameters, the model is to be restricted to the set of monitored variables (outputs). Also the model is to stress quality as well as quantity.

The challenge is to collect from present patient monitoring practice the proper elements to fill the blocks in Figure 6-3. Few approaches have been reported that delineate ideas for additional information extraction. Ream expressed caution in expanding the number of monitored variables but emphasised the use of redundancy [199]. Siegel introduced circle diagrams for different physiological states that appeal to the pattern recognition ability of the observing physician [223]. Davis et al. described the use of an X-Y plot of respiratory pressure against respiratory volume for monitoring patients in an intensive care unit [58]. An extensive survey of approaches to signal processing in patient management has been performed by Beneken et al [11].

Comparing in detail the present state of the monitoring art with the diagram of Figure 6-3, it is clear a patient model should consist of:

- ◇ Anaesthetist knowledge of demographic data and diagnosis, with a subjective, nonquantitative image of the patient.
- ◇ A set of signals derived from the patient;
 - the inputs-timing, dose, drugs, ventilation settings and phase of the operation; and

After first alarm the outputs-signal values, their derived values and statuses. limits in the normally expected range, or between in the so-called attention range.

An ideal model may denote normal band, in the CRT display and set thresholds in terms of fixed values or the maximal rates of change of the various signals.

Differences from ideal can be detected when thresholds are crossed and may be brought to the attention of the anaesthetist by an alarm or by the CRT display [113].

very briefly and look like impulses, as many disturbances do.

The anaesthetist notes the differences and makes diagnosis by consulting his internalised fault model. It is intended to automate this process by including fault models as part of an expert system which decides a fault diagnosis on the basis of a logical decision process. as may be assigned to all signals (Figure 6-4)

The foundation of the alarm validator is signal classification [10]. The behaviour of the signals is expressed:

- ◇ In a limited number of properties; and
- ◇ On which basis for signal is assigned to a certain class.

One can distinguish the following groups of signal properties [10]:

- ◇ One group based on momentary signal values (or with very noisy signals, estimated mean values).
- ◇ One group based on changes; and
- ◇ One group related to signal validity.

After fixed alarm limits have been set, mean value may be placed beyond these limits, in the normally expected range, or between in the so-called attention range.

If a signal moves consistently in one direction while maintaining its natural fluctuations, one can classify this by assigning it a trend status, in addition to a mean value and a variability. Its changes may be slow, fast, or steplike, or may last only very briefly and look like impulses, as many disturbances do.

Three groups of signal properties (safe or "green", caution or "yellow", alarm or "red") and three classes (low, normal, high) within each group have been identified. Using this classification, statuses may be assigned to all signals (Figure 6-4)

FIGURE 6-4. Signal Classification.

The service staff administering the boundaries for each classification that creating the ideal model. Distinctions between classes are subjective, of course, but rigorously defined in the signal processing algorithms. For example, impulse classification limits may be set on the basis of morphological rate of change of the variables. The transition from normal to increased variability is set using well-defined knowledge rules, and initially the threshold is fixed but it is adaptive (or learning) and may change over time.

OUTPUTS	CLASSIFICATION				
	ALARM	CAUTION	SAFE	CAUTION	ALARM
O2Sat	< 86	94	100		
HR	< 42	52	115	> 145	
BP/sys	< 79	91	162	> 190	
FICO2		0	1	> 3	
PETCO2	< 18	25	50	> 60	
RR		0.5	31	> 45	
FIO2	< 21	25	100		
TEMP	< 33	34	38	> 39	
VE	< 2	4	10	> 14	
L	< -9	-4	0		
PEEP					
H		0	7	> 14	
PIP		0	37	> 50	

CAUTION

Hypovolaemia

Figure 6-5 is a diagram of a sophisticated alarm generator. The patient model is presented as a block diagram. The model is used during the signal processing process to generate rates of change for the dynamic classification of the various signals. The model is used during the signal processing process to generate rates of change for the dynamic classification of the various signals. The model is used during the signal processing process to generate rates of change for the dynamic classification of the various signals.

The senior staff anaesthetists set the boundaries for each classification thus creating the ideal model. Distinctions between classes are subjective, of course, but rigorously defined in the signal processing algorithms. For example, impulse classification limits may be set on the basis of nonphysiological rates of change of the variables. The transition from normal to increased variability is set using well-defined knowledge rules, and initially the threshold is fixed but it is adaptive (or learning) and may change over time.

The decision-making process is presented in the block Fault Diagnosis of Figure 6-5, where examples from the statements below are reproduced in a treelike structure in Figure 6-6. The tree points up the case with which the reasoning behind the message can be

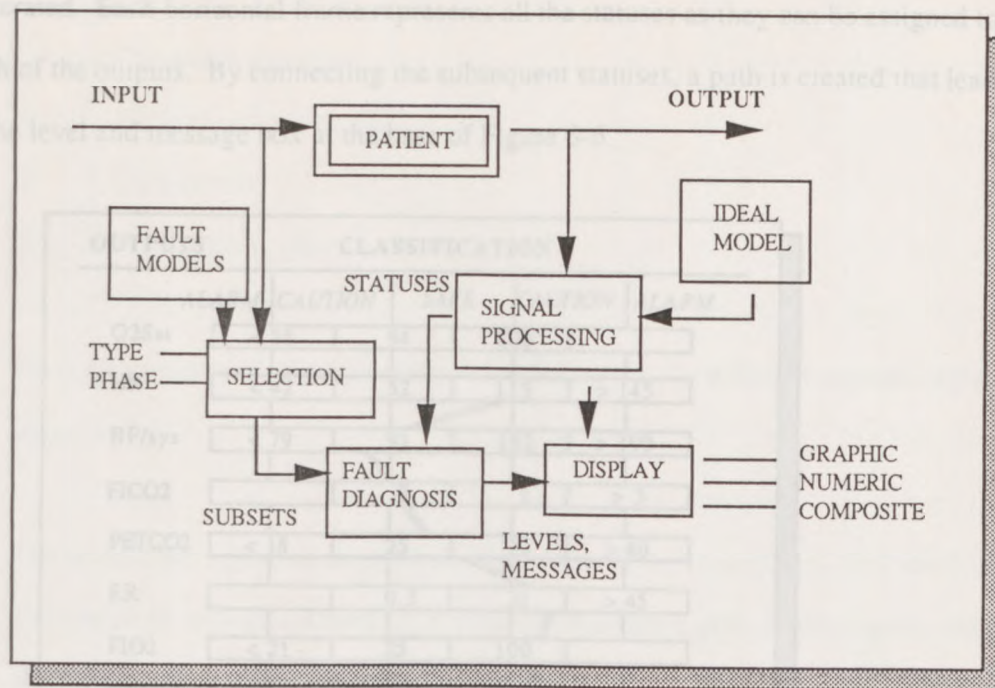


FIGURE 6-5. A Sophisticated Alarm Generator.

(Modified from [10])

Figure 6-5 is a diagram of a sophisticated alarm generator. The patient model is presented as normal and attention ranges and the discriminating rates of change for the dynamic classification of the various signals. The model is used during the signal-processing stage to assign statuses to different signals. Such signal processing yields the numeric data used to generate displays. Information about the inputs or their changes, the type of surgery, and the phase of the procedure helps to reduce the set of fault models into subsets.

On the basis of these signal statuses and the subsets of fault models the block Fault Diagnosis sends the alarm levels and the alarm messages to the display. The decision-making process is presented in the block Fault Diagnosis of Figure 6-5, where examples from the statements bellow are reproduced in a treelike structure in Figure 6-6. The tree points up the ease with which the reasoning behind the message can be

generated. Each horizontal frame represents all the statuses as they can be assigned to each of the outputs. By connecting the subsequent statuses, a path is created that leads to the level and message box at the base of Figure 6-6.

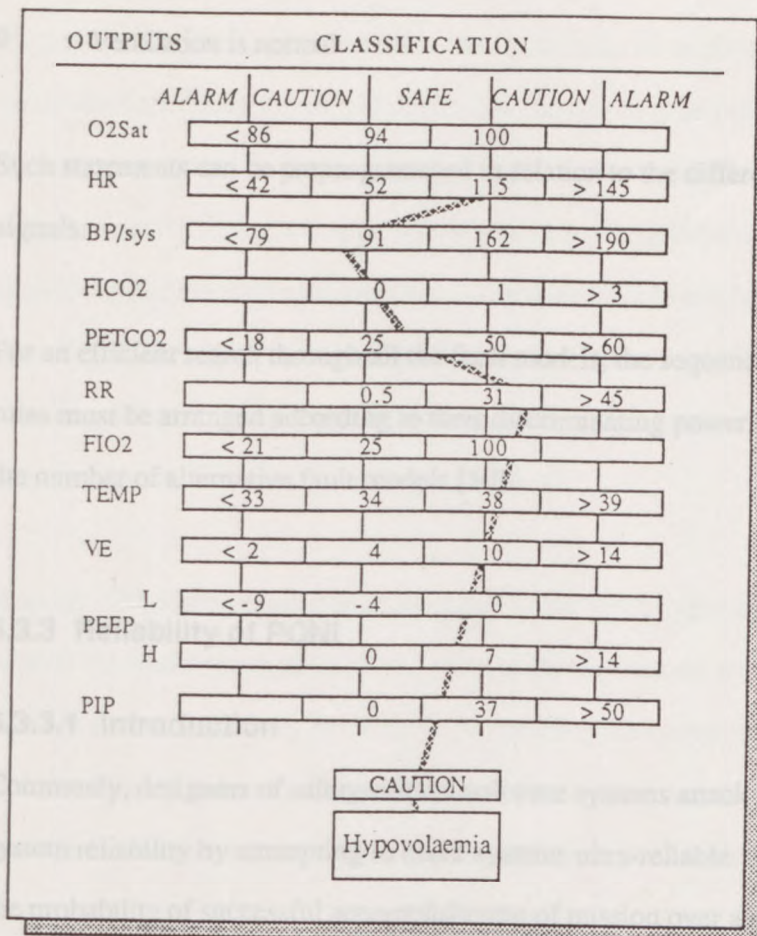


FIGURE 6-6. Tree Structure.

Figure 6-6 illustrates the system's reasoning rules questioned. Note that the system traces back the path that led to the level caution, message Hypovolaemia and displays either in reverse or forward order the following statements:

- ◇ HR is slowly rising (120)
- ◇ Systolic pressure shows an upward trend (90)

- ◇ CO₂ value is normal
- ◇ RR is slowly rising (35)
- ◇ O₂ is normal
- ◇ Ventilation is normal

Such statements can be preprogrammed in relation to the different statuses of the signals.

For an efficient search through all the fault models, the sequence of the knowledge rules must be arranged according to their discriminating power, thus rapidly reducing the number of alternative fault models [10].

6.3.3 Reliability of PONI

6.3.3.1 Introduction

Commonly, designers of safety-critical software systems attack the age-old problem of system reliability by attempting to make systems ultra-reliable. Reliability is defined as the probability of successful accomplishment of mission over a specified time and under specified environmental conditions; mission is defined as the ultimate purpose of task of the system. Thus while defining the system's mission or functional requirements it is important to determine the conditions under which the system will operate [132]. With a safety-critical system injury or damage is possible, but note that the probability of damage or injury is not synonymous with the probability of success or failure. Many system or software failures will not result in an accident. For example, a routine for archiving patient data for later research analysis may fail to accomplish its function without endangering the life of the patient. Thus some errors or failures are more serious than others, even in the most complex systems. In

general, reliability attempts to ensure no failures, whereas safety attempts to ensure no accidents [132].

Furthermore, reliability tends to relate the possibility of accidents to failures only; rarely does it involve investigation into the damage or injury than could arise if the system operated successfully. That is, reliability is measured in terms of compliance with the specifications, whereas, safety must be concerned also with specification errors, yet dealing with specification errors is a difficult problem [132]. Until methods of verifying the correctness of requirements and system specifications are developed, ensuring safety will require attention to protecting lives and property in the event of system failures caused by specification errors.

Another difference between reliability and safety tends to impact more widely. A system is considered reliable if it accomplishes the mission under specified conditions. Software correctness may be defined as providing the correct outputs given that the inputs satisfy certain conditions and that the underlying machine and support systems function as specified [132]. When these conditions are not met, safety becomes of concern.

Finally, a system may be correct in that it accomplishes its mission, but also may be unsafe. Safety and correctness are identical in systems where the mission is to sustain life, e.g. a pace maker. But many real-time systems have non-safety-critical functions, e.g., transporting people, gathering scientific data, generating power.

6.3.3.2 Reliability Models

PONI's performance is tested by using the predictive value model [248]. The model compares the results of the alarm detecting algorithm for a set of test data with a gold

standard, in this case a human observer. The comparison yields the sensitivity or reliability of detecting true alarms, and the specificity or the reliability of rejecting false positive alarms. If the incidence of alarms is known, then the predictive value of the test can be calculated. Not used for an algorithm designed to detect rare forms of alarms, it would have a poor predictive value, since few tests have a specificity of 100%, and such an algorithm would be overwhelmed by false positive artifact.

However, arterial blood pressure may be used to illustrate relatively simple algorithms for alarm detection. The signal is a waveform representing the instantaneous pressure variation with time. When available, the direct arterial blood pressure is a primary factor in the clinician's diagnostic and therapeutic decision making [196]. Yet, patterns in the waveform can be followed by a simple algorithm. The algorithm compares incoming pressure waveform with a learned template of the previous 10 instances. It uses the if-then-else production rules and a knowledge rule is fired.

FIGURE 4-7. Transition Network.

Like other models, a reliability model needs both a reliability criterion and a reliability policy. A reliability criterion is the definition of reliability for the system, i.e., it is a definition of the system faults and levels of acceptable outcome. When the reliability policy is developed to get rules for determining that a system is reliable, the policy will use the reliability criterion as a basis for decision making [132].

Process = $\langle I, F \rangle$

where $I = \langle \sigma_1, \sigma_2, \dots, \sigma_n \rangle$ and σ_i is a description of the state of component i and F is a transition function from state to state.

$$F: \Sigma \rightarrow \Sigma$$

The set of states Σ can be divided into two subsets, the reliable states S and the unreliable states U where $\Sigma = S \cup U$ and $S \cap U = \emptyset$. The unreliable states are those states that have been determined in the reliability criterion to be unacceptable in that their risk is above a specified threshold.

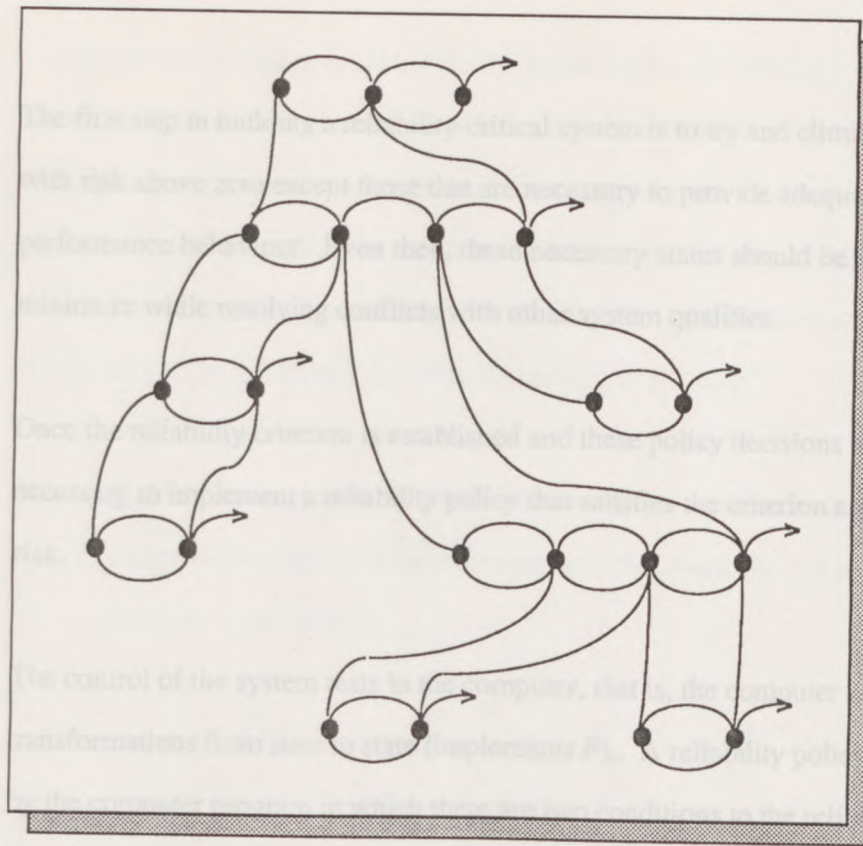


FIGURE 6-7. Transition Network.

According to Leveson [132] a process can be defined as a set of states, where each state is composed of the states of the individual components of the process (Figure 6-7).

$$\text{Process} = \langle \Sigma, F \rangle$$

where $\Sigma = \langle \sigma_1, \sigma_2, \dots, \sigma_n \rangle$ and σ_i is a description of the state of component i and F is a transition function from state to state,

$$F: \Sigma \rightarrow \Sigma$$

The set of states Σ can be divided into two subsets, the reliable states S and the unreliable states U where $\Sigma = S \cup U$ and $S \cap U = \emptyset$. The unreliable states are those states that have been determined in the reliability criterion to be unacceptable in that their risk is above a specified threshold.

The first step in building a reliability-critical system is to try and eliminate all states with risk above zero except those that are necessary to provide adequate functional and performance behaviour. Even then, these necessary states should be kept to a minimum while resolving conflicts with other system qualities.

Once the reliability criterion is established and these policy decisions made, it is necessary to implement a reliability policy that satisfies the criterion and minimises risk.

The control of the system rests in the computer, that is, the computer effects the transformations from state to state (implements F). A reliability policy is implemented by the computer program in which there are two conditions to the reliability policy, i.e., a system is "reliable" if the following occurs:

◇ The computer never initiates a control action (transformation) that will move the system process from a reliable to an unreliable state.

$$\forall s_i \in S, (F(s_i) = s_j \supset s_i \in S)$$

◇ If the system gets into an unreliable state (by a failure of a component or by a transformation that is not initiated by the computer (e.g., human error, environmental stress), then the computer-controller will transform the state into a reliable state.

$$\forall s_i \in U, (F(s_i) = s_j \supset s_j \in S)$$

It may not be possible to build a reliable system because a transition from every unreliable state to a reliable state may not exist. In that event, if the system is not to be redesigned or abandoned, a level of risk must be accepted. To manage the risk, procedures may be initiated to minimise the probability of the unreliable state causing an accident or to minimise the effects of the accident. In this case, it might be possible to add a step 3 in the reliability policy that states, as follows:

◇ If the system gets into an unreliable state and there is no transformation from the unreliable state to a reliable state, then the computer will transform the state into one with less risk.

$\forall s_i \in U$, if $\nexists s_j \in S$ such that $F(s_j) = s_j$,
then $F(s_i) = s_k \supset \text{Risk}(s_k) < \text{Risk}(s_i)$

The first step in any large software project is the specification of requirements which include normally the functional requirements of the system. In reliability-critical systems, reliability requirements must be included also. In other words the software requirements specification note not only what the system shall do but also what it shall not do. Means for eliminating and controlling hazards and for limiting damage in case of a mishap must be added. It is important to add to the specification what ways a system can fail safely and to what extent failure is tolerable.

Because it is impossible to predict all failures or errors that could occur, some method to determine only the factors that could lead to a mishap is needed. One method for doing this is fault tree analysis [133]. Fault tree analysis was first applied to the Minuteman missile system in the early 1960s in order to minimise the risk of an inadvertent launch. Recently, it has been extended to software.

A fault tree is a symbolic logic diagram that shows the cause-and-effect relationship between an undesired event and one or more contributing events. The event to be analysed is at the root of the tree with the necessary preconditions described at the next level showing either an AND or an OR relationship. Each subnode is expanded until all leaves describe events of calculable probability or events that are unable to be analysed for some reason [132]. The top levels of a fault tree for a patient-monitoring system are shown in Figure 6-8.

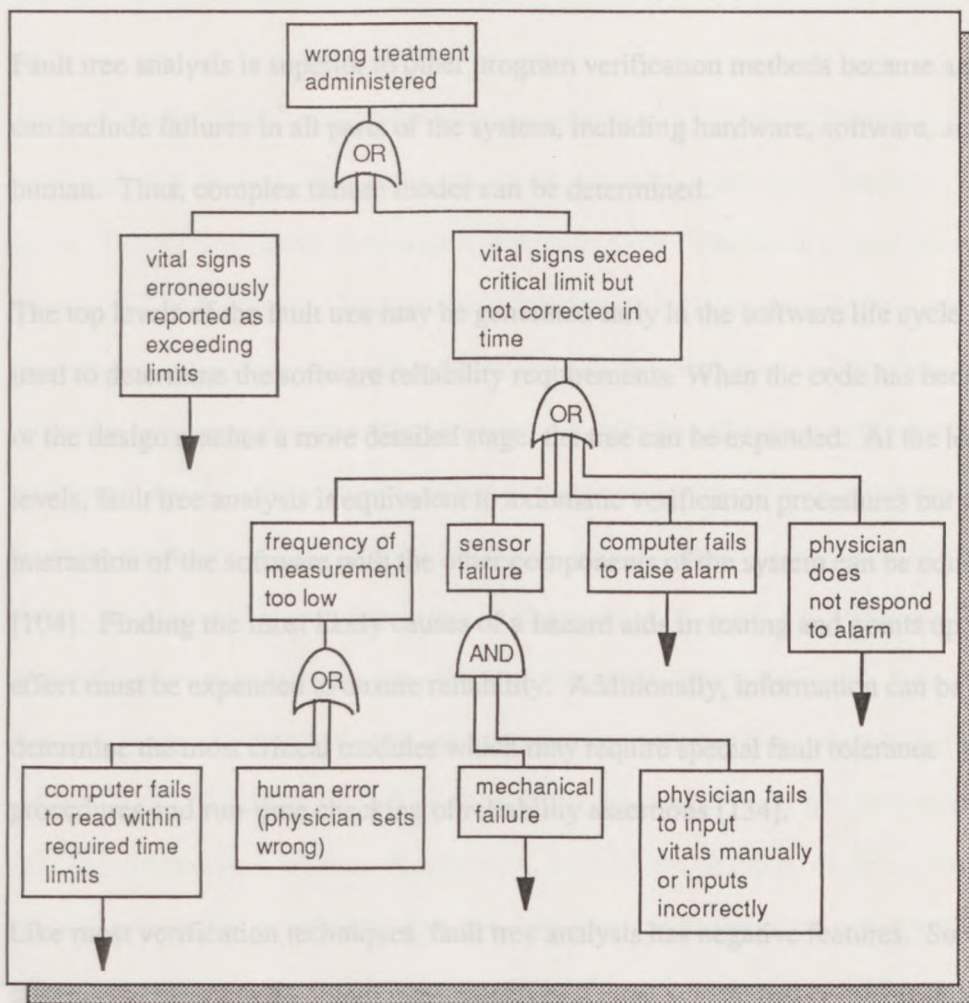


FIGURE 6-8. Top Levels of PONI's Fault Tree

(Modified from [132])

Fault tree analysis applied to software analyses a program for a propensity to cause a given event and is, in many ways similar to a hardware fault tree. Working backward from that part of the program responsible for the loss event, the method considers functional failures and successes [132]. At each step, a given statement is analysed for its ability to cause the event. Either one or more subevents prior to the original statement to be analysed in the program is generated or one or more primal conditions that, when coupled with the statement, would cause the event is noted.

Fault tree analysis is superior to other program verification methods because analysis can include failures in all parts of the system, including hardware, software, and human. Thus, complex failure modes can be determined.

The top levels of the fault tree may be generated early in the software life cycle and used to determine the software reliability requirements. When the code has been written or the design reaches a more detailed stage, the tree can be expanded. At the lowest levels, fault tree analysis is equivalent to axiomatic verification procedures but the interaction of the software with the other components of the system can be considered [104]. Finding the most likely causes of a hazard aids in testing and points up how effort must be expended to ensure reliability. Additionally, information can be used to determine the most critical modules which may require special fault tolerance procedures and run-time checking of reliability assertions [134].

Like most verification techniques, fault tree analysis has negative features. So much effort is necessary to do a fault tree analysis of a large system that complete analysis is not possible even with the use of software tools to aid in the process [132]; and it is costly. However, the fault tree analysis provides important information even with incomplete trees, such as determination of software reliability requirements, important test cases, and run-time assertion placement and contents.

By monitoring many variables with a change-detection algorithm, the number of dimensions monitored increase mathematically. Each dimension represents a different physiological process or variable. The change-detection algorithm has the potential to monitor each variable and also to note when changes in one or more variables warn that the patient is entering a dangerous state. If the algorithm can monitor all measurable variables to detect all exits from the correct state, detection will be completely effective [184].

Approximately 2,000 anaesthetic deaths per year in the U.S. are estimated to be preventable, if devices could detect potentially dangerous situations before serious harm. Types of devices and optimum of devices to be included in a good fail-safe system will be discussed. First, under consideration is the probability that adding devices to a fail-safe system will increase chances to detect potentially critical events. Here it is necessary to differentiate between the detection of a single critical event, such as a breathing circuit disconnect, an oesophageal intubation, or administration of a hypoxic gas mixture, and the detection of any one of a group of potentially critical events, or a general event. For example, if devices *A*, *B* and *C* can all be used to detect a specific adverse event, then the effects of several devices are additive, even though one device may be faster or more sensitive than the others. This means that if one device should fail, there is an added chance that the critical event will be discovered by one of the remaining devices. If devices *A*, *B* and *C* are designed to detect different adverse events, the use of more than one device is able to detect the occurrence of any one of a variety of adverse events better than using only one device [65].

Below can be found models which assume that all the devices act dependently (when one fails, the chances are increased of the others failing) or independently (if one fails, there is no reason for the others to fail).

Duberman [65] states that for D = detection, $P(A)$ = the probability of detecting the event using device A , $P(B)$ = the probability of detecting the event using device B , $P(C)$ = the probability of detecting the event using device C , $P('A)$ = the probability of not detecting the event using device A , $P('B)$ = the probability of not detecting the event using device B , and $P('C)$ = the probability of not detecting the event using device C .

Not detecting can be due to failure of the detection device (as in the specific case) or inappropriateness of the device for detecting the adverse event at all (as in the general case).

With two detection devices: Let $P(B/A)$ = the probability of detecting the event using device B in those circumstances when A fails. When only the two detection devices A and B are used, the general model is valid whether or not the devices are independent [65]. The model is:

$$P(D) = P(A) + P(B/A) P('A) \quad (6.3.3.2.1)$$

This translates as the probability of detection equals the probability of detecting with device A , plus the product of the probability of B detecting when A fails to detect times the probability of A failing to detect.

The model for independence of the device is:

$$P(D) = P(A) + P(B)P('A) \quad (6.3.3.2.2)$$

This means that the probability of detection equals the probability of detecting with device A , plus the product of the probability of B detecting times the probability of A failing to detect .

Equation 6.3.3.2.2 is a special case of equation 6.3.3.2.1: when devices A and B operate independently, A 's failure has no bearing on B 's ability to detect the event, so that $P(B/A) = P(B)$.

$$P(B/A) = P(B) \text{ and } P(C/A \text{ and } B) = P(C) \quad (6.3.3.2.5)$$

With three detection devices: Let $P(C/A \text{ and } B)$ = the probability of detecting the event using device C in those circumstances when both A and B fail. When all three detection devices are used, the general model is valid whether or not the devices are independent. The model is:

$$P(D) = P(A) + P(B/A)P(A) + P(C/A \text{ and } B)P(A)P(B/A) \quad (6.3.3.2.3)$$

This translates as the probability of detection equals the probability of detecting with device A , plus the product of the probability of B detecting when A fails to detect times the probability of A failing to detect, plus the product of the probability of C detecting when A and B both fail to detect times the probability of A failing to detect times the probability of B failing to detect when A fails to detect .

100, the probability of B failing is 1:100, and the probability of C failing is 1:100, then the probability of A , B , and C

The model for independence of the devices is:

$$P(D) = P(A) + P(B)P(A) + P(C)P(A)P(B) \quad (6.3.3.2.4)$$

This means that the probability of detection equals the probability of detecting with device A , plus the product of the probability of B detecting times the probability of A

are available for use in the mathematical models presented for calculation of actual

failing to detect, plus the product of the probability of C detecting times the probability of A failing to detect times the probability of B failing to detect.

Equation 6.3.3.2.4 is a special case of equation 6.3.3.2.3: when all three devices operate independently of one another, the failure of any one has no bearing on the ability of the others to detect the event, so that:

$$P(B|A) = P(B) \text{ and } P(C|A \text{ and } B) = P(C) \quad (6.3.3.2.5)$$

Note that with each addition of a detection device to the model, a new term is added to the existing probability statement, which increases the probability of detection. This applies to both the general model and the model for independence presented above. Duberman concludes that by adding devices there is an increased ability to detect an event, whether there is a specific adverse event or any one of a number of possible adverse events.

The product rule that defines the probability that three totally independent devices will fail simultaneously is equal to the product of the probabilities of each independent device failing [65]. If A , B , and C are three independent devices used to detect an untoward event; and if the probability of A failing is 1:100, the probability of B failing is 1:100, and the probability of C failing is 1:100, then the probability of A , B , and C all failing simultaneously is:

$$(1:100) (1:100) (1:100) \text{ or } 1:1,000,000 \quad (6.3.3.2.6)$$

Unfortunately, when using different detection devices the probabilities of detection or failure of detection of various potentially critical events are unknown. No reliable data are available for use in the mathematical models presented for calculation of actual

probabilities of detecting the various adverse events. At this time only the direction of the effect is known, i.e., the greater the number of detection devices, the greater the chance of detecting potentially critical events. It must be considered also that different devices are more useful than others in detecting different situations. For example, oesophageal intubation is detected more rapidly by a capnometer than by an electrocardiographic monitor which waits for arrhythmic or bradycardia. A disconnect alarm is designed to warn of a breathing circuit disconnect and an oxygen analyser to signal a situation in which an inspired hypoxic mixture is being administered. Each separate piece of equipment is necessary in a good anaesthesia fail-safe system, and increasing the number of elements in the system will increase the probability of event detection [65]. Of course, also true is that the greater the number of detection devices the greater the likelihood that one of these devices will yield a false-positive reading, i.e., warn of an event which does not exist. However, it was agreed that it is better to be made suspicious of an event, to investigate and reject the finding than to be unwarned of potential danger.

As noted, the greater the number of detection devices, the greater the chance of detecting an adverse event [65]. The string of continuously available monitoring devices to detect any one of three potentially dangerous situations leading to critical physiological failure in patients (the general case) is shown in Table 6-1. It would seem reasonable to select an array of monitors that would include at least one high-level monitor for every possible problem [17].

The signal is automatically transmitted to the PC when the anaesthesia monitoring device is activated. A self-test mode follows permitting the anaesthetist to check the operation of all alarms and displays. Then he presses the alarm reset switch putting the device into a ready mode, which is indicated on the display. Next he may connect the patient circuit and set the appropriate parameters of the anaesthetic machine and ventilator. When monitoring parameters have been set, the anaesthetist presses the

<i>Monitoring Device</i>	<i>Critical Event Detected</i>
Oxygen analyser	Administration of a hypoxic gas mixture
Capnometer	Oesophageal intubation
Disconnect alarm	Breathing circuit disconnect
Other airway alarms	
Electrocardiogram	
Automatic sphygmomanometer	
<i>Devices which warn of event likely to lead to physiological aberration</i>	
Capnometer	
Disconnect alarm	
Other airway alarms	
Oxygen analyser	
<i>Devices which warn of physiological aberration</i>	
Capnometer	
Electrocardiogram	
Sphygmomanometer	
Temperature monitor	

TABLE 6-1. Commonly Available Fail Safe Monitoring Data.

As stated, the greater the number of detection devices, the greater the chance of detecting an adverse event [65]. The ability of commonly available monitoring devices to detect any one of three potentially dangerous situations leading to critical physiological failure in patients (the general case) is charted in Table 6-1. It would seem reasonable to select an array of monitors that would include at least one high-level monitor for every possible problem [17].

The signal is automatically transmitted to the PC when the anaesthesia monitoring device is activated. A self-test mode follows permitting the anaesthetist to check the function of all alarms and displays. Then he presses the alarm reset switch putting the device into a ready mode, which is indicated on the display. Next he may connect the patient circuit and set the appropriate parameters of the anaesthetic machine and ventilator. When monitoring parameters have been set, the anaesthetist presses the

collect new data switch which allows the computer to identify, average, and store two consecutive, acceptable, and sufficiently similar cycles of the digitised pressure data in the pressure circuit. These are used as a basis for comparison to on-going pressure cycles. These comparisons are made using one set of absolute criteria and a second set of relative criteria; if any of the pertinent criteria are not satisfied for an initial or on-going pressure waveform, an audible alarm is activated and an appropriate warning message is displayed [151].

•	o2sat,	low alarm if:	< 85.6
•	hr,	high alarm if:	> 145.5
•	hr,	low alarm if:	< 41.9
•	bpsys,	high alarm if:	> 190
•	bpsys,	low alarm if:	< 78.9
•	fiCO ₂ ,	high alarm if:	> 2.74
•	petCO ₂ ,	high alarm if:	> 59.6
•	petCO ₂ ,	low alarm if:	< 18.1
•	rr,	high alarm if:	> 44.5
•	fiO ₂ ,	low alarm if:	< 20.7
•	temp,	high alarm if:	> 38.8
•	temp,	low alarm if:	< 32.7
•	ve,	high alarm if:	> 13.8
•	ve,	low alarm if:	< 2.06
•	peep,	high alarm if:	> 14.4
•	peep,	low alarm if:	< -9
•	pip,	high alarm if:	> 49.5

TABLE 6-2. Relative Values of Alarm Messages.

The absolute criteria include determinations of whether the current pressure data fall within acceptable limits in terms of maximum pressure, minimum pressure, inspiratory/expiratory ratio and period. Determinations of whether instantaneous and

stored values for the reference and on-going pressure data are sufficiently similar in terms of the parameters listed in Table 6-2 involve relative criteria. When storing new data, the same relative criteria are employed to determine whether two consecutive cycles are sufficiently similar [151]. If one or more of the criteria are not met, and the alarm is activated, the audio portion of the alarm can be silenced for 30 s by means of the alarm reset switch; however, the warning message continues to be displayed. The audio-visual alarm can be permanently reset only by correcting the activating condition. If the parameters of the ventilator must be changed if the patient's status changes, the store new data switch can be depressed to instruct the breathing circuit monitor to relearn or store a new pressure trend as a reference. To prevent the storing of an abnormal trend, the algorithm is designed so that a new pressure data cannot be stored as a reference in the presence of any alarm condition.

The capnogram generates data based on the integrity and function of the patient's cardiopulmonary system and the system for delivery of life-support gases.

Malfunctions in both can be detected by noting changes in the capnogram during an anaesthetic. For example:

A sudden drop of end-tidal CO_2 concentration (etCO_2) to a zero or near zero value usually indicates a potentially disastrous event [239]. When the analyser no longer reports the presence of CO_2 in the exhaled gas from the patient oesophageal intubation, complete airway disconnection, complete ventilator malfunction, and totally obstructed endotracheal tube may have occurred and may lead to damage.

A fall in the etCO_2 value toward but not reaching zero baseline, indicates that the patient's full exhalation is no longer being sensed at the airway adapter. Exhaled gas may be venting to the atmosphere through a loose-fitting tracheal tube or a poor mask

fit [239]. If an endotracheal tube is in place and the etCO_2 value suddenly drops, a leaking or defective endotracheal tube cuff may be in place.

An exponential drop in etCO_2 within a short period of time, perhaps a dozen or so breaths, almost always indicates a sudden and probably catastrophic event in the patient's cardiopulmonary system [239]. Such a critical event must be diagnosed and corrected immediately.

Occasionally, with no apparent malfunctions in the anaesthesia circuit or in the patient's cardiopulmonary status, the capnogram will show a sustained low etCO_2 and the absence of a good alveolar plateau. If this occurs, the etCO_2 value is suspect as a reliable estimate of alveolar PCO_2 and hence certainly not as a reliable estimate of arterial PCO_2 . The absence of a good alveolar plateau suggests that either full and complete exhalation is not occurring prior to the next breath or that the patient's tidal volume is being diluted with fresh gas due to a small tidal volume, high aspirating sample rate, and high fresh gas dilution from the circuit [239].

In some circumstances, the capnogram will demonstrate a low etCO_2 with a widened aADC_2 and preservation of a good alveolar plateau. Initially, the discrepancy between the etCO_2 value and arterial PaCO_2 suggest that the equipment is malfunctioning which may be true if the machine has not been calibrated or serviced recently. Note also that body temperature affects metabolism and CO_2 production adversely. If the ventilation is controlled and kept constant during a drop in body temperature, the alveolar CO_2 concentration and arterial PCO_2 will fall [239]. The capnogram will show this as a very slow fall in etCO_2 on the slow speed capnogram over many minutes as the body temperature falls. Depending on the desirability of the fall in CO_2 concentration and tension, the anaesthetist may adjust ventilation to compensate for the fall in CO_2 production.

A rise in etCO_2 with unchanging capnogram morphology may be noted; this may be caused by a leak in the ventilator system with hypoventilation, partial airway obstruction, rising body temperature, or absorption of CO_2 from exogenous source, e.g., CO_2 laparoscope. Small leaks in the ventilator system resulting in a decreased effective minute ventilation but still with adequate tidal volumes for full exhalation will present with slowly rising etCO_2 as hypoventilation occurs [239]. Correcting leaks and tightening the pop-off valve will solve the problems usually.

A sudden and transient increase in the etCO_2 may be observed and can be caused by anything that acutely increases the delivery of CO_2 to the pulmonary circulation. Commonly, the injection of bicarbonate into the systemic circulation with the resultant rise in CO_2 load presented to the lungs for excretion or the release of a limb tourniquet, which suddenly releases high CO_2 containing blood from the ischaemic limb into the central circulation are events leading to this effect. The rise from injection of bicarbonate is usually short-lived, while the rise attendant to release of tourniquet may last for several circulation times until the pulmonary circulation handles the excess CO_2 load [239]. Neither event is disastrous, but both should be recognised for the benign and expected events that they are.

A sudden rise in the baseline of the capnogram with an approximately equal rise in etCO_2 value may appear and may indicate some contamination in the sample cell, usually with water, mucous, or dirt [239]. Cleaning the sample cell is all that is necessary to restore the system to proper functioning, usually.

A gradual rise in both baseline and etCO_2 value arise to indicate that rebreathing of previously exhaled CO_2 from the circuit is occurring. The inspiratory phase of the capnogram fails to reach the zero baseline and actually may show a premature rise in

CO₂ concentration during the inspiratory phase of ventilation before the characteristic sharp upstroke associated with exhalation occurs [239]. Usually $e_t\text{CO}_2$ value climbs until a new equilibrium alveolar CO₂ concentration is reached where excretion once again equals production.

6.4 Research Design

The most ambitious use of computer technology is monitoring a large-scale information network [129]. These systems offer automatic capture or manual entry of various monitored physiological functions, observations and test results. Demographic patient information may be input, also (Figure 6-5). Manual entry of data is invariable, done by typing information into the system via a keyboard. Pertinent information is logged in an organised and timely fashion by the data presentation mechanism.

In general, a microprocessor-based monitor is applied most basically to the waveform display to digitise the physiological signal waveform. The monitor samples the waveform at a given frequency and changes the waveform from a continuous entity to a set of points. The set of points can then be manipulated by an algorithm - for example to smooth the signal. Thus, digitisation of the signal allows computer algorithms to be applied to the data [18].

Sampling has led to trending because the monitor easily and permanently stores the sample points for the heart rate, blood pressure or any measured signal frequently, perhaps every 15 s. Storing is limited only by the extent of the hard disk space. Trend plots can be formulated for a particular period of time. Generally this information is accumulated for a 24-hour period or increments thereof.

Consideration of various expressed needs led to the design of the PONI monitoring system. Each of the several anaesthesia clinical services presented different monitoring requirements and requests. Some anaesthetists insisted on capabilities for changing the sweep speed of the events on the monitor screen, freezing the events, rearranging the limits on the screen, and locating digital data in different places on the screen. Others wanted signal processing for clinical research. Since many different types of monitors would have been difficult and expensive to maintain, it was decided to standardise the hardware and provide maximum flexibility through software. Because at that time small computers could not process multiple monitoring programs, there was a need to develop a computer system that could execute all the programs in one computer. The program required in a particular operating room could be executed by the anaesthetist.

Cost was another factor. The monitoring system requires only one inexpensive computer with standard memory and one dot-matrix quality printer. Such processing uses a number of computer resources leading to greater efficiency. In addition, when programs were improved, changes need be made only once and applied to each additional monitor.

The new monitoring system was designed for use in the vast majority of surgery situation where no invasive monitoring was used. The system was not intended for use with patients needing multiple invasive monitoring catheters, since needed multichannel monitors existed already [18].

6.5 Preliminary Studies

The first task in designing alarms for a medical device is selecting the variables that will be provided with alarm outputs. Device variable, patient variables, and variables that depend on the interaction of the devices with the patient are considered. Device

variables could include temperatures, gas flows and pressures, lead connections, and power availability; patient variables maybe electrocardiogram (heart rate and/or arrhythmia detection), respiration parameters, body temperature, and blood pressure. The pressure developed in a volume-cycled ventilator or blood level in the reservoir of a heart-lung machine are combined variables that may be considered [111].

The primary basis for deciding which variables should be provided with alarms is the continuing process of the designer's own failure mode and effect analysis. The analysis begins in the early design stage and extends through subsequent development stages [111]. At first the analysis is broad but becomes increasingly detailed as the design progresses from concept to specific hardware. In general, the analysis seeks to answer such questions as: Which internal or external components can fail or malfunction? What are the most probable operator errors? What are the effects of such malfunctions or errors? What response is necessary?

The first task was the setting-up of a database and the evaluation of available means for the storage, retrieval and processing of physiological data information. After a few experiments, adaptation of the C-language, Prolog and the RS-232 communications protocol, for data processing and retrieval was implemented. Each set of information was transcribed in an individual file, with a pre-set design, to facilitate data processing.

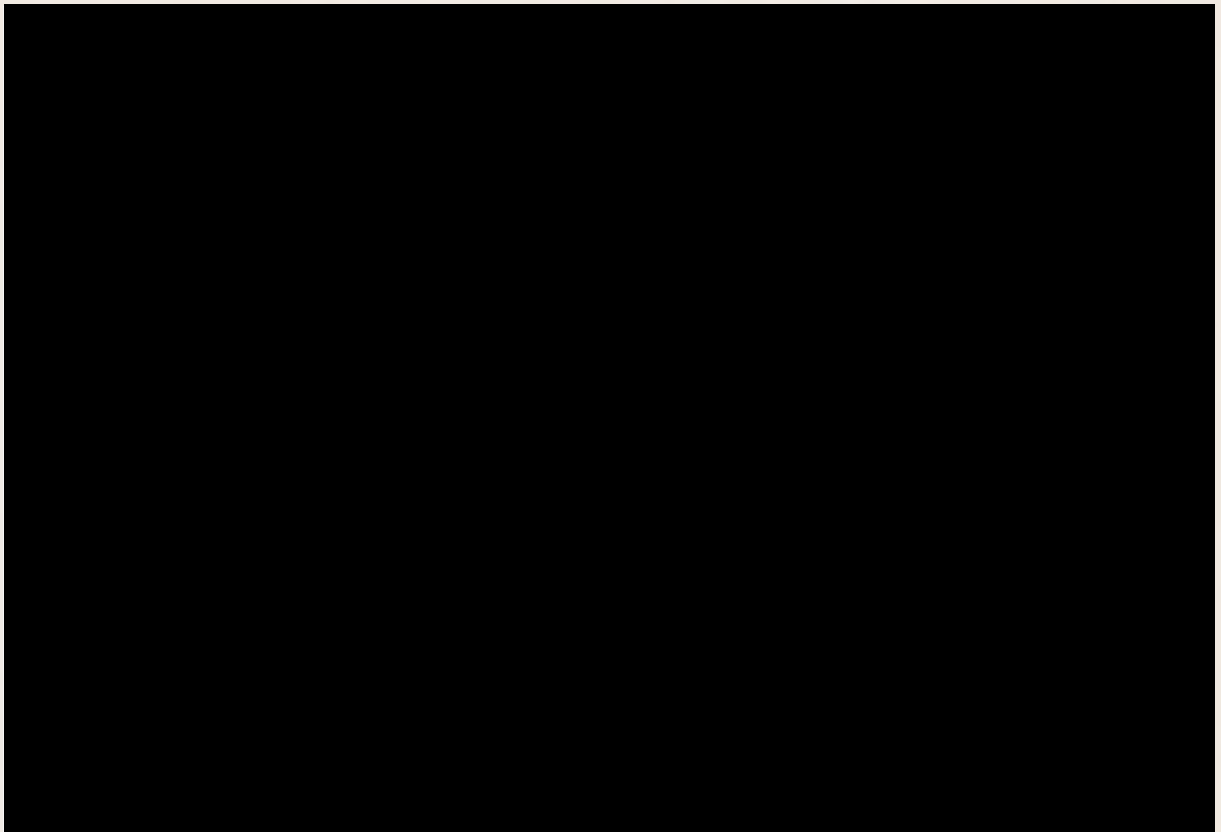


FIGURE 6-9. PONI Demographic Information Data Entry.

In the first part (Figure 6-9) the following are specified:

- ◇ The date and time;
- ◇ The operating room suite used;
- ◇ The patient's demographic information.

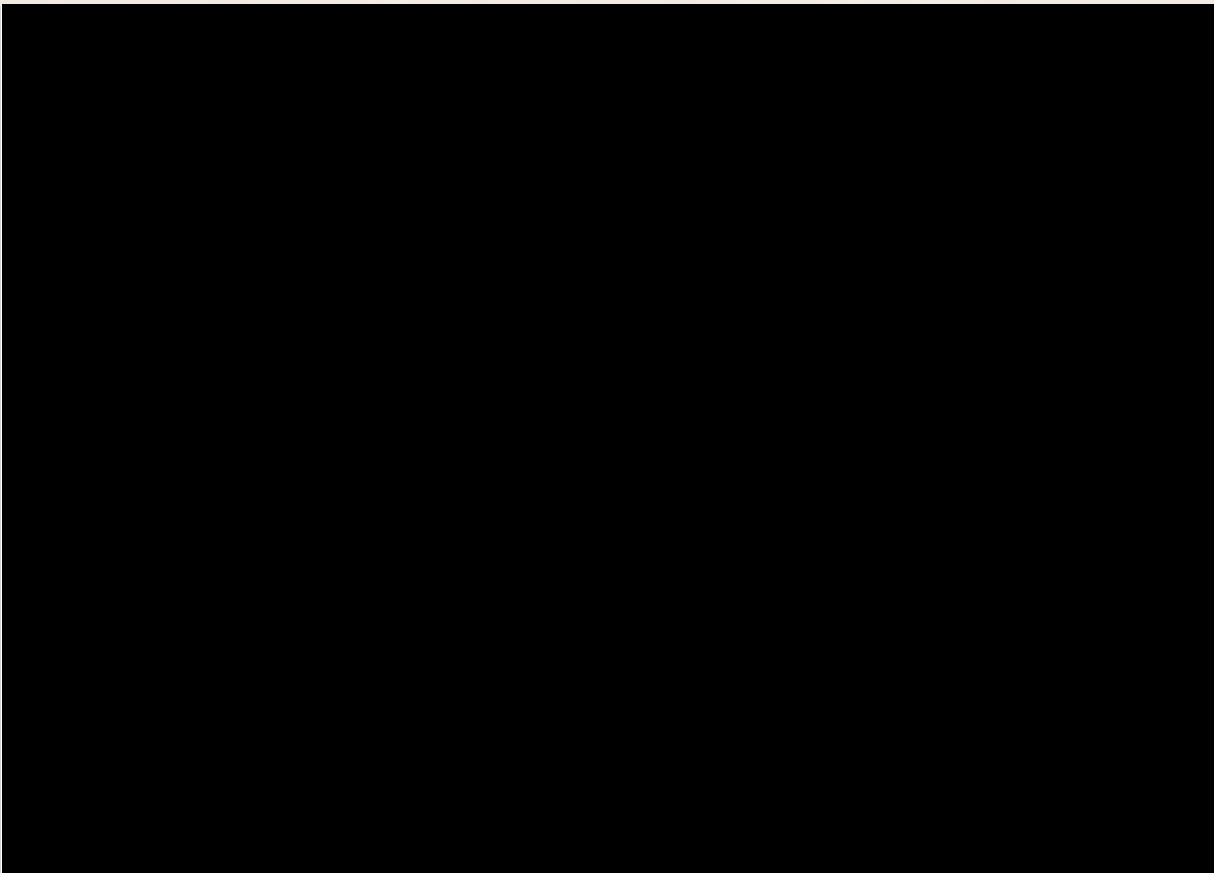


FIGURE 6-10. PONI Physiological Information.

In the second part (Figure 6-10):

- ◇ The time;
- ◇ The complete set of collected physiological information.

The first phase-assessment of the project's feasibility and formulation of a first operational data bank was completed and the second phase was initiated. During this phase, selected desk reference information forms (DSU OR Record, DSU Anaesthesia Record) were electronically prepared from the available stored data, with the relevant information on each patient listed under separate headings (name and demographics of the patient, OR times, surgical procedure, etc.). Each of these forms was provided with its own code number (Hospital ID) and the same number was used in additional

lists of the proper names of other patients for reference purposes. At the present time the database contains physiological data on over 157 different patients. Obtaining automatic diagnosis by clinical symptoms processing presents practical difficulties still because of interchangeable medical terminology (and its inconsistent use) and because of the limited specificity (or weight) of different symptoms or their combinations, especially in acute patient care. However, working on this aspect has generated some promising results.

The critical re-evaluation of the theoretical information stored in the database correlated from the collected clinical data from about 157 cases of acute care became another useful application of the adopted computerised system. This large mass of information is a resource for assessing the nature, extent and degree of various types of intoxication, correlated symptoms, and the validity of the therapeutic measures adopted [145]. Another by-product, the statistical-demographic information deriving from this assessment, is a useful guide to prevention techniques.

During the third phase initiated in 1988, storage and information retrieval system was adopted under knowledge information control system because greater processing power and feasibility of real time information retrieval was possible. This system is data processing that makes it possible, especially when the variable is unknown, to obtain information on all known potential variables, and to attribute a probability quotient to each of them [145]. At the present time both data banks are accessed by 54 possible complications; 110 knowledge rules; directly by one of the above inputs or indirectly by different combinations of them. In this way, the emergency therapeutic measures and a program indicating needed confirmatory clinical and demographic data may be obtained in addition to the basic information.

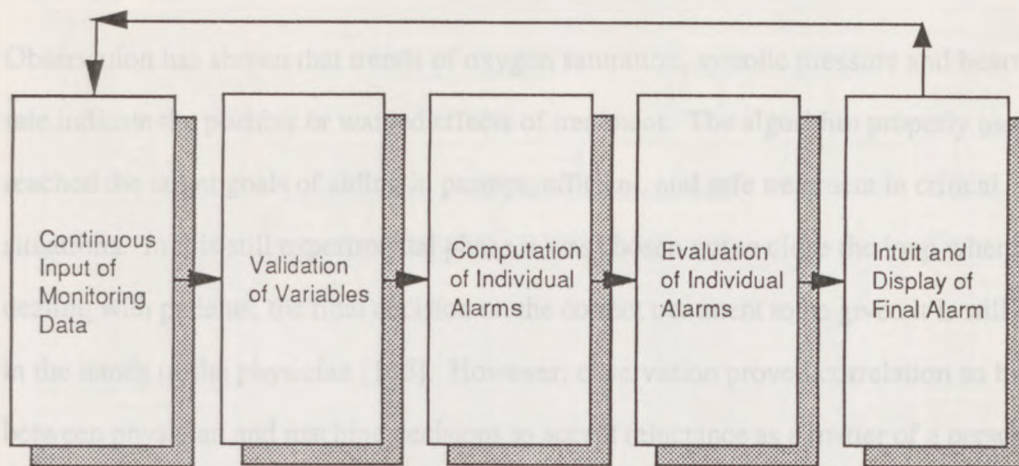


FIGURE 6-11. The Five Phases of PONI's Control Procedure.

At present attention is concentrated on the development of a system for value validation and false positive alarm evaluation in cases of operations in healthy patients undergoing minor surgery. The system (PONI) that was developed utilises an algorithm finalised to the control and an interaction program that connects the patient to the computer via the monitoring equipment. In Figure 6-11 the five fundamental phases of the control procedure are depicted. First the computer is fed the data registered by continuous monitoring; second it performs automatically the analysis of variables; third individual alarms are automatically generated, fourth, the diagnosis and measures to be adopted are evaluated; and fifth, a final alarm is generated. All phases are carried on at the same time and are complementary to each other [145]. The control system may be summarised in this way: every 15 s the data for input are measured and the derived parameters are calculated. Systolic arterial pressure, heart rate, oxygen saturation and the like are typical parameters. The optimal value of the variables are established by use of multiple and complex functions. This algorithm allows the modification of the sampling rate every 15 seconds, according to the actual physiological condition and finally to their expected future trend.

Observation has shown that trends of oxygen saturation, systolic pressure and heart rate indicate the positive or wanted effects of treatment. The algorithm properly used reached the target goals of aiding in prompt, efficient, and safe treatment in critical situations. In this still experimental phase it was chosen not to close the loop when dealing with patients; the final decision on the correct treatment to be given it is still left in the hands of the physician [145]. However, observation proved correlation so high between physician and machine decisions to accept reluctance as a matter of a personal resistance to deliver to a machine 100% control of a clinical situation.

Even if the loop is not closed the developed system has shown its utility in informing the physician in real time on the monitoring and derived parameters, showing the trends, recording data and allowing the graphic transcription in real time (Figure 6-12).

FIGURE 6-12. FORT's Knowledge Procedure.

This specific application shows the potential and actual value of computer support in the OR. The final action is reserved always for the attending physician who then can base his decisions on precise and actual data and on real time evaluation of modifications following the intervention [145].

6.5 Selection of Patient Population (Why DSU 7)

The Day Surgery Unit provided the opportunity for an intensively controlled study of a select group of healthy individuals undergoing minor surgery. Using this group allows a better definition of normality in a given population of healthy human beings to be achieved. In man, the definition can be applied in the study and understanding of deviations from the norm, that is, disease states and in understanding the increasingly important but ever elusive process of aging. Stated goals of the study are to:

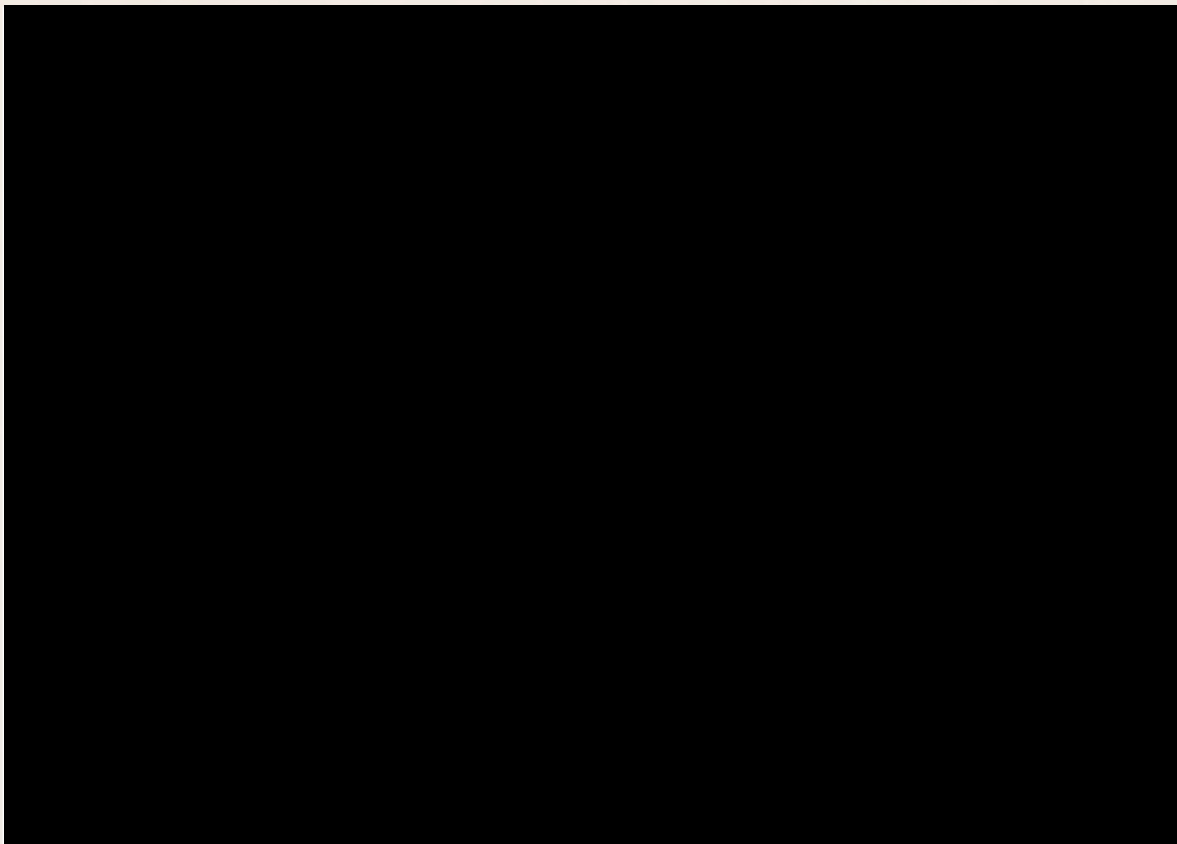


FIGURE 6-12. PONI's Knowledge Procedure.

This specific application shows the potential and actual value of computer support in the OR. The final action is reserved always for the attending physician who then can base his decision on precise and actual data and on real time evaluation of modification following the intervention [145].

6.6 Selection of Patient Population (Why DSU ?)

The Day Surgery Unit provided the opportunity for an intensively controlled study of a select group of healthy individuals undergoing minor surgery. Using this group allows a better definition of normality in a given population of healthy human beings to be achieved. In turn, the definition can be applied in the study and understanding of deviations from the norm, that is, disease states and in understanding the increasingly important but ever evasive process of aging. Stated goals of the study are to:

- ◇ Define the range of normality or physiological variation within a given age group;
- ◇ Define optimal physical condition and the means available to maintain it;
- ◇ Define those physiological and/or biochemical criteria which are of value in predicting future patient performance [14].

6.7 Hardware Selection

Although the application of the computer to data collection, analysis, and display promises to integrate discrete monitors into a functional system for decision support, one great stumbling block still exists: digital data communications. Historically monitors have not been equipped with adequate communications interfaces, and the present systems are not greatly improved. An urgent need exists for a consensus on a data-communications standard. The de facto standard is RS-232, which causes several problems. For example, there is no standard RS-232. The functions and electrical characteristics of a 25-pin interconnect are specified, but most RS-232 connections use only 4 to 6 signals, and the use of these signals for handshake signalling varies with the individual vendor. No way exists at times for one device to poll or initiate a data transmission from the other device. Thus a communications line must be dedicated to listening for data that are able to interrupt other functions when data are being received [252]. Furthermore, once a bit stream is sent, it is often not in line with American Standard Code for information interchange (ASCII) protocol characters. Instead, it may be a hodge-podge of status and data bits without separators, stop bits, start bits, or parity, and must be decoded at the bit, rather than character or word, level. In addition multiple monitors each with a dedicated serial communications port must be

connected physically to the computer. Imagine the array of monitors 5 years in the future (EEG, ECG, NIBP, Pulse Oximeter, airway gases, respiratory flow, etc.), each with its own cable and 16 connectors coming back to the computer.

The PONI system, a computerised multichannel operating room patient monitoring system, was developed by the directions of the author. The system includes a PONI monitoring cart in each operating room and a star topology computer network that interconnects the monitors to the microcomputer. First the monitors transmit both measured and derived physiological data to the micro-computer for storage, then complex statistical analysis of the data takes place afterwards [18].

Readily available commercial components make up most of the PONI system; however some circuit boards and input/output interface devices were customised to fit the specifications.

Since the PONI system was designed and constructed by those who would maintain it, it has easy maintenance features, such as rapid serviceability [18]. The modular design and special diagnostic computer programs, such as those for line monitoring, aid in serviceability.

6.8 Data Collection and Recording

The current trend is to put more monitors in or on the anaesthesia machine. Recently North American Drager (Telford, Pa) had CRT display screens built into the upper anaesthesia machine cabinet. These screens are used to display variables from the anaesthesia machine, patient, breathing circuit, and alarms. An automatic noninvasive blood pressure monitor (NIBP) is built into the machines, as are end-tidal CO₂, airway O₂, breathing circuit pressure and flow monitors, and an alarm system/information

bus. Other monitors such as pulse oximeter may be interfaced with the machine. This approach brings some order to the chaos of discrete monitors and delivery equipment but does not address all serious concerns [252]. Others have used telemetry to reduce the number of cables from the patient back to the anaesthesia machine and monitors. By far the most common example of physical integration, however, has been the multifunction monitors, which include ECG, blood pressure, temperature, and/or other combinations of monitors into one device.

The newest bedside physiological monitors use digital computers almost exclusively. These microcomputer-based monitors renew the approximately 100,000 heartbeats that occur each day and identify those of interest (arrhythmias, asystole, and so on). The measurement of heart rate and arrhythmias and the ever-vigilant logging of these data have become hallmarks of intensive care monitoring [82].

Care of the critically ill patient requires data from a wide variety of devices and instruments [82]. A patient may be connected to a noninvasive blood pressure monitor, an ECG, an anaesthesia machine, a mass spectrometer, and a pulse oximeter (Figure 6-13). Each of those devices may be made by different manufacturer, and each may have a different data communications interface.

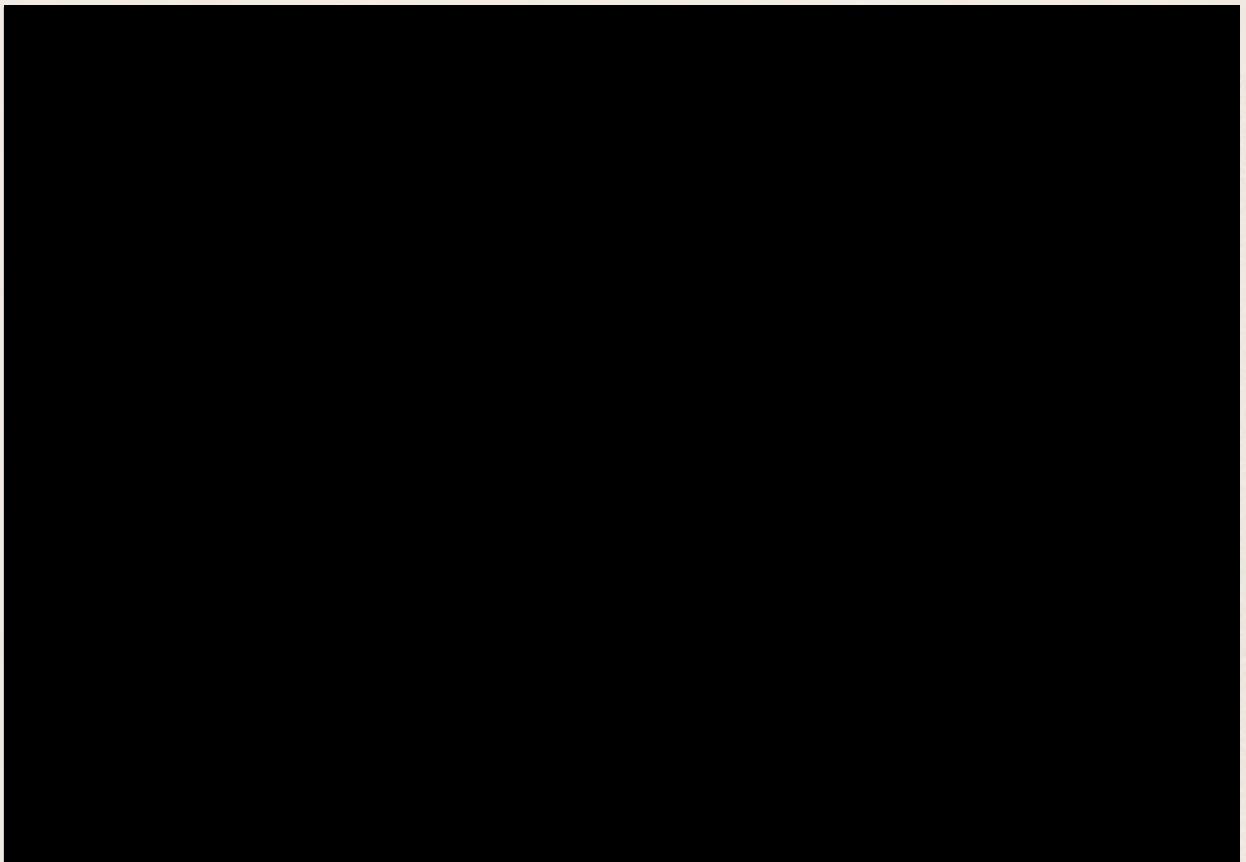


FIGURE 6-13. PONI Monitoring Devices.

To obviate the manual acquisition of data from this multitude of electronic sources, a system was designed around the patient to acquire data from all monitoring devices [81]. As noted in Figure 6-13, a large amount of device-generated data can be entered automatically into the database via RS-232 cables. The system can have up to 16 devices connected; and each device has an identification code.

The primary advantage of computerised monitoring systems is the wealth of data acquired from on-line, real-time monitoring systems, that are continually measured, calculated, reported, and stored simultaneously. Clinical therapy is maximised because data trends may be recognised promptly and decision-making processed accelerated. One research study found derived (calculated) variables to be more valuable in predicting mortality in 113 patients than parameters commonly monitored [55]. In the

study 35 cardiorespiratory variables that were measured directly or were derived from calculations were evaluated. Results showed that commonly measured parameters such as heart rate, temperature, and haemoglobin were poor outcome indicators, whereas calculated values such as pulmonary vascular resistance, left and right ventricular stroke work, and arteriovenous oxygen difference were more reliable predictors of outcome [189].

The data manager is an INTEL 80287 based microcomputer (IBM PC/AT) located in the anaesthetist's area of the operating room suite. Its memory a 4 megabyte (MB) random-access memory (RAM) and storage of 30 MB hard disk and 210 MB write once read many (WORM) laser disk (ISI) permit storage of the physiological data which may be transmitted from the monitoring equipment to the PC.

Data from 144 consecutive patients undergoing general anaesthesia in one of the day surgery operating rooms of the Hospital of the University of Pennsylvania (HUP) were collected and filed for evaluation. Output from an ECG monitor Hewlett Packard (HP 78352A), mass spectrometer (Perkin Elmer Advantage 2000), Anaesthesia machine (North American Drager, Narkomed 2B), Pulse oximeter (Nellcor, N200) and non-invasive blood pressure (NIBP) monitor (Critikon, 1846 SX) were sampled every 15 seconds. All five devices had RS232 serial communication ports. The five ports were connected to a personal computer (IBM-PC) fitted with an 8 port serial communication adapter (DigiBoard/8). The computer ran custom software written and compiled in C (Lattice).

The program was started on the evening prior to surgery and ran continuously until the following evening. It polled sequentially each of the five monitoring devices with a prompt string appropriate to the device. The output strings from all five devices were concatenated into a single string which noted also the time of data collection, the OR

from which the data originated, and a check sum. Each string was added, as a single data line, to an ASCII file identified by the date and OR number. In the evening, after completion of the last case, the file closed. The program was then restarted with output directed to a new file. Each file was parsed into several smaller files containing one patient record. Data from another program containing manually entered information including patient identification and starting and stopping times were used to provide temporal markers for the parsing operation. Each of the patient records was used as an input file for the data validation program.

The data validation routine was written in PROLOG (Arity Corp.) and it was designed to run on an AT class personnel computer (IBM PC/AT). A modular design was used.

PROLOG was chosen as an application language for AI systems, primarily because of its powerful pattern-matching capabilities offered by unification and its useful automatic backtracking for exploring search spaces [38]. Using this left-to-right, depth-first strategy made the system accurate and efficient.

The system's first module is interactive; it establishes the patient records to be processed and the user interface decides whether to process them rapidly or in real time mode. Real time mode simulates use in the OR and produces the screen output as it would be observed if being run in the OR. Fast mode runs at 4 to 5 times real time speed and produces an output file describing the action taken on all data that falls into a warning range.

The second module reads the selected file one line at a time and then parses the data lines into individual data values. Next these values are then passed to the rule module.

The core of the program is a set of 26 validation rules and 18 invalidation rules (Appendix VII). Each data value is tested, first by the invalidation, then by the validation rules. As soon as a rule returns a true state the value is tagged as either valid or invalid. Then the module moves to the next value to be tested. If no rule returns a true state the value is left in an indeterminate state. Each time a rule returns a true, a flag is set. After all data in a line have been evaluated the output is passed to a computation module.

The computation module produces the values to be evaluated in two ways. For parameter returned from only one device (e.g. blood pressure) the single value is passed along with its validation status, valid (V), invalid (I) or indeterminate (?). For parameters with more than one source (eg. heart rate) the computation module checks to see the highest validity level available, $V > ? > I$, the values with the highest validity level are averaged and the average is passed to an evaluation module.

The evaluation module compares these received values with values in a range table (Figure 6-6) (invalid data are not evaluated). The table is divided into normal (green), caution (yellow) and alarm (red) ranges. The range boundaries were set by averaging responses of eleven senior staff anaesthetists asked to specify default settings for limit based visual (caution) and audible (alarm) warnings for each condition. They assumed a healthy adult population in their analysis. Each warning was passed to an output record as a string which was made up of the device generating the warning, the level of the warning (caution or alarm), the data value, the state of validation (V, ?, I), and the rule which set the validation state.

The output file is available for further processing by rules designed to determine diagnosis or likely cause of values not in the normal range.

The output files from all patient records were passed to a relational data base (KMAN/MDBS, IN). The data base was used to determine the incidence of the clinical conditions identified by the rules. Further, it identified incidence by condition, validation level, severity and/or rule.

Once booted with the operating system the data manager loads the FILTER program (written in PROLOG) which connects to all monitoring devices. The anaesthetist is presented with a menu from which to choose parameters, tailored to the needs of a particular patient. By selecting an appropriate value, personal preferences, such as the sampling times or alarm limits, can be accommodated [18].

The computer is an ideal record keeper because it can store and recover quickly vast amounts of information. A successful database management system should be user-friendly, that is, easy to use after a few minutes of instruction. Also necessary to the real-time monitoring environment of an OR is a computer system with high availability (no failures or downtime) [82].

6.9 Data Detection Algorithm

Variables derived from the measurements of the patient are checked every 15 s as to whether they exceed their static alarm limits (Appendix VI). These limits have been set by the user of the system and correspond to the limits of the green, yellow and red of the CRT display. When a limit is crossed, the status "too high" or "too low" is attached to the variable.

On the CRT display the value of the variable in question is marked with the appropriate colour. If the variable is within the static limits it is checked on dynamic disturbances (Figure 6-14).

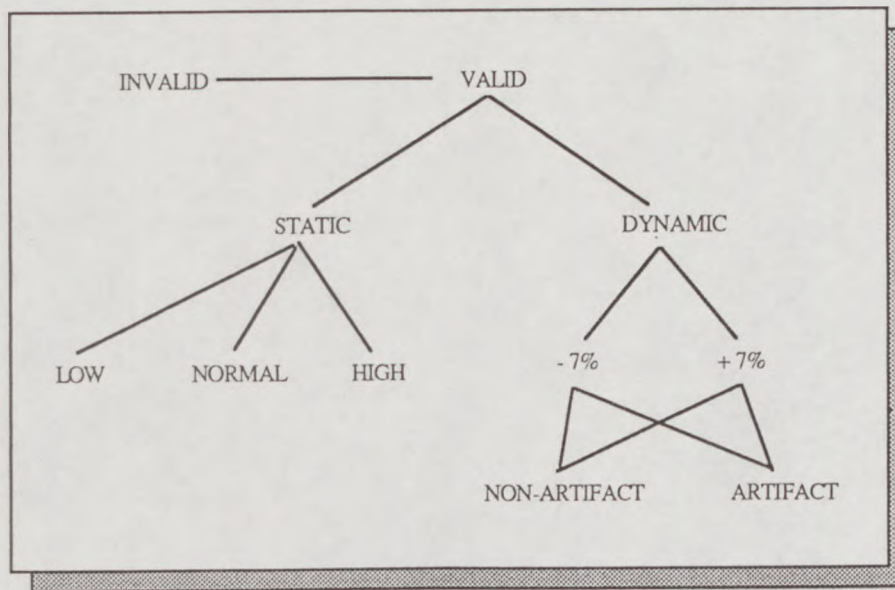


FIGURE 6-14. Possible Statuses of the Detection Algorithm.

(Modified from [156])

Thus each new datapoint is compared to its own behaviour over the previous time period, allowing behaviour to be determined by the running average of each variable.

A dynamic disturbance is defined in terms of a new datapoint that exceeds its dynamic confidence interval by $\pm 7\%$. Since confidence intervals are self adapting, alarms are generated only if the variable fluctuates strongly compared to its own previous behaviour [156].

6.10 Data Processing and Analysis

The hallmark of a good physician is the ability to make sound clinical judgements. As Bergman and Pantell [13] point out traditionally such judgements are considered to rely on art and intuition rather than science. However, in recent years the use of scientific data gathered from computers to assist in medical decision making has gained wider

acceptance [251]. Indeed, the discussion of artificial intelligence is commonplace in medicine today.

McDonald [149] has shown that a computer reminder system applied in an ambulatory clinic reduced oversights by physician errors due to channel noise or information overload rather than to ignorance [82].

Man has a number of advantages over the machine when it comes to data processing [143]. He can make inductive decisions, can generalise from few data in new situations and can handle overload situations without disruption. However, when faced with complex computations as required for the determination of secondary haemodynamic variables from source data, he is not as efficient and not as accurate as the machine. He has a poor short-term memory and is unable to accept and handle high information flow rates [107].

Man's disadvantages were taken into consideration when designing methods of data manipulation, data processing and the recording or display of the variables. It became apparent that source signals have to be treated or analysed to obtain the numbers which aid in planning various therapies.

Electrical signals representing physiological variables are frequently contaminated by electrical interference which may originate from the patient, the environment, or from the instrumentation itself. Electronic filtering techniques are used (low pass, high pass and notch filters) to remove this unwanted noise. When signals have been digitised, mathematical techniques (digital filters) are used to remove noise. Although this is not of concern to the user, it is important that the frequency content of the signals which are to be used for display or further analysis is known. If a user is unaware of the

setting on many ECG monitor filters, serious distortion of the S-T interval may occur causing false interpretation [107].

Trends, prognostic techniques which develop indices representing a patient's condition, and trend prediction using mathematical modelling are precise, complex mathematical and statistical processes not readily available [107]. If the manufacturer's representatives suggest that trend plots are available, a clear definition should be requested. Often, all they are offering is a simple graph [11].

To implement automatic monitoring several steps must be negotiated. First, signals from monitors must be accessed by a direct connection between the monitor and the interface of the computer. The monitors must be modified correctly to achieve this or may be rendered electrically unsafe. Also, modification may cause the warranty to become void. A number of monitors available are fitted with output plugs that connect directly to a computer. Mainly, these are RS232 plugs which provide a digital signal for further computer processing. These plugs overcome the problems of electrical safety and warranty; however, these communication ports have frequently a comparatively slow rate of communication [207].

Second, as soon as a pathway has been established for transfer of data from the monitor to the computer via the interface, it is necessary to ensure that the signals received reflect changes in patient parameters rather than artifacts. Error-handling routines exist to cope with errors arising from the use of diathermy in the presence of equipment which does not have filters to filter out such interference, or to filter out interference from movement during a blood pressure measurement or pulse rate estimation. However, errors due to mistakes will persist and may not be recognised or if recognised, may not be rectifiable readily. The only satisfactory way of dealing with these errors is to prevent them; therefore they remain a serious drawback to

automation, and they produce a feeling of insecurity about the consistency and reliability of the displayed parameters [207]. Fortunately the study discovered these errors infrequently. Still when they do occur they are a considerable nuisance and cause frustration to the user. Because such errors may crop up, automated systems must have the facility to allow manual data entry.

Once the data are processed and displayed on the computer screen, they need to be transferred to a permanent storage medium. Problematically, if any power loss to the computer occurs prior to data storage, all data will be lost. Transferring data after each measurement to a non-volatile storage medium such as magnetic disk will obviate the problem; however this is a time consuming task for the computer becoming progressively more time consuming as more data are stored. Transferring data intermittently at preset intervals is more practical. This process is slower but lessens the potential for loss of data arising from power failure [207]. Another alternative is to save all the data at the end of the procedure. However, the success of such a system relies on uninterrupted power supply (UPS) or the use of back-up batteries. Such batteries are charged from the main supply while providing power to the system, and are capable of continuing to supply power until the main source is restored.

Once data have been transferred to disk no guarantee exists that they are or will remain stored safely as disks can be corrupted, disrupted, mistreated or lost. Even if they escape these hazards they still only have a finite lifetime of several years [207]. Therefore, if they are to be stored for long periods, they need to be copied regularly. At the end of the procedure the system prints out a hardcopy of the record to be placed into the patient's history providing a practical method of long-term storage.

Lambert and others [130] suggested the use of a central information panel for the measurement of physiological variables to be placed in the central field of vision of the

anaesthetist. The panel would receive the information from all the monitors and could work on the traffic lights principle: green is safe; yellow is warning; and red is danger. It should function as a master alarm with separate enunciators for the different variables [31]. The yellow condition would be associated with the alert tone and red with the alarm. This system cuts down the number of places the anaesthetist looks for information, and the variety of noises he hears thus improving the flow of useful information. His task would be made easier and his vigilance improved as modern microcomputers make such developments feasible.

6.10.1 On-line Processing

All the programming for the PONI, the data manager, the network and the PCs was developed within the department over three years. A PROLOG interface that runs the system and allows other programs to function in its environment was developed. The PROLOG allows system subroutines to be written which provide functions routinely needed by the program and involved in manipulating the sample timing or in processing tables and lists. The number and kind of parameters required determine if the PROLOG subroutines pass parameters in registers, on the stack, or in user program areas. A library of subroutines was developed to facilitate the generation of monitoring packages, ensuring the correct allocation and formatting of these subroutine calls and avoiding tedious, redundant calculation of monitoring variables [18].

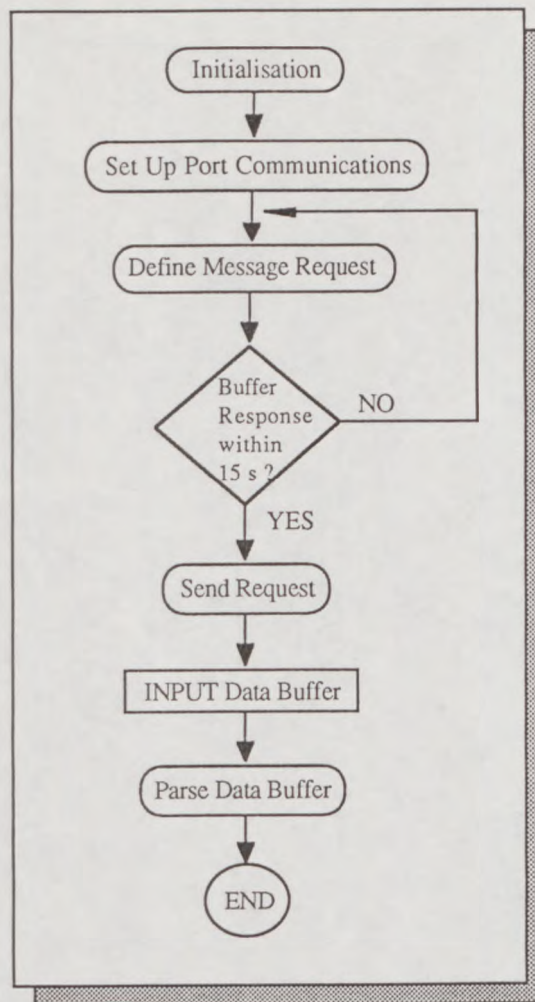


FIGURE 6-15. Flow Diagram of the Computer Program.

The program is in the form of a compiled PROLOG handling section and an assembly language data acquisition routine (Figure 6-15 shows simplified diagram). Unlike some other systems the data acquisition routine is not interrupt driven, but triggered periodically by the internal clock of the computer. No disadvantage has been found in running the system this way, and indeed it seems useful that each interaction with the computer is completed before the next task is initiated [62].

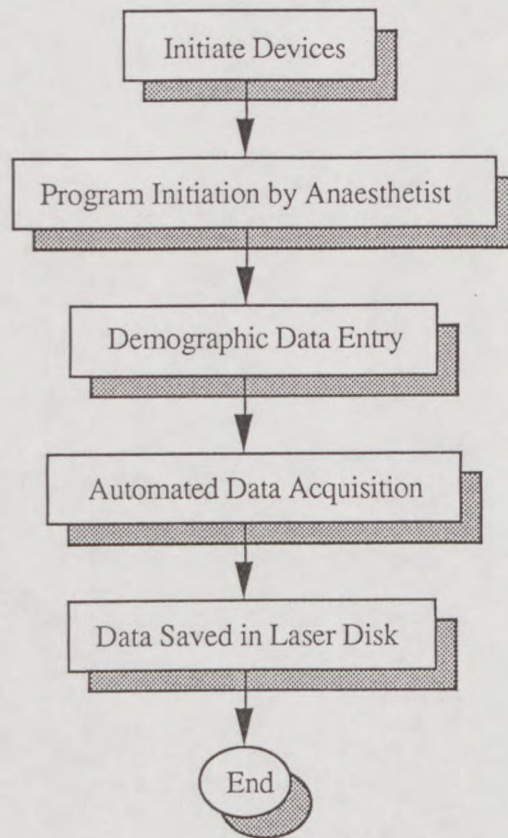


FIGURE 6-16. Program Flow.

On loading and running the program, a short initialisation section is executed (Figure 6-16). This sets the data acquisition algorithm, the number of RS-232 lines to be monitored, and a number of other details for the display and for record annotation. For example, during non-invasive blood pressure monitoring intervals are set so that the trend data is acquired every 3 min or less, with the samples being 15 s long. So far data sampling time of 15 s has been shown to be sufficient to fully describe all data monitored [89].

Built in is an option to monitor systolic and diastolic pressures or mean pressure for any arterial pressure channel. The systolic and diastolic pressures allow a pulsatility index to be calculated by using the expression $PI = \{(Systolic - Diastolic) / Mean\}$ where

the mean is defined as $\{2 \times \text{Diastolic} + \text{Systolic}\} / 3$. If this index falls below a predetermined level a warning message is displayed to indicate that the patient's condition should be checked or that significant damping is occurring in the pressure-measuring equipment.

Once the initial routine is completed the program passes on to the main control section which awaits trigger signals from the data capture or trend acquisition timers. Also, the main control monitors the keyboard to determine whether any of the interaction facilities have been requested.

A feature of this system is that before any data are acquired the settings of the pressure switches on the transducer amplifiers are checked. Because transducer amplifiers offer a number of output configurations suitable for different recording or display options, the checking is facilitated.

Both the trend data and monitoring sample storage sections use the assembly language routine to fill a data array. The type of request triggered determines the handling of the data.

If an event of special interest occurs, a data sample capture may be initiated by a keyboard signal. Otherwise captures may take place at pre-programmed intervals. The data are stored on disk together with the relevant details for the current acquisition conditions.

The trend routine processes the data for each channel by calculating either an overall mean pressure or systolic and diastolic pressures as selected during the initial phase.

The data are stored on disk in a random access file which is closed after every write operation so that no data are destroyed by power loss. Then the trend information is displayed for the selected channel. The information is updated after every trend acquisition, and displays 15 s of the data in current memory.

The screen displays one set of data at a time, selected by a single key. To date, this data presentation technique has proved satisfactory.

Additionally, the program offers a subtraction capability to improve monitoring. The user is able to subtract any one device from another to form a resultant device. For example, if more accurate CO₂ analysis is required then the mass spectrometer may be disconnected and CO₂ analyser connected instead.

At times it is useful to review monitoring trends over periods greater than 15 s. The program allows all previous recorded data stored on disk to be retrieved and presented in a hard copy for simple review.

Finally, if a noteworthy event has occurred, short text messages are stored on a disk; concurrently, a marker flag is set for the current trend data point and an asterisk appears on the screen at the relevant position. These signals enable the medical staff to monitor the effect of any therapy being administered [62].

Coloured characters for visual warning signals were adopted according to the convention which allocated red and yellow to alarm states and green to a normal operating condition. Of course, characters were to be placed in a prominent position upon the screen, and to be visible through a wide arc. Installing flashing characters or placing characters near a window screen will improve alarm visibility.

For hypoxia problems (failure to deliver oxygen) the attendant's attention is focused on the oxygen supply pathway leading to the sensor site. For ventilatory problems, the attendant needs to check the airway and ventilator. For cardiovascular problems, the attendant's attention is drawn to the patient's circulatory status [122].

6.10.2 Off-line Processing

Using a dot matrix printer (Epson FX-85) the data stored on disk are available for processing at the conclusion of monitoring. The full span of the period is printed out (Table 2-3) and any selected sections of data with special interest may be printed.

Stored data samples (caution or alarm) are printed on the screen automatically as they occur. The data samples may be printed out in hard-copy if required (Table 2-3).

More importantly, they are available for analysis as part of subsequent research work [62]. As with the acquisition and storage program, the hard-copy routines assume no computing background on the part of the operator (Figure 6-17). A knowledge of the file names involved is all that is necessary.

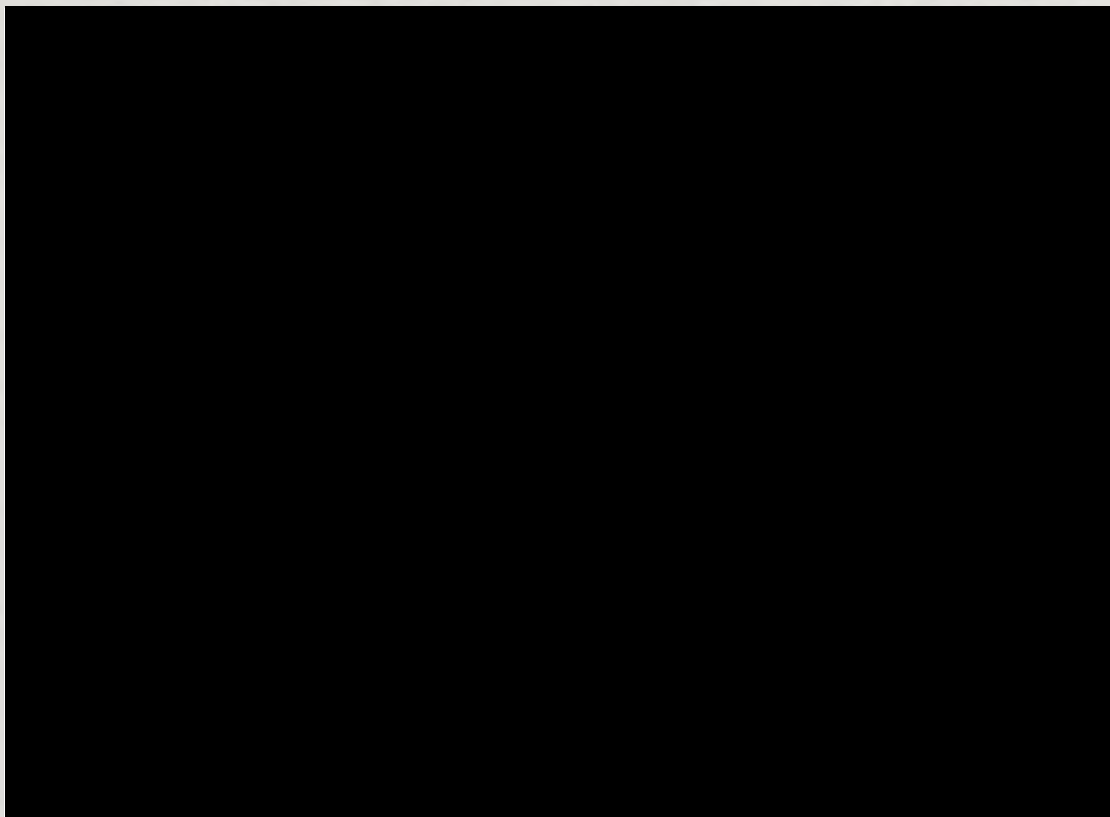


FIGURE 6-17. Off-line Processing.

6.11 Limitations

The limitations of current monitoring practices cause them to fail to detect potentially disastrous events early enough.

While the ECG furnishes valuable data regarding heart rate, arrhythmia, heart size, and myocardial ischaemia, it does not detect severe myocardial ischaemia. Often, ECG continues for 5 or 10 more min after cardiac arrest in a nearly normal pattern. If a patient with a normal preoperative ECG develops as ST depression change, a severe bradycardia, or an arrhythmia under anaesthesia, his ECG shows myocardial ischaemia only when the patient is highly hypoxic [255]. Additionally, intravenous xylocaine or atropine may mask these hypoxic changes. Thus, using ECG is a dangerous early signifier of hypoxia.

An adequate BP does not mean that cardiac output, blood volume, and peripheral vascular resistance are sufficient to maintain organ perfusion. In fact, an acceptable BP can be maintained for some time with cardiac, cerebral, hepatic, or renal hypoxia.

The precordial or oesophageal stethoscope gives a fine indication of ventilation, but its use will not identify whether hypo- or hyperventilation is present or the wrong gases are being administered. Also, it tethers the physician to the patient and forces him to listen for heart and breath sounds in the noisy operating room or ICU at a time when he must make numerous corrective measures [255]. Newbower et al. believe the oesophageal stethoscope is "far from a foolproof aid in monitoring breath sounds" and "excessive reliance on it may in itself be a pitfall" [167].

One of the most valuable monitoring instruments in routine use today, the oxygen analyser, measures oxygen in the breathing circuit only. No indication that the patient is being oxygenated is given. Therefore, oxygen levels within the patient must be measured [255].

These new monitoring systems can fail. They have problems with calibration, drift, electrocautery, informational overload, and multiple alarm confusion; capnographs have problems with drift, moisture, or proper sensitivity, and may have display and/or recording speeds that make waveforms difficult to interpret. By breathing through the sensor, the clinician may verify the waveform rapidly. Pulse oximeter readings can be influenced by changes in perfusion, the finger's shape, skin thickness and colour, and its position on the finger. Special knowledge is required for etCO_2 monitoring and it can be cumbersome and time-consuming. Special personnel are needed for mass spectrometry which is not continuous when multiplexed. Despite these limitations, these systems are significant early warning systems [255].

Computers have limited ability to process certain information. For example, numerical information can be manipulated in many useful ways and its storage requires less space in memory than alphabetical data.

Patient identification and relevant information are entered usually at the beginning of each case. A solution to this time-consuming problem is to by-pass this step; the user is not required to perform this task [207]. In most hospitals the necessary information is stored on a mainframe computer. The microcomputer communicates directly with the mainframe so that all the user needs to access that information is to type in the patient's unit record number (HUPID); the computer automatically yields the predetermined relevant information.

Initially, the problem with computerised monitoring systems is the time necessary to learn how to use, interpret, and troubleshoot the system. Additionally, inexperienced staff may be unable to sort through the enormous amount of data that are generated and to apply this information to the clinical status of the patient.

The computer is more diligent in accessing and analysing patient data than humans, but staff members are superior in determining the significance of the data and applying this information to the patient's clinical status. Another problem is that monitor residents without an extensive knowledge base may be responsible primarily for monitoring the system causing increased time in anaesthesia staff supervision. Additionally, false data generated routinely by the movement of nursing activities, such as turning, bathing, and suctioning may be accepted incorrectly and used for the basis of clinical decision making. Lastly, a major disadvantage to optimum patient care exists if the clinician treats the monitor and not the patient. For example, if the dysrhythmia monitor alarm

sounds, the anaesthetist should assess the patient for signs of clinical deterioration, not accept the system's interpretation of the alarm [55].

A major stumbling block was finding a suitable location for the PONI in the main ORs. The anaesthesia machine and a large equipment cart are occupying the space near the head of the OR table. In many of the operating rooms the PONI had to be located on the anaesthetist's right or behind the anaesthetist where he could not see it without turning away from the patient [18]. In a few rooms only could the PONI be placed at the anaesthetist's left, in his field of vision. Last minute revision of operating room layouts was not possible in all cases as in many operating rooms electrical outlets were located on the way away from the head of the operating room table.

The main problems with the device alarms were as follows:

- ◇ The alarm limits were preset and could not be altered during the procedure;
- ◇ One or more variables were almost always in an alarm condition because of errors, artifacts, or unconnected transducers; and
- ◇ The various alarms could not be activated or deactivated separately.

ORs with the system are susceptible to hardware failures only. If power is lost temporarily, normal operation resumes shortly after power is restored. Software problems, or "bugs," appeared frequently in the original version of the PONI, less so in later versions. Both hardware or software problems could halt the microprocessor and cause the loss of all communications [18].

A sophisticated automated system should require the user simply to turn on and connect the patient to monitors. Further data entry should be simple, rapid, and not distracting. Any system which is more difficult to the use than this or slower than a manual record is doomed to fail because it will prove to be time-consuming both in user-training and in data entry. It must be less distracting than a manual system as well or it will fail to improve its main aim of patient care, even if the quality of the record is better [207].

6.12 Discussion

Section 6.3.2 described the necessity of having three different models:

- ◇ The model of the normal or ideal patient. This consists of a set of normal bands and acceptable rates of change as responses to inputs or input changes; the limits are defined by the anaesthetist.
- ◇ Models of the possible alarm or fault conditions. These consist of subsets of fault models which are prescribed by the type and phase of the operation and the inputs applied to the patient.
- ◇ The model of the patient under observation. This consists of the measured input and output values and changes; it is expressed in terms of the signal statuses.

The concept of fault models is central to this approach, the models are based on the statuses of the patient's output and input signals and the time elapsed since the occurrence of certain events [10]. From this information tables or decision trees are generated.

In order to better address the requirements, a model with the combination of the above three was formulated. The model's principal characteristics can be discussed in terms of the way an anaesthetist deals with the problem of false positive alarms. The purpose of the model is to permit the exploitation of the particular capabilities of a computer.

In general, an anaesthetist confronted with a potentially ill patient initially does not have sufficient information about the patient to decide on a therapeutic action. The information the anaesthetist does have (the model of the ideal or normal patient; in addition to his/her general medical knowledge and experience), however enables formulation of some tentative hypotheses about the state of health of the patient. This opinion will exert a considerable effect on the strategy the anaesthetist will employ in dealing with the patient. For convenience, it can be said that the options available to the anaesthetist are the physiological raw data (models of the possible alarm or fault conditions). The anaesthetist employs those data that are expected to provide results of significant value in improving the current view of the patient's problem. The selection of an appropriate treatment for a given problem is strongly dependent on the superimposing of the anaesthetist's opinion about the patient's problem on the physiological raw data (the model of the patient under observation).

Although this description of the manner in which an anaesthetist deals with diagnosis-treatment is simplified and somewhat artificial, it does emphasize the fundamental role that formalised decision making plays in the process.

The PONI system is used to combine the statuses and generate alarms and messages notifying the anaesthetist of present or impending danger for the patient. The system suppresses trend messages when these trends are in accordance with given drugs or other interventions. Mathematical methods to execute these algorithms are available

[10]. A useful additional step would be the incorporation of drug interaction messages into the alarm message generator. The proposed sophisticated alarm generator must be considered as a decision support system. One can envisage the incorporation of this message generator into the monitoring equipment, so the anaesthetist will be able to see analysed trends on the available displays and may base patient assessment on all available information both primary and analysed. The main goal of the new system is to avoid false alarms and suppress unnecessary alarms such as those triggered by normal responses [10].

6.13 Summary

The explosion of information gathering technology that surrounds today's OR patient has made it essential that monitoring equipment do more than indicate when a fixed limit has been exceeded. A modern system should be able to combine many monitored variables and present OR personnel with sophisticated messages as an aid in determining condition and deciding proper action [10]. Using available algorithms for signal analysis, it has been found possible to assign different statuses to the patients' signals, statuses that reflect the static, the dynamic, and the statistical properties of the signals. These classifications are designed to mimic, in a simplified manner, the thought processes of the anaesthetist in describing the patient's condition. Thus, the system completes some of the anaesthetist's basic thought work, saving his time for more complicated decision making. Hopefully, understanding of these ideas will facilitate clinical acceptance of the proposed PONI system in a much larger scale.

The current chapter indicated the ways in which interaction between systems science and physiology can be beneficial. The concepts presented were illustrated by references to frequent physiological examples. The various benefits and limitations of models were described in detail, together with a general discussion of the practical

problems which can arise and the means which are available for their solution. The following chapter will now evaluate PONI in a more rigorous format.

7. EVALUATION OF PONI

7.1 Introduction

The previous chapter considered the modelling, as well as a variety of aspects of the PONI system and systems science in an analytical way. The present chapter is concerned with designing issues, acceptability and testing of PONI.

Medicine has provided such a challenging domain for the development of AI-based systems that much of the early expert system research during the 1970s was performed in areas of medicine. Different medical systems were developed and, in the process, a number of AI-based tools were developed [36]. During the 1980s, this technology spread rapidly to fields outside of medicine and generated considerable commercial and industrial activity [25]. At the same time, however, the application of AI in medicine has remained in the research prototype stage.

Ironically, medicine has proved to be a productive domain for developing powerful computer-based tools, but it has been proved easier to apply those tools in more structured, less complex domains than medicine, such as in the diagnosis of faults in a manufactured device.

To assist the physician, a sophisticated computer system is needed, one that should be able to integrate many different types of information. Diagnosing a patient is much more complex than debugging a manufactured device [204].

7.2 Design & Implementation

Performance is a principal concern in evaluating database systems in a hospital environment. Because hospital information systems are often expected to process data on a real-time basis as well as to provide conversational mode operation, quantitative information about workload characteristics and processing activities is needed in order to evaluate system performance.

This chapter attempts to evaluate the performance of the new user-friendly type of physiological data collection monitoring system and to compare it with a number of possible alternatives. Analysis of the performance characteristics of an experimental monitoring system used with encouraging results for a number of months has given the basis for the evaluation. The overall goal was to test whether such monitoring systems are viable operationally in a hospital environment; objectives were to measure the resources required; to study the price paid for the convenience offered to the users, and to test whether monitoring systems could become acceptable as the basis for the implementation of integrated hospital information systems [176].

As with computerised record systems for ambulatory patients, evaluation of cost and benefit of critical care computing is crucial. Unfortunately, no well-formulated technique for studying either manual or computerised medical record systems exists, none with medical decision-making capabilities. Shortliffe [222] mentions seven guide-lines for assessing the effectiveness of such systems. A system must:

- ◇ Demonstrate that it is needed;
- ◇ Demonstrate that it performs at the level of the medical expert;

- ◇ Show that it is usable;
- ◇ Demonstrate its acceptance by physicians;
- ◇ Demonstrate its impact on management of patients;
- ◇ Show its impact on the well-being of patients; and
- ◇ Demonstrate its cost-effectiveness [82].

These seven steps for demonstrating the effectiveness of an expert physiological monitoring system are idealized and difficult to traverse. The author knows of no medical decision-making system that rigourously been shown to meet formal validation criteria at all seven steps of development.

7.3 Acceptability (Usability)

When the 5 new Day Surgery Unit operating rooms were opened in May 1988, the PONI monitoring system was available in one of these rooms. More than 5 anaesthesia personnel, faculty, residents, nurse anaesthetists, and anaesthesia technicians - were trained to guarantee safe patient monitoring from the first day and to ensure user acceptance of the new system.

To facilitate training and acceptance, the system that was introduced was much simpler than its planned ultimate configuration; minimal understanding was needed to set it up as a monitor.

All members of the engineering and maintenance staff participated in teaching the anaesthesia personnel. Small groups and a one-on-one method was tried. One-on-one teaching was the most successful training method; in-service training in small groups was the least successful. Most users received approximately one hour of training.

During the first week, a member of the engineering and maintenance staff was available in the OR. In the first several months of operation, engineering and maintenance personnel were on call 24 hours a day to assist with questions or problems. At this time one technician is available in the operating room suite during the day; early each morning he checks each device to ensure that it is working properly.

Other teaching aids included a detailed instruction manual placed on the system, and a computer-assisted instruction program. Though these users began to learn of the more sophisticated features of the system such as changing sampling times or enlarging windows with important information, and this knowledge was passed on by word of mouth. Some users, particularly residents, showed a healthy curiosity and read every alarm status to see what would happen. When refinements of the system, such as addition of more monitoring devices, were made available, they were demonstrated to selected clinical users and explained in detail by new on-line help.

During the early phase the reactions of the anaesthesia personnel to the monitors was noted, which may or may not reflect the prevailing situation in medical monitoring practice today. Monitoring has been a longstanding tradition at our hospital; the anaesthesia personnel could be expected to interact with monitors more willingly than the average user.

Some users approached the new monitoring system with open minds, but early problems caused them to become frustrated. Some felt they were "laboratory animals"

in someone else's experiment with computerised monitoring. Anaesthesia faculty and other personnel seem to want something different from what they had asked to be designed.

The author believes that the human factor remains the greatest barrier to the introduction of computerised operating room monitors. Certainly, new monitoring equipment should not be introduced simultaneously with other operating room changes. Under the best circumstances, however, many anaesthesia personnel will not learn how to use properly any new system. Some will make mistakes and fail to make necessary adjustments. They cannot be assumed to interact with the system in a useful way. They will monitor only those variables they want to monitor [18].

Before the performance of a monitoring system is evaluated, the objectives of the performance analysis must be specified. An analysis may measure the resource requirements; the way the system behaves; the costs involved; or compare the system with another. The techniques will be determined by the objective of the analysis. In this study, the hospital monitoring system will be examined in terms of machine usage response times and resources required.

The biggest obstacle to performance measurement is the discovery of a model which describes it adequately. Currently, analytical and experimental approaches are used to define such a model [195]. The purely analytical approach breaks the system down into elements so small that (ideally) their exact cost is known. To estimate the total cost of a particular operation, the number of times each element is executed is used. In theory no experiment is needed: the estimated result is correct. The main problem in using this approach has been that with large complex systems, like the monitoring ones, the flow of control may be so complicated that it becomes practically impossible to break it down into its numerous elements.

The experimental approach for the performance analysis of the monitoring system was used. It treats the system essentially as a black box. For example, PONI [84] will be regarded as a single monitoring machine which accepts control sub-language statements and outputs the results. A model is formed in which the possible input variables are combined in an arbitrary way to give an equation for the performance in terms of unknowns [195]. In this case the unknowns are the parameters which govern the combination of the effects of the inputs on the performance. The behaviour of the system is measured over as wide a range as possible of the variables at the external interface. These results are used to solve the equation and give values to the parameters. The whole equation may be used then for prediction.

The experimental approach offers several methods to analyse the performance of the monitoring system, best known among them are resource exercisers, and instruction mix techniques [141]. Neither of these, however, can be regarded as an adequate performance analysis technique for systems with the complexity of a multichannel monitoring system. Instead, the measuring and deducing systems activity approach was used. Three basic techniques available when following this approach are analysis, simulation and measurement. The emphasis here will be put on measurement, which may be done using special hardware facilities and software.

For best results any performance criterion must be measurable using instruments which produce consistent results, and the exact conditions under which the measurements are taken must be known [176]. The hospital monitoring system performance, for example, was measured by the following instruments supported by the operating system and its compilers:

- ◇ The elapsed time clock, which measures time after midnight of a particular date;

- ◇ The CPU utilisation clock, which measures the CPU utilisation of the system; and
- ◇ The block transfer meters, which measure the number of block transfers to and from a file between the time it is opened and the time it is closed.

Each measure of performance also requires specification to the work load that is to be handled. It was practical, however, to select only a few of the many possible jobs as benchmarks, i.e., the most representative of the work expected of the system [176]. Jobs chosen for the evaluation were those that:

- ◇ Run most frequently;
- ◇ Account for most of the system time; and
- ◇ Have response times that are most critical to the proper functioning of the monitoring system.

Manageability is defined as the degree to which the system provides a reasonable interface between the patient, system, and anaesthetist. The patient-system interface must be simple, with the fewest number of sensors and connectors. All of the senses linking the anaesthetist to the patient must be facilitated or undisturbed. The system-anaesthetist interface must be effective as well. The system must be easy to set up, calibrate and use. The monitoring system should foster or automatically produce a concise, accurate anaesthetic record. Physical characteristics, i.e., size, shape, weight, power consumption, portability, and attachment mechanism, must enhance manageability [182].

The PONI system has been used on one operating room to monitor healthy patients undergoing minor surgery in the Day Surgery Unit. Experience with the system lead to improvements and currently the program is in its acquisition mode and friendly with respect to keyboard interaction and data display for medical and nursing staff. The system is used routinely whenever continuous direct monitoring takes place. Congestion problems were solved by placing the microcomputer a short distance from the anaesthetist so that it does not interfere with routine duties.

The PONI's continuous display of physiological data has been found to be very useful in assessing the condition of sick patients. Its ability to manipulate the data and in the early recognition of deterioration or the effect of any therapeutic measures taken.

7.3.1 Didactic and Research Applications

Didactic and research applications of the program were vital since the development and operationalisation of the system PONI came in a teaching structure. Thus, a special running mode was added which allows the simulation, by a batch method of the behaviour of the physiological parameters of a healthy patient undergoing minor surgery.

Implementation of the didactic mode makes it possible for personnel to shorten the time of instruction and to increase students' experience without posing risks to actual patients.

Computer-based simulations of a patient's condition allowed students, physicians, and nurses the opportunity to use computer programs designed for operating rooms and to familiarise themselves with the strengths and weakness of this type of technology.

After simulation diagnostic process is negotiated and sequential problem strategy are discussed, medical students and physicians respond favourably. In many authors opinion, computer based educational material are a useful instructional tool for medical education [145]. They provide physician's self-assessment facilities, also.

7.4 Effectiveness (Testing the System)

Effectiveness is the ability of the system to identify the patient's state quickly and to monitor the processes that link the present state to potential new states. Choosing an effective set of monitoring capabilities is difficult, however, first the possible patient states must be divided into those with good and those with bad outcomes. The processes that link the patient's state to previous and subsequent states must be identified. These processes must be assigned value according to the likelihood of occurrence, interval to detection, and observability. The relative values of various successful and adverse patient outcomes must then be determined. The ability of the selected set of variables to identify the patient states and monitor the interconnecting processes selectively, sensitively, and quickly must be measured. Finally, the monitoring array's ability suggest treatment methods that will improve the patient state must be ascertained [182].

A patient state diagram is shown in Figure 7-1. Appropriate on-going treatment (T_x correct) keeps the patient in the correct state. The patient may enter an incorrect reversible state when anaesthetic, surgical, or patient conditions change. Detection of this state and identification of the process that led to it should suggest a treatment method that will return the patient to the correct state [182]. For example, if a tracheal tube moved inadvertently into the right mainstream bronchus during the administration of a general anaesthetic with 25 percent inspired oxygen, significant hypoxia could develop. Probably, a noninvasive pulse oximeter would identify desaturation of the

arterial blood. An assessment of the causes of the hypoxic state would show apparently normal ventilation (normal CO₂ waveform), reasonable inspired oxygen concentration (25 percent oxygen), and a stable cardiovascular state (e.g., normal ECG, blood pressures). However, a stethoscope reviewing bilateral breath sounds would reveal diminished sound amplitude over the left lung. Thus, the pathway that led to hypoxia would be identified, and therapy, withdrawal of the tracheal tube by a few centimetres, would be indicated [182].

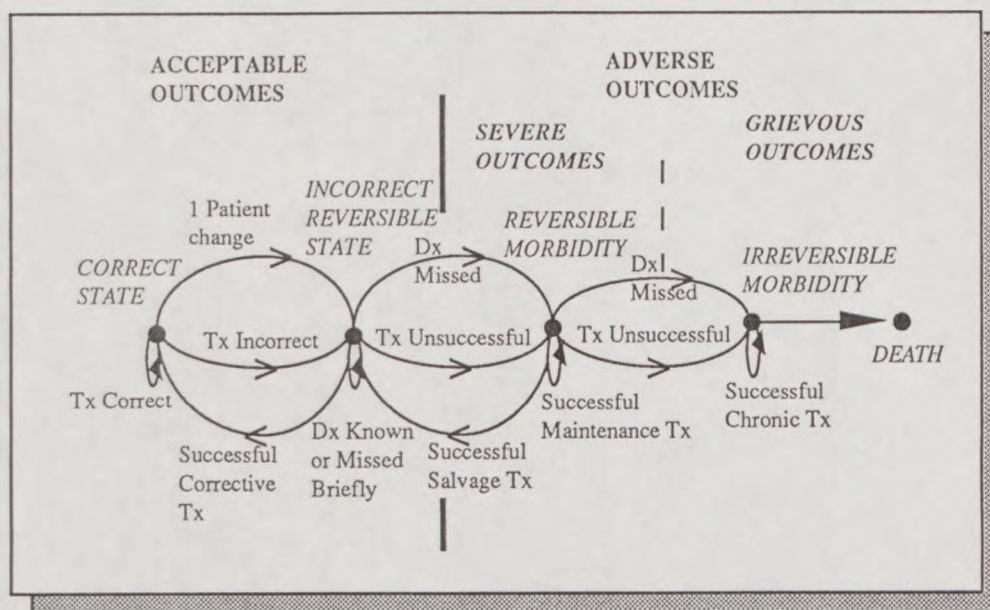


FIGURE 7-1. State Diagram for Outcomes of Anaesthesia.

(Modified from [182])

If the incorrect reversible state is not identified quickly (D_x missed) or the appropriate treatment is not implemented, the patient could proceed to a state of reversible morbidity, e.g., brain or other major organ hypoxia [182]. If the presence of this state remains undetected and appropriate salvage treatment is not administered, irreversible morbidity could result, e.g., permanent brain injury or death. Common to these two states is failure of cellular respiration, usually caused by lack of oxygen delivery [182].

- **Catastrophic**

Loss of life or major organ

- **Profound**

Permanent organ injury, partial functional loss

- **Severe**

Transient injury, increasing level or duration of care

Infection

Transient respiratory failure

Transient renal failure

Repairable injury

Corneal damage

Nerve damage

Broken teeth

- **Undesirable**

Discomfort

Pain

Nausea

Vomiting

TABLE 7-1. Classification of Adverse Outcome States in
Anaesthesia.

When evaluating the effectiveness of a monitoring array, each selected variable must be weighed in importance by the severity and likelihood of the adverse outcomes prevented. Adverse outcome states are classified in Table 7-1. Court settlements may serve as a guide to quantify the severity or cost of adverse outcome [161]. Negligence is defined as "failure to use a reasonable amount of care when such failure results in injury to another." Local or national standards of practice define reasonable care. It requires usually:

- ◇ Anticipation;
- ◇ Timeliness of diagnosis; and
- ◇ Adequacy of treatment

In some cases the courts may apply the most stringent requirement of adequate expenditure to ensure that the appropriate protection is afforded [214]. A Federal Court ruling by Judge Learned Hand [95] and subsequent opinions established an overriding principle for "reasonable care" in monitoring: Reasonable care exists when the precautions taken are commensurate with the product of the probability of loss and the value of the loss [182].

A monitoring system is effective when it is sensitive and specific in detecting a particular state or pathway. Often, indirect measurements are insensitive or nonspecific, yielding high false-positive or false-negative detection rates [91]. Actual measurement of detection sensitivity and specificity are required to evaluate a monitoring modality, not anecdotal study [110]. Sensitivity and specificity are determined by the measurement, processing, and presentation characteristics for each variable and by the interaction among them. Accuracy, reproducibility, range, speed of response, and noise rejection are examples of measurement characteristics. The anaesthetist should be aided in identifying the critical processes involved in moving the patient from a satisfactory to an unsatisfactory state by the system's variable processing and data presentation. Intelligent monitoring algorithms that can detect adverse trends or changes are superior to those that depend on fixed thresholds. Data presentation should be organised, with only the optimal amount of information displayed. Whenever possible, the variables monitored by the system should be combined for

single presentation to the anaesthetist. Audio and visual alarms should be graduated, with warning, caution, and advisory levels [182].

All warning messages for 157 anaesthetic processes were recorded, representing 201 hours of surgery. A total of 25,507 warnings were recorded (Table 7-2) of which 20,471 were classified as cautions and 5,036 were classified as alarms. Of this total, 19,354 were validated and 3,284 invalidated, leaving 2,869 in an indeterminate state (Table 7-2). The anaesthesia machine was the most frequent source of valid cautions (6,079); Second was the pulse oximeter (4,557) and ECG (3,837). The Mass spectrometer and NIBP issued the fewest valid cautions (2,070 and 1,729 respectively). Valid audible alarms were produced also most frequently (565 times) by the anaesthesia machine; Second was the mass spectrometer (242), followed by the pulse oximeter (117), NIBP (83), and ECG (75). Overall, of 5,036 device/conditions in the alarm range approximately half (2,757) were invalidated and one quarter (1,082) validated, leaving one quarter (1,197) in an indeterminate state.

<i>CAUTIONS</i>						
<i>ECG</i>	<i>MS</i>	<i>AM</i>	<i>PO</i>	<i>NIBP</i>	<i>TOTALS</i>	
3989	3626	6387	4740	1729	20471	Total
42	463	0	22	0	527	Invalid
110	1093	308	161	0	1672	Question
3837	2070	6079	4557	1729	18272	Valid
<i>ALARMS</i>						
<i>ECG</i>	<i>MS</i>	<i>AM</i>	<i>PO</i>	<i>NIBP</i>	<i>TOTALS</i>	
2444	1089	1039	176	288	5036	Total
2352	220	63	17	105	2757	Invalid
17	627	411	42	100	1197	Question
75	242	565	117	83	1082	Valid
<i>CAUTIONS/ALARMS</i>						
<i>ECG</i>	<i>MS</i>	<i>AM</i>	<i>PO</i>	<i>NIBP</i>	<i>TOTALS</i>	
6433	4715	7426	4916	2017	25507	Total
2394	683	63	39	105	3284	Invalid
127	1720	719	203	100	2869	Question
3912	2312	6644	4674	1812	19354	Valid

TABLE 7-2. Number of Cautions & Alarms.

Valid warnings were ranked by condition using total enunciations (Table 7-3). Tachycardia was seen most frequently (8,916/3,815), followed by tachypnoea (2,789/1,471), hypoventilation (2,124), hyperventilation (1,740), low FIO₂ (692/564), and continuous positive airway pressure or "inadvertent" CPAP (395). Hypoxia evidenced by valid low arterial oxygen saturation was reported 538 times. Incidence of hypotension exceeded hypertension (379 vs 370), and hypercapnoea exceeded hypocapnoea (458 vs 231). Bradycardia, rebreathing, and barotrauma were reported from 177 to 349 times each.

ECG	MS	AM	PO	NIBP	Valid_TOTAL	
3912	2312	6644	4674	1812	19354	Total
0	0	0	538	0	538	hypoxic
3815	0	0	4067	1034	8916	tachycardic
97	0	0	69	29	195	bradycardic
0	0	0	0	379	379	hypotensive
0	0	0	0	370	370	hypertensive
0	177	0	0	0	177	rebreathing
0	231	0	0	0	231	hypocapnic
0	458	0	0	0	458	hypercapnic
0	1318	1471	0	0	2789	tachypneic
0	128	564	0	0	692	lowFiO2
0	0	2124	0	0	2124	hypoventilation
0	0	1740	0	0	1740	hyperventilation
0	0	395	0	0	395	continPa
0	0	1	0	0	1	negAirwayPressure
0	0	349	0	0	349	barotrauma

TABLE 7-3. Alarm Enunciations.

A single rule; "If the prior value was valid and the value showed a 7% or smaller change, then the new value is also valid" (Table 7-4) validated nearly 50% of warnings (9,413). This is called the "small change rule". Another frequently employed rule (6,354) stated that a specified value from a specified device was inherently accurate and should be validated by default. Readings from the NIBP fall into this category. When using the small change rule an initiator is needed. The possible initiators include 3 values in a row with serial changes of 7% or less (invoked 282 times) and agreement between multiple devices (invoked 1,064 times). If a valid value previously existed and two or more devices returned a new value, none within 7%, then the device showing the smallest change from the old valid value was forced valid (10 occurrences). Validation of inspired CO₂ (FI-CO₂) and arterial O₂ saturation warnings were accomplished by prior validation of the issuing device, but for another value. There were 538 warnings of arterial hypoxaemia and 177 warnings of high inspired CO₂ validated by this rule.

ECG	MS	AM	PO	NIBP	Valid	TOTAL
3912	2312	6644	4674	1812	19354	Total
10	0	0	0	0	10	v_hr11a
0	0	0	74	0	74	v_hr11b
3733	0	0	3717	932	8382	v_hr12
12	0	0	14	0	26	v_hr13
0	0	0	0	131	131	v_hr14
27	0	0	89	0	116	v_hr15
130	0	0	242	0	372	v_hr16
0	0	514	0	0	514	v_fiO2
0	0	50	0	0	50	v_fiO3
0	128	0	0	0	128	v_fiO5
0	177	0	0	0	177	v_fiCO1
0	458	0	0	0	458	v_petCO2
0	231	0	0	0	231	v_petCO4
0	0	3864	0	0	3864	v_ve3
0	0	1297	0	0	1297	v_rr2
0	956	75	0	0	1031	v_rr4
0	25	0	0	0	25	v_rr5
0	337	99	0	0	436	v_rr6
0	0	0	538	0	538	v_o2sat2
0	0	0	0	749	749	v_bpsys2
0	0	396	0	0	396	v_peep1
0	0	349	0	0	349	v_pip1

TABLE 7-4. Enunciations of Validation Rules.

Invalidation of values (Table 7-5) was accomplished when system rules determined a value was physiologically impossible (frequently zero) or determined a value from another source was valid and not in agreement. Physiologically impossible values were invalidated 113 times and values not in agreement with valid ones 1,103 times. Some respiratory values (82) were invalidated because sample contamination with N₂ indicated a integrity of the monitoring system had been breached.

<i>ECG</i>	<i>MS</i>	<i>AM</i>	<i>PO</i>	<i>NIBP</i>	<i>Invalid_TOTAL</i>	
2394	5594	63	39	105	8195	Total
0	0	0	8	0	8	v_hr1
2343	0	0	0	0	2343	v_hr2
45	0	0	0	0	45	v_hr5
2	0	0	0	0	2	v_hr6
4	0	0	0	0	4	v_hr7
0	0	0	31	0	31	v_hr8
0	48	0	0	0	48	v_fi01
0	626	0	0	0	626	v_fi04
0	3924	0	0	0	3924	v_fiN1
0	19	0	0	0	19	v_petCO3
0	0	5	0	0	5	v_ve1
0	0	58	0	0	58	v_ve2
0	10	0	0	0	10	v_rr1
0	967	0	0	0	967	v_rr3
0	0	0	0	105	105	v_bpsys1

TABLE 7-5. Enunciations of Invalidation Rules.

Ranking warnings by condition was complicated because two or more devices might signal the same condition simultaneously. However, the rankings did not change significantly whether accomplished by total enunciations or by enunciations from the device most frequently reporting the condition. Notably, the data proved that warnings occur at a rate of more than one per minute. A system with no validation would yield an audible alarm at a frequency of one every four minutes. The data indicates that validation could eliminate a substantial portion of both cautions and alarms.

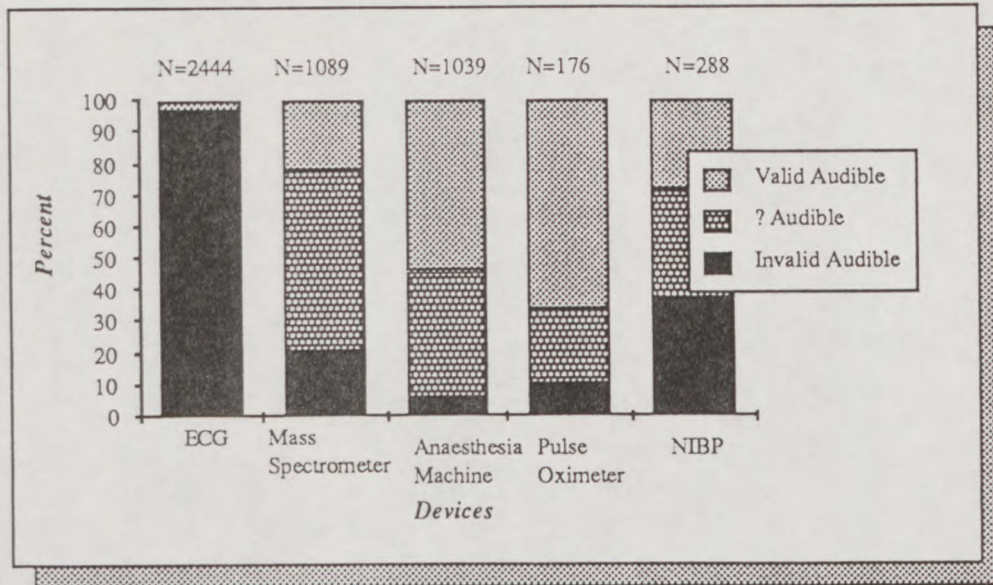


FIGURE 7-2. Distribution of Audible Alarms.

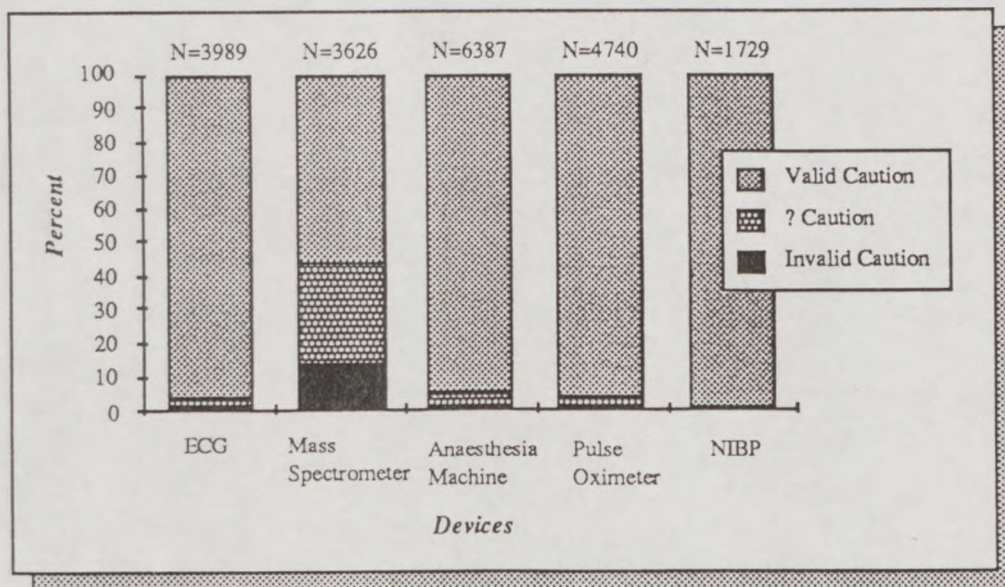


FIGURE 7-3. Distribution of Caution Alarms.

Figures 7-2, 7-3 and 7-4 illustrate the efficacy of the rules at validating cautions and alarms from each of the five monitoring devices used. Nthe rule set validates

the vast majority of cautions from all devices with the exception of the mass spectrometer from which only 52% are validated. However, when alarm data are reviewed, validation is accomplished for only 4% of ECG, 22% of Mass spectrometer, 65% of anaesthesia machine and 81% of pulse oximeter enunciations. Thus as the rule set validates more cautions than alarms; similarly, far more alarms are invalidated. This is not surprising in that artifacts are very likely to generate values far from the normal range and thus in the alarm range. The condition most frequently invalidated was a pulse rate of zero reported by the ECG. Fully half of the ECG warnings were eliminated by this one rule. Pulse oximeter zero saturation values were eliminated by the data collection routine before being subjected to the rule set, and thus were not counted.

Finally, facilitation of appropriate treatment is critical to the effectiveness of a monitoring system. Usually, presentation of the raw data along is sufficient to suggest appropriate treatment. Self-correcting or automatic therapy systems may be on the horizon. Some modern anaesthesia machines monitor the ratio of oxygen to nitrous oxide delivery to the breathing circuit and add needed oxygen as soon as the ratio drops below a preset limit [182].

Before introducing the PONI, it was tested thoroughly with multiple simultaneous demands on the processor, deliberate attempts to overload or confuse it with keyboard commands and continuous simulation of physiological signals. Still, when the system came into use its small successes were overshadowed by numerous, unanticipated problems. Minor hardware or software changes solved many problems but others could not be solved within the confines of the existing PONI system. The results were coloured by these technical problems, but human difficulties made the greatest impact [18]. Many anaesthesia personnel seemed hostile to the new monitoring system and showed little interest in learning how to operate it by reading the instruction manual or

consulting the computer-assisted instruction program. The original user prompts on the video terminal screen had to be replaced with coloured prompts that provided more detailed instruction. Many who did show an interest in the system, were discouraged by the original interface problems. In conclusion, those with a natural curiosity for new technologies were more susceptible to work with the system than those who lacked interest.

7.5 Summary

Enormous problems arise with automation. The prefix "micro" in microcomputer refers to the processing capacity compared with mainframe computers rather than the size of the unit and many microcomputers available are large, a definite drawback in situations where space may be limited. Add the microcomputer with its screen and keyboard to the equipment used to monitor patients and a considerable amount of space is required. To prevent the anaesthetists and surgeons from disliking the system, care must be taken to ensure they have adequate room in which to perform their duties [207]. Because bulk and size pose these problems, newer, smaller microcomputers are being designed and manufactured. Monitors are being reduced in size for similar reasons, but they are still large and may threaten space invasion. A well-designed trolley may be a means of reducing the impact and appearance of bulk.

Related to the problem of size is the problem of portability. It is difficult to transport a patient connected to a monitor by leads or cables when the monitors are connected to a computer by separate cables and all need to be moved together and remain attached. Such a situation may arise, for example, when anaesthesia is induced in the anaesthetic room and the patient then transported to the operating suite. If it is decided that the patient will not be connected to the monitors until arrival in the operating suite after induction, the system will not be utilised to its full extent. Improved patient care will

not be achieved under these conditions because the patients are unlikely to be monitored at the times they are most susceptible, viz. during induction of anaesthesia and during transport [207].

This problem might be solved by telemetry which uses a frequency modulated (FM) transmitter capable of transmitting signals arising from the monitors over short distances to the computer eliminating the need for leads or cables between patients and monitors. State of the art telemetry transmits a signal from each monitor which is filtered by a receiver to produce the appropriate signal at each monitor [207]. When two systems are in close proximity, the potential for interference is present but very small, as each system can be turned in to its own frequency. Telemetry would free the patient physically from tetherings to monitors and simplify the process of connecting the various cables; it would permit monitoring in the anaesthetic room, operating room suite, and recovery room without moving the computer.

Until technology is advanced sufficiently to overcome the above problems, automated monitoring with manual recording of the remaining information on a separate chart. In summary, considerable technological advance will be necessary before methods of data entry are reliable as well as easy and non-distracting [207]. Only at that time it may be feasible to attempt full automation of the anaesthetic record.

This and the previous chapter contain the quantitative material of the thesis which complements the earlier chapters. The whole text up to this point has presented an account of the theory and application of systems and medical science, the main topic of this thesis. The next and final chapter considers PONI at a philosophical level in a search for some additional understanding that will tie together some of the issues that have emerged in this and the previous chapters.

8. CONCLUSIONS

8.1 Summary of the Previous Chapters

In the previous chapters the focus has been in the areas of systems science, monitoring and alarms in the operating room environment. In detail, in the first chapter some history was reviewed, some issues were summarised and the philosophical tone for the chapters that followed was set.

In the second chapter greater detail was presented on the information content appropriate to anaesthesia and physiological data collection. Up to this point, the reader has essentially been presented with some fundamental concepts of monitoring, alarms and systems science (including terms and concepts). Chapter three reflected the problems of false positive alarms and the anaesthetist's problem in general.

Additionally, Chapter three made a thorough appraisal of the ideas and concepts of complications in respiratory and circulatory environments. In Chapter four the collected experience in struggling with the issues of prototype system development for automated data acquisition in monitoring was presented.

Chapter five offered a compact introduction to the knowledge and the data base system. In chapter six the design and implementation of PONI as a prototype system for respiratory and circulatory management was examined. The chapter then drew together systems terms and concepts, frequently found in system science publications. Chapter six constitutes the "heart" of the thesis. The chapter is concerned with arguments and ideas on methodology and methodological assumptions, theoretical background, modelling, as well as data collection and analysis.

Evaluation of the PONI system followed in chapter seven and the conclusions of this thesis in chapter eight.

8.2 Conclusions

The PONI research has demonstrated that if the task, domain and researchers are carefully matched, then the application of existing techniques can result in a system that successfully performs a moderately complicated task of alarm detection. The system described in this thesis has a great deal of flexibility in the role in which it is employed, and in the degree of processing of the raw data which can be carried out. The system may be used as a dedicated single patient monitor. Alternatively, as the technology improves, it is possible to monitor more physiological data than the non-invasive ones (Table 8-1). However, at no point was this system envisaged as a complete computerised patient record store.

•	<i>Respiration</i>
	Oxygen saturation
	Ventilation triad
	CO ₂ waveform
	Ventilatory flow
	Breath sounds
	Inspired oxygen
•	<i>Circulation</i>
	ECG waveform
	Heart sounds
	Peripheral pulse amplitude
	Intermittent arterial blood pressure
	CO ₂ waveform

TABLE 8-1. Optimal monitoring array.

The system was developed for healthy patients (physical status I & II of the American Society of Anesthesiologists patient classification system), but it can be used for other categories of patients with equally successful results.

The microcomputer-based monitoring system, PONI, is in routine use. It has proved to be of value during the monitoring period and subsequently when a review of overall patient management is made. The physiological data samples collected have been useful in research as well [84]. It has improved the accuracy of early alarm detection with the integration of data from diverse sources; it has improved the reliability of clinical decisions by avoiding bias; it has improved cost efficiency by balancing the expenses of time and risks of definitive actions; it has improved the understanding of the structure of medical knowledge; and it has improved the understanding of clinical decision making.

In general, PONI achieves all its stated goals mentioned in Chapter one, most notably, it provides means for objective evaluation. Every case record is methodically built so that problems are identified easily and early in the treatment. They can be referred for expert evaluation within days or weeks, when viable options are available still, rather than in months or years when surgery or unnecessary complications or physiological problems may have occurred. Similarly, patients who may have been misdiagnosed can be identified and examined by experts [261].

Next, the system improves patient care. Because it builds a profile of each patient and compares this with the algorithm, it warns if a procedure is being used inappropriately, i.e., too often, or ineffectively under the circumstances. Also, if it appears that the patient is more seriously ill than his diagnosis would indicate (he fails to respond to treatment or to return to a normal condition in the time period expected), he can be identified for appropriate expert evaluation.

Third, the system achieves the objective of enhancing detection of adverse events; it sets specific goals for the patient's return to normal condition, and continuously monitors progress toward that goal. It intervenes if the patient fails to achieve it.

Finally, successfully negotiating these goals, the system saves money and gains other benefits such as reduction of malpractice claims. As the pilot programs at PEPCO and USPS [261] demonstrated, continuous monitoring of health care to achieve these objectives can result in dramatic savings in benefits, efficiency, morale, and human suffering.

The data-acquisition, computation, and data presentation advantages of the PONI are evident. Overall, 75% of all warnings were validated and 12% invalidated. Such a system has proved so efficacious in handling alarms that it has the potential to reduce audible alarms from one every four to one every 16 minutes. Hopefully, soon the computer will conquer OR medicine so that future patients will be monitored in a continuous, non-invasive, and silent fashion with trend presentation of the data [206].

It has been demonstrated that computer and systems engineering in conjunction with knowledge engineering methods from expert systems can be used to full advantage in producing an effective model, which can then be transferred with ease to a microcomputer.

The minicomputer should be used at all stages of patient care, i.e., to record the history and physical exam through to monitoring and controlling much of OR care to keeping the record and assisting in clinical research and quality control. The challenge is to develop an OR computer technology which capitalises on low cost hardware and software and the networking available with microcomputers. Surprisingly, the

constraints of cost control will prove an asset to this development. Historically, the last of cost control has fostered inefficiency and bad technology allowing medical computer research to rival the military industrial complex in extravagant and useless technology.

In developing systems in OR care, simplicity is better than complexity, available technology better than unique hardware and software which is expensive, and less likely to be well documented debugged, simple to maintain [180].

If the current declining trend in the number of anaesthesia mishaps continues, anaesthetists will end up in a lower medical liability category, as has been demonstrated recently. Mark Wood, Medical Services Manager of Risk Management for the St. Paul Fire and Marine Insurance Company, which provides medical liability insurance to some 15% of the U.S. anaesthetists, recently stated, "Because of this improvement, St. Paul Insurance reduced the rate relativity of anaesthetists from 5.0 to 4.0, effective July 1, 1985. Anaesthetists now pay less for their professional liability coverage than they would with a 5.0 relativity factor" [264][185].

In a similar vein, Controlled Risk Insurance Company, the liability insurance company representing nine Harvard Hospitals and their medical staffs, lowered anaesthetists from class 5 to class 4, with a significant savings (17%) in the cost of premiums. Third, in early 1987 the Massachusetts Joint Underwriting Association, which insures the majority of Massachusetts anaesthetists, offered a 20% reduction in occurrence premiums (15% for claims made) to anaesthetists in Massachusetts who guarantee to use pulse oximeters and end-tidal carbon dioxide tension monitoring when-ever possible [174].

Computers, like cars, are only vehicles for getting us where we want to go to improve patient care. The computer must be used as an effective tool to integrate, evaluate, and simplify the necessary data so it can optimise the human skills in patient care [81].

Limited experience allows someone to draw conclusions, and to present points of discussion. Due to the lack of specific hardware designed for medical use, it is necessary to use and experiment with different types of computers in monitoring. This approach presents the following advantages:

- ◇ The possibility of utilisation of peripheral structures of the system most feasible to solve the particular problem.
- ◇ The need to balance the computer power with the type and magnitude of problem. It is useless and uneconomic to utilise a computer with a large memory for small problems, and vice-versa impossible to solve complex diagnostic-therapeutic problems or attempt to constitute a large data bank in micro or personal computers.
- ◇ The utilisation of different types of computer at the same time greatly enhances the education in this technology of the medical and paramedical staff.

In developing software it must be underlined that one cannot work alone. At each stage in the past and also in those stages to come, the problems will grow in complexity and need the input of many experts in many fields. The knowledge that is formalised in PONI did not come from the textbooks; some is heuristic, developed through experience and passed down by apprenticeship. Thus, the author in collaboration with physicians, systems and computer scientists and logicians of the University of Pennsylvania, City University and HORNET Group formalised the

medical knowledge. This cooperation has given the possibility of always utilising specific and personalised types of software.

Viewing health care as a system, it has been shown how techniques of signal analysis, filtering, and modelling can be applied in clinical medicine. There is a need for an even wider exchange of information among all the ORs dealing with these problems.

Finally, one may say that in this field there is still too much theoretical debate and not enough practical experience. More experience is needed to bring systems science closer to the expected better care delivery [145].

With the advent of the PONI, computers evolve from a tool to manipulate data to one which applies attributes of humans - reasoning, judgement, experience, and intelligence to the data, or at least appears to do so [142].

8.3 Contributions to Systems Science and Medicine

PONI is a comprehensive attempt to integrate physiological systems into models (Chapter 6). Adoption of a systems approach to this problem provided a useful framework for the next step. These models resulted in the prediction of alarms with less uncertainty and are essential where the purpose is the inferential measurement of non-accessible variables and/or parameters. Using the systems analysis approach, detection of inconsistencies in current concepts was made. Furthermore, analysis of processed signals has allowed more quantitative hypotheses concerning physiological mechanisms to achieve considerable precision [48]. PONI proved that in systems science there is an opportunity to examine effectively the structure and behaviour of complex systems.

In the past, expert systems have attempted to simulate an anaesthetist's decision-making behaviour. They accept as input information about the patient, and produce a set of conclusions and recommendations. The clinical effect of such a system is that it is trying to tell an anaesthetist what to do [160]. As discussed in Chapters 6 and 7, PONI differs from this traditional approach in that it accepts as input both information describing a patient and the physiological data from the monitoring equipment. The system then validates the alarms and discriminates between measurement errors and artifacts on one hand and real physiological changes on the other. This way, it structures its advice around the anaesthetist's own thinking and style of practice. Overall, the methodology has made substantial contributions to representation of medical knowledge and its processing.

Because anaesthetic risks are so immediate and so critical, anaesthesia is an excellent initial domain for exploring artificial intelligence [160]. PONI is one of the first systems to implement the three-model validation approach whose domain is anaesthetic management. PONI's concurrent monitoring of physiological variables is used for warning if the patient is endangered. This technique promises to be an important adjunct to clinical care in the future. The system is a powerful tool for medicine that can be used in two modes: 1) monitoring mode, and 2) tutorial mode. In monitoring mode, as described in Chapter 6, an anaesthetist describes an actual patient's underlying physiological status by a process of menu selection. In tutorial mode however, the system can be used as an instruction vehicle for clinical students (i.e., anaesthesia residents).

8.4 The Future

Future developments should reflect a redefinition of goals that accompany the expansion of system boundaries. Advancements should continue in the areas of

physical integration, functional integration, and new sensors/instrument development, but with slightly different objectives. Commonly, future objectives are to improve the quality of information made available to the anaesthetist; improve its presentation, transmission, and reception; and aid the anaesthetist in its interpretation. However, when the computer is able to take advantage of technological advances in physiological measurement, and apply the methodologies of ergonomics and human factors, the monitoring system of the future should aim to be the intelligent assistant that the anaesthetist requires and deserves [252].

Both the cost and size of computer hardware have decreased dramatically in the past several years. This trend is to continue in the future. Thus, the proliferation of personal computers in the OR is inevitable. With the recent introduction of cost-effective local area networks (LANs) for personal computers, new communication links will be established, encouraging a further integration of OR patient record keeping. ORs are using already closed-loop therapeutic devices which sense a physiological variable and control it by altering therapy. These systems work well under a wide range of clinical situations, and provide better patient control while saving nursing time. Several investigators are trying to expand application of closed-loop control to a variety of OR problems [81].

As many physiological data as possible should be acquired automatically, without user interaction. Unfortunately, drug information and commentary are easier to enter manually and today's automatic record will contain little more than physiological data. A successful mechanism for entering drug information and commentary must await further advances in technology.

The future may see some further data processing incorporated into the program. Of particular interest to the PONI work are the results on the monitoring component. On

the horizon appears the possibility of assessing the correlation of two separate parameters obtained from the same patient, for example, comparing any changes in heart rate levels with measured S_aO_2 ; however, a full off-line analysis of existing data must take place before such an improvement is implemented on-line [62].

8.4 Epilogue

Techniques for sensing, acquiring, processing and displaying physiological variables used to assist the process of monitoring in anaesthesia care have been reviewed. The role of instrumental monitoring in clinical practice and the comparative effectiveness of man and machine has been outlined. Future trends of monitoring in clinical practice have been identified. It is important that physicians stay abreast of developments in the technology of measurement and monitoring instrumentation and have a complete understanding of the precision and real usefulness of any given item of equipment in order to purchase wisely and to assist in the development of profession wide standards [107].

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APPENDIX I

(Survey Letter)

HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA

3400 Spruce Street/G1 Philadelphia, PA 19104 (215)662-4000

H O R N E T

To : Medical Staff
Dept: Anesthesia



Re : Anesthesia Equipment Alarms

Date: June 6, 1988

Dear Colleague,

We are all besieged by multiple alarms from anesthesia equipment in use in the O.R. Many of these alarms are "false" in that they arise from artifact rather than real changes in patient status. Others are real but unnecessary in that they arise from out of range values we are aware of, or tolerant of.

As a first step toward improving alarm presentation in anesthesia equipment could you fill out the enclosed chart. Assume the devices are entirely free of artifact and that no history or values for comparison are available.

Red alarms should indicate values with which you almost always would be uncomfortable. Yellow alert values are those which usually would necessitate further study, or intervention.

Results of the survey will be returned to those who indicate interest. Thank you for taking the effort to fill out the form.

HUP

<u>COMPLICATIONS</u>	<u>GREEN</u> (Safe Range)	<u>YELLOW ALERT</u>	<u>RED ALARM</u> (Definite Problem)
Hypoxic (O_2 sat)			
Tachycardic (HR)			
Bradycardic (HR)			
Hypotensive (BP/sys)			
Hypertensive (BP/sys)			
Rebreathing ($F_I CO_2$)			
Hypocapnic ($P_{ET} CO_2$)			
Hypercapnic ($P_{ET} CO_2$)			
Tachypneic (RR)			
Apneic (sec)			
Low $F_I O_2$			
Hypothermic ($^{\circ}C$)			
Hyperthermic ($^{\circ}C$)			
Hypoventilation (V_E)			
Hyperventilation (V_E)			
Contin. P_A (PEEP)			
Barotrauma (PIP)			
Neg. Airway Press. (P_A)			

Comments:

APPENDIX II

(Survey Results)

COMPLICATIONS	GREEN (Safe Range)			YELLOW ALERT	RED ALARM (Definite Problem)		
	MEAN	RANGE	N		MEAN	RANGE	N
Hypoxic (O_2 sat)	> 93.3	(90-96)	(11)	43.5 - 85.6	< 85.6	(70-94)	(11)
Tachycardic (HR)	< 114.5	(100-125)	(10)	114.5-145.5	> 145.5	(120-180)	(9)
Bradycardic (HR)	> 51.8	(40-60)	(11)	51.8-41.9	< 41.9	(35-50)	(10)
Hypotensive (BP/sys)	> 91.0	(80-100)	(10)	91.0 - 78.9	< 78.9	(70-90)	(9)
Hypertensive (BP/sys)	< 161.5	(140-180)	(10)	161.5 - 190	> 190	(160-250)	(9)
Rebreathing ($F_I CO_2$)	< .821	(.05-2)	(7)	.821-2.74	> 2.74	(3-6)	(9)
Hypocapnic ($P_{ET} CO_2$)	> 24.5	(15-35)	(10)	24.5 - 18.1	< 18.1	(5-30)	(9)
Hypertcapnic ($P_{ET} CO_2$)	< 49.5	(40-60)	(11)	49.5 - 59.6	> 59.6	(45-70)	(10)
Tachypneic (RR)	< 30.9	(15-100)	(11)	30.9 - 44.5	> 44.5	(25-120)	(10)
Apnaic (sec)	< 26.6	(5-120)	(10)	26.6 - 48.1	> 48.1	(10-121)	(10)
Low $F_I O_2$	> 25.2	(18-30)	(10)	25.2 - 20.7	< 20.7	(15-25)	(10)
Hypothermic ($^{\circ}C$)	> 34.3	(30-36)	(11)	34.3 - 32.7	< 32.7	(29-34)	(10)
Hyperthermic ($^{\circ}C$)	< 37.8	(37-39)	(10)	37.8 - 38.8	> 38.8	(375-40)	(10)
Hypoventilation (V_E)	> 3.62	(2-6)	(8)	3.62 - 2.06	< 2.06	(1-3)	(8)
Hyperventilation (V_E)	< 9.71	(7-12)	(7)	9.71 - 13.8	> 13.8	(8-20)	(7)
Contin. P_A (PEEP)	< 7.43	(3-14)	(7)	7.43 - 14.4	> 14.4	(5-20)	(9)
Barotrauma (PIP)	< 37.3	(25-40)	(11)	37.3 - 49.5	> 49.5	(30-60)	(10)
Neg. Airway Press. (P_A)	> -4	(-2 to-8)	(6)	-4 to -9	< -9	(-3to-20)	(6)

APPENDIX III

(Anesthesia Form)

APPENDIX IV

(PONI Monitoring Equipment)

- NON-INVASIVE BLOOD PRESSURE MONITOR

[Russ Heeschen

Host Serial Communications for the DINAMAP Monitor

Criticon, Inc. 1985]

The Dinamap Blood Pressure Monitor is equipped with RS-232 compatible serial interface circuitry. It can transmit and receive ASCII characters asynchronously with a host processor or terminal through the Data Interface connector on the back of the unit.

Baud rate: 600 (not changeable)

of bits: 8 data, 1 stop, no parity

An example of the overall status request is the following:

BEA12033900110205099077120082

- PULSE OXIMETER

OPERATOR'S MANUAL NELLCOR N-200 PULSE OXIMETER

Nellcor Inc., Hayward, CA

The NELLCOR-200 provides continuous, non-invasive, automatically calibrated measurements of both oxygen saturation of functional haemoglobin and pulse rate.

The instrument combines the principles of spectrophotometric oximetry and plethysmography. It consists of an electro-optical sensor that is applied to the patient and a microprocessor-based monitor that processes and displays the measurements. The electro-optical sensor contains two low-voltage, low-intensity light emitting diodes (LEDs) as light sources and one photodiode as a light receiver. One LED emits red light (approximately 660 nm) and the other emits infrared light (approximately 920 nm).

When the light from the LEDs is transmitted through the blood and tissue components, a portion of both the red and infrared light is absorbed by the blood and by each tissue component. The photo-diode in the sensor measures the light that passes through without being absorbed, and this measurement is used to determine how much red light and infrared light was absorbed.

With each heart beat, a pulse of oxygenated arterial blood flows to the sensor site. This oxygenated haemoglobin differs from

deoxygenated haemoglobin in the relative amount of red and infrared light that it absorbs. The N-200 measures absorption of both red and infrared light and uses those measurements to determine the percentage of functional haemoglobin that is saturated with oxygen.

Initially, light absorption is determined when the pulsatile blood is not present. This measurement indicates the amount of light absorbed by tissue and nonpulsatile blood, absorption that normally does not change substantially during the pulse. This is analogous to the reference measurement of a spectrophotometer. Absorption is then measured following the next heartbeat, when the pulsatile blood enters the tissue. In that measurement, the light absorption at both wavelengths is changed by the presence of the pulse of arterial blood.

The NELLCOR N-200 then corrects the measurements during the pulsatile flow for the amount of light absorbed during the initial measurements. The ratio of the corrected absorption at each wavelength is then used to determine functional oxygen saturation.

The N-200 baud rate can be set by using the rear-panel BAUD RATE switches. PONI is using the 1200 baud rate. Once every 15 seconds, and when the status or limits change, the following data are transmitted:

R83S100P006L055H140O085A000M011T102333Q100

R:HR, S:O2sat, P:PA, L:Low Rate Alarm Limit, H:High RAL, O:Low
Saturation AL, A:Alarm Status, M:Monitor Status, T:Elapsed Time
hhmmss, Q:High Saturation AL.

- ELECTROCARDIOGRAM (ECG)

[Patient Monitor / RS232C Programming Guide

Hewlett-Packard GmbH, D-7030 Boblingen 8/85]

The EIA (Electronic Industries Association) standard RS232C defines the electrical and mechanical characteristics for an interface between data terminal equipment (DTE) and data communication equipment (DCE).

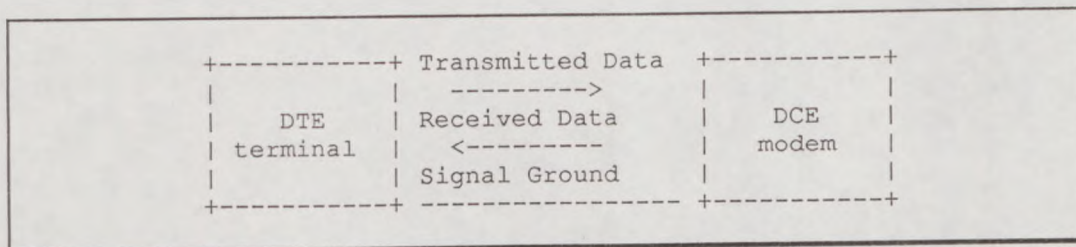


Figure 1

Figure 1 shows the 3 wires necessary for basic data communication. All the names used are from the perspective of the DTE. The DTE transmits on the transmitted data line and the DCE receives on it. Similarly the DTE receives data on the received data line and the DCE transmits on it.

The problem, however, is that often two instruments have to be connected to each other using their "standard" RS232C cable and it is not clearly defined which is a DTE and which is a DCE type of instrument.

If two instruments of the same type are to be connected, a crosswire cable may have to be assembled to get the signals on the correct line.

Besides using the correct wiring, there are several parameters on which the transmitter and receiver must agree:

- ◊ bit rate: defines the length of time each bit will be given on the line. The receiver samples the data in the middle of the bit. The bit rate that we use in our system is 19200.
- ◊ parity bit: (optional), may be used to determine whether the transmission was received in error. The number of "ones" in a data word (including the parity bit) will be defined as being either odd or even, and the parity bit is correspondingly set to '0' or '1'.
- ◊ number of data bits (typically 7 or 8 bits).
- ◊ number of stop bits (usually there is one bit).
- ◊ handsake: either hardware handsake (using the control lines) or software handsake (either DC1/DC3 or ENQ/ACK) is implemented.

Ø character code: both transmitter and receiver must have the same code in order for them to interpret the data. A commonly used code is the ASCII-code.

The UART of the Patient Monitor is set up in the following mode (for both ports):

- * Bit rate 19200
- * Parity None
- * Data format 1 start bit, 8 data bit, 1 stop bit
- * Handshake Hardware handshake (CTS-line)

On request the following data can be accessed for all parameters:

Ø all numerical values

To access this data, you request a certain message type (MSG-type) from the Patient Monitor by sending the corresponding mode command to it. Eight different operating modes can be requested from the Patient Monitor. PONI's mode is #2 for all accessible numerical data with MSG-type character (02H).

A sample of the ECG's data follows (in Hex):

(1BH) (0AH) (02H) (11H) (00H) (09H) (53H) (00H)

• ANAESTHESIA MACHINE

[VITALINK ver. 1.00 Technical Reference Manual
NAD, Inc. 1987]

Communications settings are: 1200 baud rate, 8, 1, no parity.

A device transmits a command to request information from or issue a control function to another device. A command may be embedded within the response to another command, but a new command may not be transmitted until a response from the previous command has been received. If, however, a device sends a command and a full response is not received within 10 seconds, a new command may be transmitted. All commands have the following format:

[ESC] [COMMAND CODE] [CHECKSUM] [CR]

There are three general categories of commands: Update Request commands, Control commands, and Configuration commands.

Update Request Commands are transmitted to request the current values for data (measurements, alarm limits, or alarm status) from a device. A currently defined Data Request command is:

<24H> Request Current Data Measurements

Control commands are transmitted to a device to control a certain function of that device. A currently defined Control command is:

<51H> Initialise Communications

The system's response has the following format (in Hex):

(01H) 02 08 E1 89 EB 99 F0 88 B5

• MASS SPECTROMETER

[Phillip M. Erwin

Perkin-Elmer Advantage Host Computer Interface User Manual

Perkin-Elmer Corp., Pomona CA 03/04/86]

An RS-232/RS-422 asynchronous serial interface is available in the ISU of Advantage. The purpose of this interface is to allow a host computer to receive data from the ISU and sometimes to send data to an ISU. RS-232 or RS-422 communication is jumper selectable.

Baud rates are switch selectable. The 1200 baud rate choices are used on the PONI system. The baud rate selection is made using switches on the serial interface board. The ISU reads the the switches and sets the rate of data transmission and reception.

Data format is switch selectable. The format in the PONI system is always 8 bits, with 1 stop bit.

When the ISU is first powered on or if the ISU resets itself due to an error condition, the HOST I/O software of the ISU will send messages containing the ISU's information to and from the host. An example of the ISU's messages is:

To the HOST

\$IC,1700-2258-4.00,1,52,16,7,CO2,O2,N2,N2O,ENF,ISO,HAL,&

(ISU configuration message)

\$SN,16,1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,&

(Station name message)

\$GI,5,08:18:43,713,0,9911,0,0,0,0,0,&

(Inspiratory gas data)

\$GE,5,08:18:43,14,433,6578,2903,0,0,0,0,&

(Expiratory gas data)

████████████████████
(PDU ident record)

From the HOST

\$IR,IC,SN,&

(ISU initial request message)

\$IR,ET,NOAL,NORD,&

(ISU request message)

**APPENDIX V C-Language Data Collection Routines
(pp.274-281)**

has been removed for copyright reasons

**APPENDIX VI Raw Data from Collection Routines
(pp.283-291)**

has been removed for confidentiality reasons

**APPENDIX VII PROLOG Data Validation Routines
(pp.293-301)**

has been removed for copyright reasons

**APPENDIX VIII PROLOG Data Validation Results
(pp.303-306)**

has been removed for copyright reasons

**APPENDIX IX C-Language Post-Filtering Routines
(pp.308-313)**

has been removed for copyright reasons

APPENDIX X Data Base Table Structure (p.315)
has been removed for copyright reasons

APPENDIX V

(C-Language Data Collection Routines)

APPENDIX VI

(Raw Data from Collection Routines)

APPENDIX VII

(PROLOG Data Validation Routines)

APPENDIX VIII

(PROLOG Data Validation Results)

APPENDIX IX

(C-Language Post-Filtering Routines)

APPENDIX X

(Data Base Table Structure)

GLOSSARY

ADVERSE REACTION: A reaction which is not desired following administration of a drug.

ALGORITHM: A set of directions, rules, and procedures for solving a particular problem or accomplishing a particular process.

APNOEA: The absence of respiration.

ARRHYTHMIA: An irregularity of the heartbeat or the pulse rate.

ARTERIAL BLOOD PRESSURE: The pressure of the blood on the walls of the arteries.

AVERAGE: The arithmetic mean or the sum of all the values in a set divided by the number of values within that set.

CALIBRATION: The process of comparing a measuring device to a known standard to determine its accuracy or to device a new scale.

CAPNOGRAPH: An alternate name for an infrared CO₂ analyser.

CARDIAC CATHETERISATION: A diagnostic technique in which a catheter is passed along veins or arteries into the heart to examine the structure of the heart.

COMA: A condition in which a patient is unaware of his/her surroundings and is unarousable by powerful stimulation.

CONTINUOUS POSITIVE AIRWAY PRESSURE (CPAP): A method of spontaneous or mechanical ventilation in which the pressure of the upper airways is not allowed to decrease to atmospheric pressure (zero).

DEVICE: A manufactured implement, usually mechanical or electric in nature, used for a single purpose or related set of purposes.

DIASTOLIC PRESSURE: The arterial pressure when the ventricles are at rest and filling.

EFFICACY: The relative ability of a drug to cause a specific biological effect.

ENDOTRACHEAL TUBE: The semiflexible plastic catheter used to deliver anaesthetic gases directly into the trachea of a patient.

ENTROPY: A measure of the disorder of a system.

EXPIRATION: The expelling of air from the lungs, usually due to the elastic recoil of the lungs and the thoracic wall.

EXTUBATION: The process of removing an endotracheal tube.

- FILTER*: A device or program which separates particulate matter, data, or signals in accordance with selected criteria.
- FLOWMETER*: A device for measuring the flow rate (usually in millilitres or in litres per minute) of a gas passing through it.
- FOURIER ANALYSIS*: The expression of a complex waveform as the summation of sine wave components.
- HALOGEN*: An atomic group made up of the elements fluorine, chlorine, bromine, iodine, and astatine.
- HAEMOGLOBIN (Hb)*: The O₂-carrying pigment of the erythrocytes which is formed in the bone marrow.
- HYPERCAPNIA (HYPERCARBIA)*: An excessive amount of CO₂ in the blood.
- HYPOCAPNIA (HYPOCARBIA)*: A deficiency of CO₂ in the blood.
- HYPOTENSION*: An arterial blood pressure which is lower than normal for the age and level of physical activity of the patient.
- HYPOTHERMIA*: A subnormal body temperature.
- HYPOVENTILATION*: A reduced ventilation which is insufficient in rate and/or total volume to maintain alveolar O₂ tension and eliminate CO₂ (PaO₂ falls and PaCO₂ rises).
- HYPOXIA*: The relative lack of O₂ transported to or used by the tissues.
- INDUCTION*: The period in anaesthetic administration which includes the time that the first drug is administered until the desired depth of the anaesthetic state is reached.
- INFRARED ANALYSER*: A device for measuring the content of a particular gas in a gaseous mixture.
- INTUBATION*: The process of passing a tube through the nose or the mouth so its tip rests below the vocal cords and above the division of the trachea into right and left mainstem bronchi.
- MANOMETER*: An instrument for measuring the pressure of liquids and gases.
- NONINVASIVE MONITOR*: An instrument used to observe physiological functions that does not invade or puncture tissues.
- POSITIVE END EXPIRATORY PRESSURE (PEEP)*: A modality for the treatment of patients who require ventilatory support.
- RESPIRATORY RATE*: The number of complete respirations (inspirations and expirations) per minute.
- SEDATION*: A drowsy state of consciousness which allows an individual to respond to commands appropriately.

SYSTOLIC PRESSURE: The peak pressure reached in the large arteries due to the contraction of the ventricle.

TACHYCARDIA: An abnormally fast heart rate.

TACHYPNOEA: An abnormally fast breathing rate.

VARIABLE: A value which is subject to change.

WAVEFORM: The shape of a curve generated by plotting the instantaneous values of a variable against time.

NOTE: The definitions of this glossary were modified from:

S.L. Klein *A Glossary of Anesthesia and Related Terminology*. Medical Examination Publishing Co.:New York 1984

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