Intelligent alarms in anesthesia : a real time expert system application

INTELLIGENT ALARMS IN ANESTHESIA

a real time expert system application

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PROEFSCHRIFT

ter verkrijging van de graad van doctor aan de Technische Universiteit Eindhoven, op gezag van de Rector Magnificus, prof. ir. M. Tels, voor een commissie aangewezen door het College van Dekanen in het openbaar te verdedigen op vrijdag 11 mei 1990 te 16.00 uur

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Prof. dr. ir. Jan E. W. Beneken
en
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(University of Florida)

The work reported in this dissertation on the "Intelligent Alarms Project" is the result of a collaboration between the Department of Anesthesiology at the University of Florida (Chairman: Prof. Jerome H. Modell M.D.) in Gainesville, Florida and the Division of Medical Electrical Engineering (Chairman: Prof. dr. Jan E. W. Beneken) from the Eindhoven University of Technology in Eindhoven, the Netherlands.
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"And at night you will look up at the stars. Where I live everything is so small that I cannot show you where my star is to be found. It is better like that. My star will be just one of the stars for you. And so you will love to watch all the stars in the heavens...."

Antoine de Saint Exupery
The Little Prince

In memory of Ans

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CONTENTS

1. INTRODUCTION

1.1. Background

Well over 20 million anesthetic procedures are performed in the United States (US) each year (Newbower 1981, Gravenstein 1989: Personal communication), by physicians and nurses with specialized training in anesthesiology. At Shands Teaching Hospital at the University of Florida in Gainesville, Florida, the Department of Anesthesiology performed 13,743 anesthetic procedures in 1987, 13,666 procedures in 1988. The number of procedures performed in a recently opened outpatient surgical center, which is associated with Shands Hospital is not incorporated in these figures. For the two years combined, about 74% of these procedures were general anesthesia, while 26% were regional anesthetic procedures (figure 1.1).

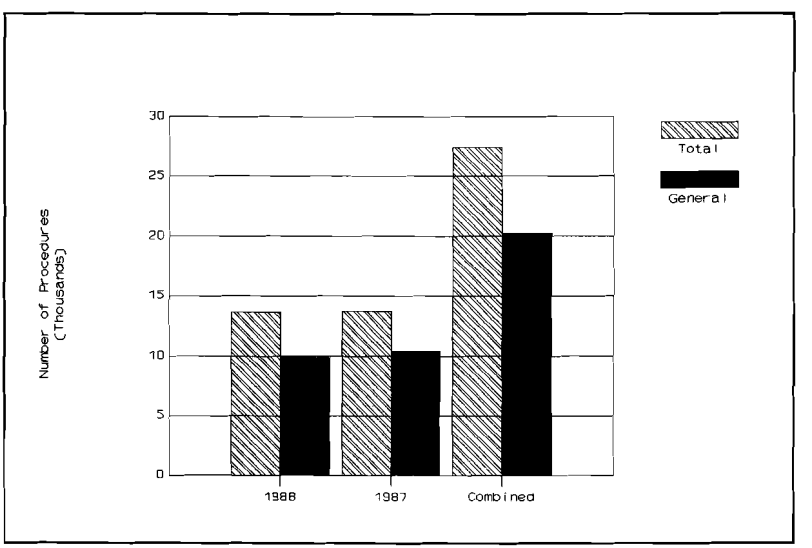

Figure 1.1 The number of procedures under general anesthesia compared to the total number of procedures.

In the US, general anesthesia is induced predominantly with the help of intravenous techniques followed by nitrous oxide (N_2O) and volatile halogenated agents, often in combination with intra-venously (IV) administered drugs including muscle relaxants, opiods, and opiates. Apart from causing anesthesia, these drugs depress vital organ functions and, thus, pose a potential risk to the patient. It is estimated that between 2,000 and 10,000 anesthesia-related deaths occur in the US each year (Epstein 1978, Cooper 1984). These "patients do not die from too much analgesia or amnesia; they die from too much anesthetic in the heart, not enough perfusion to the brain, or not enough oxygen in the blood" (Gravenstein 1987 p:1). The anesthesia pioneers recognized that the effects of anesthetics on the respiratory and circulatory systems could have disastrous consequences (Simpson 1848, Sykes 1960). The anesthetics are one source of potential hazards. The anesthesia machine and system can introduce other hazards, specially when some hazards are the result of flaws in the equipment design or of misuse due to inadequate knowledge of the functioning of the equipment (Eger 1964, Good 1988). Cooper et al. more recently studied anesthesia mishaps systematically and introduced the term "critical incident" to anesthesia (Cooper 1978). They defined a critical incident as a mishap that could have led (if not discovered in time) or did lead to an undesirable outcome, ranging from increased length of hospital stay to temporary, then permanent disability, to death. Analysis of critical incidents reveals that the majority of them were preventable and were caused by human error (Cooper 1978, 1980, Newbower 1981, Cooper 1984, Davies 1984).

It is the aim of patient monitoring, by continuous surveillance, to detect early or dangerous deterioration, with reliability and accuracy (Stewart 1970). Intuitively, monitoring patients under anesthesia during surgery and painful diagnostic procedures with or without the help of mechanical, electrical, or pneumatical devices will, indeed, improve patient safety through prevention, provided the devices function properly. A more accurate description of the goals of monitoring is offered by Gravenstein: Monitoring of patient and equipment function has 2 goals: the titration of drugs, fluids,

and ventilator to a desired end point, and to detect all changes that require correction if the patient is to be spared ill effects (Gravenstein 1979, 1986, 1987, 1989b, 1990). In response to the need for improved monitoring techniques called for by surgery of increased complexity and sophistication, new advanced diagnostic procedures that require anesthesia, and advances in monitoring technology, devices that allow the clinician to monitor patients extensively have become available in recent years. Despite all the advances however, monitoring is not yet able to provide data to address certain clinical concerns. For example, with the current technology one is still unable to measure, among other things, depth of anesthesia, the effect of anesthesia on the brain, the level of analgesia or amnesia, and oxygen supply to vital organs. Apart from inherent limitations, monitoring techniques themselves may impose a danger to the patient or will, as some argue, give the clinician a false sense of security (Hamilton 1988, Moyers 1988, Stoelting 1988, Orkin 1989). Also, the cost of some monitoring modalities can be a concern (Hamilton 1986, 1988, Plantes 1988). However, studies suggest that a combination of monitoring devices can, indeed, prevent anesthetic mishap and patient injury (Cooper 1984, Duberman 1984, Cheney 1988, Pierce 1988). The US judicial system corroborates this assessment as evidenced through a number of well published, and extremely expensive lawsuits. The implementation of standards in monitoring to enhance safety, both nationally and internationally, are materializing (ASA 1986, Eichhorn 1986, Block 1988a, Gravenstein 1989: Personal communication).

Even though the majority of mishaps have been well described in case reports and in the anesthesia literature, mishaps continue to occur. We suspect that the dismal man/machine interface of monitoring instrumentation and the lack of built-in intelligence to help the clinician may contribute to this. But there are other forces at work. Monitoring requires a sustained high attention level (vigilance) from the observer: the clinician. A breakdown of vigilance is implicated in a number of anesthetic mishaps (Cooper 1978, Craig 1981). Monitoring devices should provide for an adequate backup

system in case the clinician is too busy performing other tasks or when vigilance is less than perfect. There is also another aspect to consider. From the ever increasing number of monitors used during clinical practice a new pitfall has emerged, information overload. Simply put, information overload exists when the clinician cannot keep up with all the data bombarding him from the monitors. Here we turn to alarms for help.

In anesthesia, as in other fields, an alarm is a warning of an approaching or existing danger. The concept of alarms is simple, attractive, and sound. Merely set a limit around a variable, and when these alarm limits are exceeded, an auditory and/or visual alarm sounds. However, the clinical reality is that current alarms often annoy rather than help the clinician as is evident from the frequency with which alarms are disabled and ignored by clinicians. For an alarm to be effective, a basic requirement that the monitoring device provides correct and accurate data must first be satisfied. Too often, alarms sound when there is no danger to the patient because of artifact or inappropriate alarm limits. Other difficulties include the non-specificity of the alarm and, with the proliferation of monitors in the operating room, the large number of possible alarms. In an average modern operating room, as many as 30 different alarms may go off when (in many instances inappropriate) alarm limits are exceeded. With the increase in the use of alarms, the excessive number of alarm messages can deteriorate the quality of patient care because they take the clinician's attention away from the patient (Sykes 1989). A number of criteria for helpful alarms have been suggested. Alarms should be specific, sensitive, integrated, prioritized, inconspicuous, supportive, helpful, and complement the clinician (Beneken 1987, 1989, Philip 1987, 1989, Schreiber 1989, Sykes 1989). The need for "smarter" alarms led to the inception of the "Intelligent Alarms" research project.

1.2. Project Objective

In the Intelligent Alarms project, the Department of Anesthesiology at the University of Florida in Gainesville Florida and the group of Medical Electrical Engineering at Eindhoven University of Technology in the Netherlands collaborate toward the development of a system that reduces the number of superfluous alarms and generates messages aimed to help the clinician detect changes in the state of the patient and to aid in the differential diagnosis. The project's central idea is, that an analysis of the clinical decision making process and the differential diagnosis during a number of major complications guides the development of more intelligent ("smarter") alarms and thus, helps prevent potential hazardous complications from developing.

1.3. Chapter Outline

We will briefly introduce the non-clinician to anesthesiology (chapter 2). We will define anesthesiology and discuss actions taken by the anesthesiologist and the specific equipment (s)he uses to induce, maintain, and reverse anesthesia.

Because monitoring is an essential element of the administration of anesthesia, chapter 3 explains the why, what, and how of monitoring and how monitoring can help assess the patient's condition in terms of oxygenation, ventilation, circulation. We will demonstrate that monitoring and alarms are essentially interrelated.

Chapter 4 discusses the current alarms technology, identifies essential shortcomings, and suggests potential improvements. It will be argued that with existing monitoring technology, smarter alarms are possible.

Chapter 5 builds upon the framework set in preceding chapters and proposes an implementation. The selection of area on which to concentrate the prototype implementation, and the decision to use of an expert system for the implementation are discussed in detail.

A brief general introduction to expert systems is presented in chapter 6, followed by a detailed description of the expert system tool SIMPLEXYS. SIMPLEXYS was developed to enable the implementation after the search for a suitable available real time expert system failed.

The next three chapters cover the implementation of three smart alarm prototypes. Chapter 7 describes a prototype that concentrates on the integrity of the circle anesthesia breathing circuit during mechanical ventilation. Based on features derived from the capnogram, airway pressure, and expiratory flow waveforms, a number of malfunctions commonly, yet infrequently, observed are identified automatically. This first prototype was evaluated in the laboratory, on the Gainesville Anesthesia Simulator, and in the operating room.

Based on the evaluation of the first prototype, several improvements were recommended and implemented in the second prototype described in chapter 8. Changes in settings of the mechanical ventilator and the fresh gas flow were able to deceive the first prototype. When setting changes are taken into account, an automated adaptation to new ventilatory settings made by the anesthesiologist can be performed.

The integrity of the breathing system is but one important, element in the differential diagnosis. Chapter 9 describes the implementation and evaluation of a third prototype more advanced than the two previous described prototypes because it considers the underlying clinical concerns that challenge the clinician such as hypoxia, hypoventilation, and perfusion-to-ventilation mismatches.

Finally, a discussion and recommendations for future implementations are detailed in chapter 10. While the current prototype implementations concentrate on ventilation, other areas of clinical concern such as hypovolemia, inadequate levels of anesthesia, and hypertension have not been addressed. With the methodology and implementation described in the following chapters, this extension should be possible.

2. ANESTHESIA ISSUES

Anesthesiology is the medical specialty concerned with the study and applications of anesthetics (agents that cause unconsciousness or insensitivity to pain (Morris 1981 p:50)). A more comprehensive definition was rendered by the American Society of Anesthesiologists (ASA) House of Delegates, who defined anesthesiology as the discipline within the practice of medicine specializing in: 1) the medical management of patients who are rendered unconscious and/or insensible to pain and emotional stress during surgical, obstetric and certain other medical procedures, 2) the protection of life functions and vital organs, 3) the management of problems in pain relief, 4) the management of cardiopulmonary resuscitation, 5) the management of problems in pulmonary care, and 6) the management of critically ill patients in special care units. In this chapter, issues relating to equipment used in general anesthesia will be discussed. Patients under general anesthesia are dependent on the anesthesiologist for life support, and for maintaining vital body functions in the light of possible adverse side effects caused by drugs, clinical events, or preexisting disease. Furthermore, the surgical procedures become increasingly complex. This calls for a parallel increase in monitoring. Because of the importance of monitoring, it will be discussed separately in chapter 3.

2.1. General Anesthesia

General anesthesia is pharmacologically induced and affects the entire body. It is administered to induce analgesia (insensitivity to pain), amnesia (loss of memory), and loss of response to noxious stimulation. The most common way to producing a state of anesthesia is through a combination of drugs given intravenously and/or by inhalation. Another form of anesthesia is regional anesthesia, which include spinal, epidural, nerve and field blocks. Regional anesthesia does not produce loss of consciousness or amnesia.

The administration of general anesthesia involves a typical sequence of events combined with the use of certain equipment and anesthetics. This will be illustrated by following a hypothetical patient scheduled for a routine operation and anesthetic.
The anesthesiologist visits the patient prior to surgery, the so called preoperative visit, and evaluates the patient's history and current condition, inquires about current use of drugs, and evaluates his specific medical problem. During the visit, the anesthesiologist also decides on the particular anesthetic procedure or technique and discusses the upcoming anesthetic and any concerns. If a patient is apprehensive, a medication may be prescribed to be given on the evening prior to the operation.

When the patient arrives in the operating room, the anesthesiologist applies a number of optical, mechanical, and electrical monitoring devices that provide information on the function of vital organs. This assures that the patient's safety is not jeopardized during the operation (Gravenstein 1987). Besides other preparatory activities, a small catheter is inserted into one of the patient's veins through which fluids and drugs can be administered.

2.2. Anesthesia Equipment and Stages during Anesthesia

The anesthesiologist uses a combination of inhalation agents and drugs to induce, maintain, and reverse anesthesia. Specific equipment prepares the gas mixtures, delivers these mixtures to the patient, and allows respiration to be assisted or controlled when the patient can no longer breathe spontaneously.

2.2.1. The Endotracheal Tube

Most of the drugs used to maintain the anesthetic state have a depressant effect on respiration. In addition to inhalation anesthetics, long-acting muscle relaxants are used, which cause partial to complete muscle relaxation or paralysis. Since these drugs make it difficult or even impossible for the patient to maintain an open upper airway and breathe spontaneously, the anesthesiologist will place a tube in the trachea and apply

mechanical ventilation. The process of placing a tube into the mouth, between the vocal cords, and into the trachea is called tracheal intubation. Tracheal intubation is accomplished during *induction*, the first phase of anesthesia.

Induction of anesthesia is achieved using rapid acting and short lasting intravenous drugs, or through inhalation of a mixture of oxygen and an anesthetic with the help of a face mask. When the patient is unconscious and his muscles are relaxed with the help of a brief acting muscle relaxant, the anesthesiologist uses a laryngoscope to view the larynx and the surrounding tissues; he then places an endotracheal tube through the glottis into the trachea. An inflatable, elastic, plastic cuff is located at the distal end of the endotracheal (or ET) tube. Once the tube is in place, the cuff is inflated, creating a seal between the trachea and ET tube. This seal prevents stomach contents from reaching the lungs and enables gases to be moved into and out of the lung without a leak. Through this tube, the anesthesiologist is able to insufflate the patient's lungs and control the patient's breathing.

Various types of endotracheal tubes are available in a variety of sizes. An example of a correctly placed endotracheal tube following oral intubation is shown in figure 2.1.

2.2.2. The Anesthesia Machine

The anesthesia machine is one of the most important pieces of equipment used by the anesthesiologist. The machine permits the preparation of gas mixtures of variable composition during the course of anesthesia. The gas mixture consists of oxygen, nitrous oxide and anesthetic gases or vapors. Oxygen and nitrous oxide are generally provided in each operating room from a central supply with a wall pressure of 50 to 55 psig. Auxiliary cylinders of these gases are mounted on the anesthesia machine in case the central supply systems fail. The gas from these cylinders is regulated down inside the anesthesia machine to a level of 40 to 50 psig. From this high pressure system the gases

enter flow control valves and flow meters. With the flow control valves the gas flow can be regulated.

Halogenated inhalation anesthetic agents are available in liquid form in containers called vaporizers. In the vaporizer, a fraction of the gas about to be delivered to the patient comes in contact with the liquid anesthetic, and upon exit becomes saturated with vapor. The flow fraction of the gas that comes in contact with the anesthetic can be regulated. This regulates the concentration of anesthetic in the gas mixture.

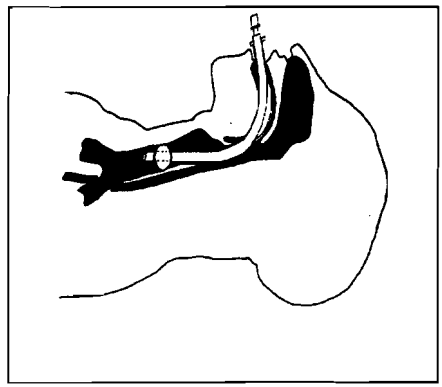

Figure 2.1 Correctly placed Endotracheal Tube

The anesthesia machine also helps the anesthesiologist control the amount of gas that leaves the machine per minute, and, therefore, control the amount of gas administered to the patient per minute.

The continuous flow that exits the anesthesia machine needs to be modulated in order to create an inspiration and subsequently to allow for an expiration. This is realized by employing positive pressure during inspiration, either with a mechanical ventilator, or by the clinician squeezing a breathing bag. The anesthesia ventilator is discussed below, but first the connection between anesthesia machine and patient will be discussed.

2.2.3. The Anesthesia Breathing System

With the endotracheal tube properly in place and the gas mixtures correctly prepared in the anesthesia machine, the anesthesiologist can control the administration of the gas mixture to the patient using an anesthesia breathing system. This breathing system connects the anesthesia machine to the endotracheal tube of our patient. The gas

mixture is driven to the lungs using positive pressure as the driving force, similar to mouth-to-mouth ventilation. After the forced inspiration, the lungs are allowed to empty passively and the cycle is repeated. Thus, the breathing system also helps to modulate the constant flow produced by the anesthesia machine into an inspiration followed by expiration.

A number of breathing systems are commonly used, each with their own characteristics and applications. The two most common types are the circle system (Dorsch 1975) and the Bain system (Bain 1972). The circle system is the breathing system most commonly used in the United States. This system, the focal point of our research, will be covered in detail in paragraph 2.3.

2.2.4. The Anesthesia Ventilator

With all pieces now properly in place and the necessary connections made, the anesthesiologist can begin to ventilate our hypothetical patient. The positive pressure that forces inspiration and is responsible for the transport of the gas mixture to the lungs can be obtained by several means. The anesthesiologist can generate positive pressure by manually squeezing a breathing bag (reservoir bag) or by mechanical means. The manual technique initiates an inspiration when the bag is squeezed. Expiration is passive during which period the breathing bag fills up with gas. Although a constant involvement of the anesthesiologist is required, many clinicians employ this method of ventilation during induction of anesthesia and during emergence when the patient is awakened and is encouraged to breathe spontaneously again.

An electrical and/or mechanically controlled device called a ventilator can replace the clinician's bag squeezing, freeing him to perform other tasks.

A number of mechanical ventilators with various drive mechanisms for generating the necessary positive pressure are available. The ventilators are classified according to the waveform they generate of either flow or pressure waveforms entering the lungs during inspiration. These include constant flow or constant pressure, decreasing flow or

decreasing pressure, and non-constant flow or non-constant pressure. (Dupuis 1986) Most anesthesia ventilators include a bellows, i.e., "bag in a box" design, which functionally replaces the breathing bag in the manually operated system. During inspiration, the space between bag and box is pressurized forcing a volume reduction of the bag. This volume reduction is approximately equal to the inspired volume of the patient. During expiration the positive pressure is removed, thus allowing the patient to exhale.

The ventilator has controls that allow the anesthesiologist to adjust a number of parameters. The most important parameters are: tidal volume (the volume of gas allowed to enter the lung per breath), respiratory rate (the number of breaths per minute), and inspiratory-to-expiratory ratio, known as I:E ratio, indicating the fraction of time spent during inspiration compared to expiration during each breath.

Now with our patient safely connected to a ventilator, well under general anesthesia, the surgeon may perform the scheduled operation, and the second phase of anesthesia begins: *maintenance*. During this period the patient is kept under anesthesia at a level with the least risk to the patient, while allowing for the surgical procedure to take place. Throughout the operation the anesthesiologist's constant vigilance is required to maintain the level of anesthesia, to counteract the potential threatening effects of the surgical procedure, while assuring the integrity of vital organs and the overall safety of the patient.

When the surgeon is finishing the surgery, the anesthesiologist initiates a reversal of the induced anesthetic state with drugs counteracting the effects of previously administered drugs. This is the third and last phase of anesthesia: *emergence*. The patient will be encouraged to breathe on his own. Upon awakening, the endotracheal tube is removed (extubation). The patient will subsequently be transported to the Post Anesthesia Care Unit (also called recovery room) where the patient is monitored and evaluated to assure that no complications are emerging while the patient awakens fully.

Chapter 2 Anesthesia Issues

2.3. The Circle Breathing Circuit

The breathing circuit most widely used in the United States for the ventilation of patients undergoing anesthesia is the circle system (Dorsch 1975).

The anesthesia circle breathing system gets its name from the circular configuration of its components. As can be seen in figure 2.2, the circle breathing system is composed of many parts:

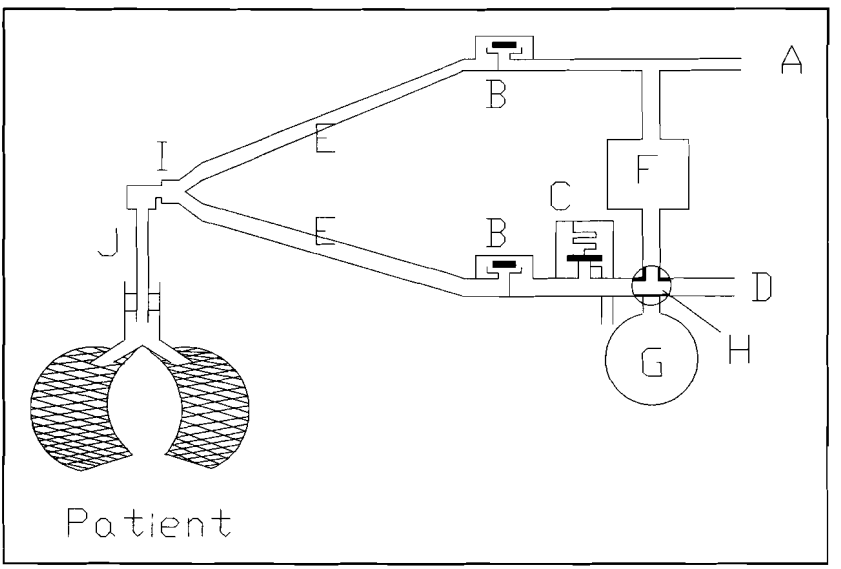

Figure 2.2 Anesthesia Circle Breathing Circuit

1. Fresh gas inlet (A): the point at which fresh gas from the anesthesia machine enters the breathing system.

2. Two unidirectional valves (B): One of these valves is inserted into the inspiratory limb of the system, the other one into the expiratory limb. This forces the gas to flow into well defined directions. These valves may consist of a rubber, metal or plastic disk that sits in the valve seat. In the forward direction the disk is lifted out of the seat allowing flow; reverse flow is blocked by the disk (figure 2.3).

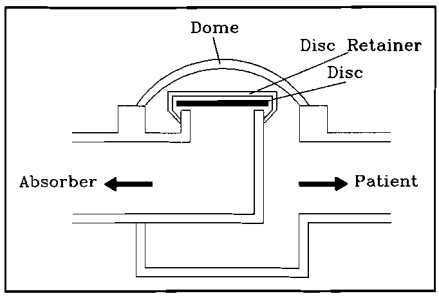

Figure 2.3 Inspiratory Valve.

3. Adjustable Pressure Limiting Valve (APL or "pop-off" valve)(C): A valve that limits the maximum pressure in the system to the selected setting and vents excess gas from the system. A mechanical switch (H) removes this valve from the breathing circuit during mechanical ventilation.

4. Ventilator connecting tube (D): connects the ventilator to the breathing system.

5. Two corrugated tubes (E): These tubes make up the inspiratory and expiratory limbs of the system. They keep resistance to a minimum and should be highly unyielding to kinking.

6. Carbon dioxide (CO_2) absorber (F): The canister contains an absorbent that scrubs any CO_2 from the gas passing through, thus allowing rebreathing of expired gases without the risk of CO_2 build-up. Two absorbents are

commercially available: soda lime, which contains a mixture of hydroxides of sodium and calcium, and Baralyme, which is a mixture of hydroxides of barium and calcium.

7. Breathing bag (G): This bag, also referred to as reservoir bag, allows the anesthesiologist to assist or control breathing, if necessary, by manually squeezing the bag, thereby forcing gas into the patient's lungs. During spontaneous and manual ventilation a mechanical switch (H) removes the ventilator from the circuit.

8. Connectors/adapters: The circle system is connected by means of a Y-piece (I) to the mask or endotracheal tube (J).

The flow of gas during controlled ventilation is best explained starting with an inspiration initiated by a mechanical ventilator. The ventilator forces a volume of gas out of the ventilator bellows, through the ventilator hose and the canister with CO_2 absorber, through the inspiratory limb, toward the patient. From the inspiratory hose, gases pass through the Y-piece to the endotracheal tube and into the lungs. Much like a balloon, the lungs fill with gas and expand. At the end of inspiration, when the desired volume has been delivered, the positive pressure in the ventilator is removed allowing exhalation to supervene. During expiration, the expanded lungs exhale passively, forcing gas to flow through the expiratory limb, via the unidirectional expiratory valve and toward the ventilator hose. Here the expiratory flow is joined by the continuously flowing fresh gas. Together they make their way through the ventilator hose back into the bellows. Once the bellows is filled completely, a pressure relief (exhaust) valve located in the ventilator allows excess gas to escape.

To prevent pollution of the operating room, these excess gases are drawn into a scavenging system and removed from the operating room. In general, the scavenging

system is connected to the hospital's vacuum system through a manifold and relief valves. A needle valve controls the flow rate of the removed gases.

3. MONITORING DURING ANESTHESIA

Potent and potentially toxic drugs are necessary to induce anesthesia in patients undergoing surgical, or painful diagnostic procedures. It takes a skillful anesthesiologist to administer these drugs in such amounts to produce the desired effects while avoiding potential hazards to the patient. Monitoring the patient facilitates the early recognition of untoward trends and events. The anesthesiologist's primary resources to monitor a patient are his sense of sight, hearing, smell, and touch (Dripps 1977 p:87). Relying solely on these resources the clinician can gain ample insight in the state of the anesthetized patient (Vandam 1985, Gravenstein 1986, Hug 1986 p:411-413). Yet, side effects and accidents do occur (Cooper 1978, 1984, Craig 1981, Green 1984, Holland 1984). Apart from the "why monitor" issue, immediately many other important considerations should be raised including: what, where, how, and how often to monitor. When is there too much or not enough monitoring, when does the risk of monitoring outweigh its potential benefit, and when is the cost of monitoring no longer justified?

In this chapter a number of these issues will be addressed. We start with the effects of anesthesia on the patient.

3.1. Why Monitor

It has been well recognized over the years that "Anesthetics are poisons, useful, controllable, but dangerous" (Gravenstein 1979). The first successful public demonstration of surgical anesthesia using inhaled diethyl ether vapor was performed in Boston by William T. Morton in 1846, followed one year later by the introduction of chloroform anesthesia by James Simpson. It was quickly recognized that anesthetics not only produce anesthesia, but also have side effects on the patient. Ether first stimulates and then depresses both respiration and circulation and, since it is explosive, can produce definite calamities, while chloroform depresses both respiration and circulation and damages the liver.

As early as 1848, Simpson himself described what appeared to be the first anesthetic death attributed to chloroform (Simpson 1848). That monitoring was an essential element of safety during the administration of anesthetic agents was recognized almost from the beginning. James Syme stated that chloroform was safer than ether only when properly administered and respiration was monitored (Sykes 1960). Syme's emphasis on monitoring was well put, but some dangerous side effects of chloroform on the liver cannot be monitored with current techniques, and the drug was taken out of use.

Since the first demonstration of surgical anesthesia, an evolution propelled by the introduction of a variety of drugs has taken place from the pure ether anesthetic to the combination of inhalation- and IV drug anesthetics of today. The combination has become possible with the introduction of neuromuscular blocking agents (e.g. *d*-tubocurarine in 1946 and succinylcholine in 1951), volatile inhalation agents (e.g. halothane in 1956, enflurane in 1972 and isoflurane in 1981), sedative-hypnotic drugs (including barbiturates like thiopental, and benzodiazepines like diazepam and midazolam, and other categories as for example represented by propofol), narcotics (e.g. morphine, meperidine, and fentanyl), and a new category represented by ketamine. These drugs are potent, potentially toxic, and not free from side effects and complications. In addition, the effects brought on by these drugs vary among patients. Areas affected include the cardiovascular system (i.e. depressed myocardial contractility, decreased or increased blood pressures, decreased cardiac output), respiratory system (hypoventilation secondary to central or neuromuscular depression), and parenchymatous system (liver and kidney damage) (Julien 1984, Dripps 1977).

The potential toxicity and side effects produced by drugs used during anesthesia are not the only sources for untoward effects on the patient's condition. Preexisting diseases, for example, diabetes and hypertension, or extensive blood loss from trauma already may have jeopardized the physical condition of the patient and his ability to tolerate anesthesia and surgery. Clinical interventions by the surgeon and

anesthesiologist while intended to be therapeutic, sometimes can endanger the patient. For example, artificial ventilation, blood loss, and fluid therapy are potentially hazardous. Add to this the many possible positions the patient can be put in during surgical procedures with the associated effects on circulation, tissue perfusion and alveolar ventilation, and one can appreciate the difficulties that challenge the anesthesiologist.

Monitoring (from the Latin: *monere*, to watch) has therefore three equally important aspects: 1) to aid in clinical management: for drug titration or ventilator setting changes; 2) the identification of (primarily untoward) trends; and 3) to improve (or maintain) patient safety: the early recognition and the estimation of the importance of a potential problem. Monitoring requires that measurements are being made either relying solely on the human senses, or augmented with optical, mechanical, pneumatic, or electrical instruments. In terms of control theory, the anesthesiologist monitoring the patient, is the feedback element in the control loop that constitutes anesthetic management. (Ream 1979, Cooper 1979, Beneken 1983, Meijler 1987).

3.2. What to Monitor

Although it was recognized from the early days of the practice of anesthesia that monitoring was an inherent element of anesthesia, what to monitor has been (and still is) a controversial issue. Not every individual patient requires the same amount of monitoring. There are 25 year old healthy athletes scheduled for the most benign surgery under general anesthesia. These low-risk patients would require only a minimal amount of monitoring. But what is minimal monitoring? What should always be monitored and what is required in the non 25-year-old. Who determines what should be monitored in each individual patient and how? These issues can be studied from the viewpoint of what is *needed* and what is *possible*. But there are also other forces at work, including how widespread a monitoring device is used and accepted by anesthesiologists, the cost of the monitoring modality, and also pressures from the judicial system mandating monitoring standards.

In the *needed* category, the clinician is concerned about the level of anesthesia, ventilation, (removal of carbon dioxide (CO_2) and supply of oxygen (O_2)), the central nervous system (brain, nerves, and cognitive functions), the transport system within the body, (i.e. heart, circulation, and perfusion of other vital organs), body temperature, and muscle relaxation function during anesthesia and surgery. The anesthesiologist's sense of sight, hearing, smell, and touch are the primary resources to monitor the patient. Instruments can not replace these clinical skills. From this, Pask concluded that the best patient monitoring device was "a tube of contact adhesive: Place a small dab of it over the patient's temporal artery, another small dab on one of the anesthetist's fingers and bring these two into contact so that they could not be readily separated...." (Pask 1965).

The use of optical, electrical, mechanical and pneumatical devices, however, can substantially augment and extend the clinicians ability to monitor the patient more efficiently. The use of increasingly more monitoring instruments, with increasing sophistication and their impact on patient care was questioned recently (Hamilton 1986, Orkin 1989).

Additional monitoring modalities have become *possible* through technological advances. New successful monitoring techniques are usually introduced in an effort to solve immediate problems cost effectively. The development of monitoring equipment has paralleled the advances of the electronics industry, although a lag was noticeable (Schneider 1979).

The first monitoring standard was introduced because of a bet. At stake was a dinner for giving the best anesthetic (Beecher 1940). To document this, both heart rate and respiratory rate were recorded. In the early 1900's, it became practical to measure blood pressure using the Riva-Rocci method combined with the changes in sound distal to a slowly deflating cuff described by Korotkoff (Geddes 1966). Subsequently the electrocardiogram (ECG), built upon Einthoven's original work but introduced as a practical instrument in anesthesia in 1952 (Himmelstein 1952), gained wide applicability and acceptance. Both ECG and arterial blood pressure have become standards and are

commonly used in evaluating the state of the cardiovascular system. Developments in monitoring the central nervous system, respiratory system, neuromuscular blockade, and temperature have brought an onslaught of monitoring techniques and instruments. Initially, anesthesiologists adopted monitoring techniques because they presumed that the patient would benefit. Indeed, several studies suggest, although after the fact, that monitoring does increase patient safety (Cooper 1978, Amaranath 1979, Taylor 1980, Cheney 1988, Eichhorn 1989). The American Society of Anesthesiologists (ASA) in 1986 defined and adopted minimal monitoring standards applicable to all anesthesia care (Am Soc of Anes 1986). At the Harvard Medical School standards for patient monitoring during anesthesia have been adopted since 1985 (Eichhorn 1986). Whitcher et al. point out that in addition to the moral imperative to monitor the patient, there is an economical incentive to adhere to monitoring standards (Whitcher 1988). Recently minimal standards also gained acceptance in Australia and New Zealand (Cass 1988). In the following discussion we will adhere to the ASA standard. The ASA standard states "The patient's oxygenation, ventilation, circulation, and temperature shall be continuous evaluated" and goes on to define the means.

Ensuring adequate levels of oxygen (O_2) concentrations in the inspired gas requires the use of an O_2 analyzer with a low O_2 concentration limit alarm. The use of a pulse oximeter is currently recommended to assess blood oxygenation, but will be a requirement in 1990.

The ASA requires the adequacy of ventilation to be evaluated with qualitative clinical signs. In addition, quantitative monitoring of carbon dioxide (CO_2) content and/or volume of expired gas is recommended. When an endotracheal tube is inserted, its correct positioning must be verified. Again, apart from clinical signs, the measurement of end-tidal CO_2 is recommended. If a mechanical ventilator is used during controlled ventilation, a device capable of detecting disconnects in the breathing circuit is mandated.

Adequacy of circulation shall be judged with the help of a continuously displayed ECG, and of arterial blood pressure and heart rate each measured at least every five minutes. In addition, continuous evaluation of at least one of the following is required in patients under general anesthesia: palpation of the pulse, auscultation of heart sounds, monitoring of a tracing of intra-arterial pressure, ultrasound peripheral pulse monitoring, or pulse plethysmography or oximetry.

Finally, to aid in the maintenance of appropriate body temperature, the ASA standard requires that the means to measure continuously the patient's temperature be readily available.

It is evident that in encouraging these standards the emphasis is on patient safety, and the implementation of these standards can be considered as guidelines for minimal monitoring in the "25-year-old" low risk patient. Beyond the low risk group there are many other monitoring modalities available, e.g., central venous and pulmonary artery pressure monitoring, cardiac output monitoring, and the electroencephalogram (EEG). These are indicated predominantly in patients considered at risk of suffering harm during anesthesia because of the nature of the operation, or because of the patient's disease.

3.3. How often to Monitor

Monitoring is an ongoing activity during anesthesia practice. Drugs are administered and anesthetic gases and vapors are delivered based on the current level of anesthesia compared to the desired, or projected level. The anesthesiologist must be familiar with the effects of anesthetics and their time of onset and action in order to *control* the level of anesthesia. In addition, knowledge of the pharmacokinetics of administered drugs and insight in the uptake, distribution and excretion properties of anesthetic agents is required. Monitoring for titrating the level of anesthesia does not require frequent observations.

Drugs cause changes in monitored variables, as do clinical actions. Identification of slow unidirectional changes in variables (trends) induced by drugs or clinical actions

require periods of intense monitoring, followed by stretches of potentially lower intensity.

For patient safety the identification of a trend or a change in a variable without the trigger of a clinical action can be significant. The rate of change in signals and variables can be different from trends secondary to clinical actions. Monitoring for trends and significant events require frequent observations. If trends are identified, or a potential untoward state is evident, monitoring becomes an unremitting endeavor with even more frequent observations.

Causes for potential damage include insufficient oxygen to vital organs, stress caused by the trauma of surgery and anesthesia, or excessive depth of anesthesia. It takes only minutes before irreversible brain damage or even death can result due to deficiencies in, or a total lack of, ventilation or circulation.

The American Society of Anesthesiologists has recommended in the adopted monitoring standards, that blood pressure and heart rate are to be measured at most five minutes apart (see paragraph 3.2 and Am Soc of Anes 1986). This has been the traditional practice on the anesthesia record. Gravenstein et al. concluded that the five minute interval is not frequent enough, and that the clinician might miss important events (Gravenstein 1989).

3.4. How to Monitor

With the essential monitoring elements defined, the next issue is how to monitor. The ASA standards hint toward the use of a number of specific monitoring instruments, but leave enough leeway to accommodate many monitoring techniques.

Monitoring can be performed with or without the help of instruments, noninvasively or invasively. Because of potential complications, which include bleeding, infections, discomfort to the patient, and (even for a skillful clinician) the time consuming placement of sensors, noninvasive monitoring is preferred. In the low risk patient noninvasive monitoring is the technique of choice (Gravenstein 1987 p:3).

Much information about the condition of the patient can be gathered through inspection, palpation, percussion and auscultation. Furthermore, all this information is available noninvasively. Inspection of skin color or the color of the blood in the surgical field can provide clues on the patients circulation, ventilation, and temperature. Other prime areas suitable to be inspected include the patients eyes (tears are indicative of light anesthesia), skin (hematomas), chest (chest motion with ventilation) and the volume of blood loss. Palpation of an artery indicates rate and rhythm of a pulse, or allows the evaluation of the patient's temperature. Percussion can be used to judge a suspected pneumothorax, while auscultation can be employed to monitor heart sounds (rate, rhythm and murmurs) and breath sounds (ventilation of both the lungs). Except auscultation, where a stethoscope is frequently utilized, none of the previous techniques rely on the use of instruments; many regard them as the foundation of monitoring. These fundamental techniques are an integral part of the standards recommended by the ASA (paragraph 3.2).

Instruments augment rather than replace clinical observations. The next sections cover instruments utilized in the evaluation of the patient's oxygenation, ventilation, circulation, and temperature as indicated by the ASA standards for basic intra-operative monitoring, plus monitoring of the neuromuscular junction, included by many in the minimal monitoring set (Ali 1986, Block 1986). Monitoring instruments, particularly electrical and electronic instruments are referred to as: monitors. The same is done in the following part of the text.

3.4.1. Monitoring Oxygenation

Whether the patient receives enough O_2 can be monitored by measuring inspired O_2 concentrations and the delivery of these O_2-rich volumes to the patient. During anesthesia inspired O_2 concentrations are usually kept above 25%. Many of the oxygen monitors currently commercially available employ measuring principles that have a slow response time (1-2 minutes) to concentration changes and, in addition, are sensitive to

water vapor. Despite the slow response time, these instruments can still be used to measure inspired concentrations to assure that enough O_2 is present in the gas mixture. When placed in the inspiratory limb of the breathing circuit (chapter 2), humidity is less of a problem.

To assure adequate oxygenation of vital organs, the clinician measures the O_2 levels in the blood. A number of techniques for measurement are available. Oximetry exploits the differences in absorption characteristics of hemoglobin and oxyhemoglobin. Clinically available oximeters have a sensor (with light-emitting diodes and photodiodes) that easily fits on the ear, finger tip, or other perfused part that allows transillumination. Pulse-oximeters have become very popular in the last five years. These instruments employ oximetry in combination with the pulsatile (arterial) signal in the finger to analyze (primarily arterial) hemoglobin. With this technique, O_2 saturation of the arterial blood, in addition to pulse rate and rhythm are available (Kelleher 1989).

3.4.2. Monitoring Ventilation

How well the patient's lungs are ventilated can be monitored with the help of capnography. A typical capnogram, displaying the excursions of the CO_2 partial pressure in the inspired and expired gas mixture shows zero inspired partial pressures that are followed by a quick rise toward a nearly constant plateau throughout expiration (figure 3.1). Deviations from the typical capnogram indicate possible problems origination in the patient (e.g. developing shunt, light anesthesia, malignant hyperthermia), breathing system (e.g. leaks, unidirectional valve insufficiencies), ventilator (e.g. disconnects), or anesthesia machine (e.g. leaks). The information

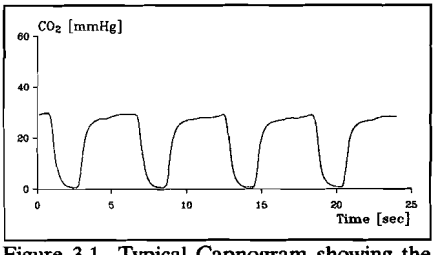

Figure 3.1 Typical Capnogram showing the inspired and expired fluctuations in CO_2 partial pressures during the respiratory cycle.

content of the capnogram is therefore high (Gravenstein 1989a). Capnographs measure CO_2 concentration by analyzing a gas sample obtained from a location close to the patients mouth. Two types of analyzers are available: mainstream and sidestream. The mainstream analyzer relies on a sensor that can be mounted in the breathing circuit, while sidestream models aspirate a gas sample from the patient's breathing circuit.

Inspired and/or expired volumes can be monitored by observing the rise and fall of the ventilator bellows (although the rhythmic movements of a hanging bellow can be deceiving), and by mounting spirometers in the breathing circuit. Spirometers or flow probes are used to quantify the gas flow.

3.4.3. Monitoring Circulation

The adequacy of the amount of blood perfusing vital organs cannot be monitored with current technology. To make up for this deficiency, the electrical activity of the heart, the ECG and arterial blood pressure are often monitored continuously. Blood pressures are monitored at most five minutes apart if not continuously.

Noninvasive measurement of arterial blood pressures employ predominantly occlusive techniques, commonly in the upper arm using an inflatable pressure cuff. At first the inflated cuff occludes the artery. Then during slow deflation, the point at which blood flow is reestablished can be detected. This is referred to as systolic pressure. Further deflating the cuff allows mean arterial pressure and diastolic pressure to be identified until unrestricted blood flow is possible again. Noninvasive techniques use either auscultation, photo-electric, oscillometric or ultra sound based automatic devices. A new method (the Peňaz method) employs a cuff around the finger (Peňaz 1976, Boehmer 1987), which allows the continuous measurement of arterial pressures.

Invasive methods depend on the insertion of a catheter into an artery. Through this canula, arterial pressure changes are transmitted continuously to a pressure transducer, which converts the pressure signal into an electrical signal. When to use

invasive instead of noninvasive techniques in the light of possible complications and indications is well described (Hug 1986 p:433-457, van der Aa 1983, Gravenstein 1989b).

The ECG traces the rhythmic electrical activity of the heart. From the ECG, information on rate, rhythm, electrolyte changes in the body, and O_2 supply to the heart (ischemia) can be obtained. Commonly, skin electrodes placed in a number of possible configurations can be used for diagnostic purposes (Kaplan 1986).

3.4.4. Monitoring Temperature

The body's ability to regulate its temperature is altered by most anesthetics making the measurement of body temperature necessary. Temperature monitoring is based on either mechanical, electrical or chemical principles. The common liquid filled thermometers are considered impractical for use during anesthesia. Most temperature sensors in current use are based on thermocouples or thermistors. Usually a temperature probe is inserted into the esophagus, the nasolarynx or rectum, or attached to the skin.

3.4.5. Monitoring the Neuromuscular Junction

With the use of neuromuscular blocking agents, the degree of muscle relaxation is assessed by monitoring the transmission of an impulse from a motor nerve to voluntary muscle. In commercially available units, an electrical pulse through skin electrodes close to the nerve stimulates the nerve. Typically, a single stimulus, a train of four, or a multi-second high frequency (tetanic) stimulus is applied; then the muscle's response (either twitch or action potential) to the stimulus is subsequently gauged. Using this technique, the degree of muscle relaxation can be adjusted as needed.

3.4.6. Vigilance

A vigilant anesthesiologist is considered the best monitoring device. "Anesthesia vigilance" can be defined as a state of clinical awareness whereby dangerous conditions are anticipated or recognized and promptly corrected (Gravenstein 1986a, Stoelting 1988).

With the help of monitoring instruments, the clinician's senses are augmented. However, with the additional information, the clinician is taxed increasingly to remain on top of the abundance of presented data. Factors that decrease a clinician's vigilance (i.e. fatigue, distractions, or even boredom) have resulted in the implementation of alarm limits in the monitoring instruments. A better approach to the concept of alarm limits is needed, however. Chapters 4 and 5 will elaborate on this aspect.

3.4.7. Preoperative Information

The clinicians preoperative visit to the patient serves a number of functions. One important reason is the gathering of pertinent information on the patient's medical history, drug allergy, and current physical condition. Also, baselines for intraoperative anesthetic management, against which intraoperatively measured variables are compared, are established during the visit. Failure to evaluate the patient's condition preoperatively has been shown to increase to risk of adverse complications (Amaranath 1979). As a result of the preoperative visit, the clinician may elect to use more advanced or invasive monitoring techniques instead of or in addition to the essential monitoring modalities outlined in the previous paragraphs.

3.5. Signal Processing and Data Presentation

With the many measuring techniques introduced during the last twenty years, more and more signals are obtained from the patient. In turn, each signal can produce a number of derived variables (e.g. maximum, minimum, mean, rate of change) thus increasing the amount of information that is presented to the clinician. In the essential monitoring set, already ECG, blood pressure, capnography, temperature and pulse oximetry signals are competing with the patient for the attention of the clinician. Each signal produces a number of variables and in the case of the essential monitoring set already up to 10 additional variables are calculated. Because each signal contains not only information, but also may be fraught with artifact and/or transducer inaccuracies, the

signal curve is displayed for evaluation by the clinician. This increase in the number of variables relevant for patient assessment is the first potential problem and is referred to as the "information explosion" (Blom 1982, Beneken 1983). Merely providing the clinician with more information will make it even more difficult to keep up with details.

Another problem closely related to the first is how to display all the data. Commercial monitors in the majority of cases are dedicated to measuring only one signal. Most of the time though, the real time display of the curve has to share available space on the display unit with the derived or calculated variables. Each manufacturer is compelled to implement a display layout capable of presenting the available information as clearly as possible. However, the different manufacturers don't agree on the optimal layout. Furthermore, simply placing monitors side by side does not provide an easy overview of the relevant data.

The third problem, which is related to the second is that each signal is measured and its results displayed by a separate unit. The space allotted to the anesthesiologist and his basic instrumentarium: the anesthesia machine, breathing circuit, and intravenous access routes, is already most of the time minimal for his extensive task. Additional individual monitoring devices are, therefore, placed in such fashion to least infringe on the available space: away from the patient.

Finally, one last problem with the current monitoring instrumentarium is the danger that the anesthesiologist's attention might be drawn away from the patient and toward the extensive monitoring facilities in order to evaluate the performance of the equipment and the quality of the signals, to consider all information in their temporal context, and, since many interrelations are present, to integrate all measurement results in his mind.

It has been widely recognized that the uncontrolled proliferation of monitoring devices has created problems in need of solutions. The increase in monitored variables must be combined with multi-variable signal processing techniques (Beneken 1983).

Over the last two decades, a number of solutions have been proposed,

implemented, and evaluated, and have proven themselves invaluable along the path toward a generic solution (Block 1985, Meijler 1987). Also, manufacturers have realized the shortcomings of the current generation of intraoperative monitors and recent announcements of new products are intended to address some of the problems. This thesis describes additional steps contributing toward the ultimate goal of the development of a truly integrated approach to monitoring.

Chapter 3 Monitoring during Anesthesia

4. ALARMS

An alarm is a warning of an approaching or existing danger. In anesthesia, an alarm's main intent is to draw attention to a problem that can be solved before the patient is harmed. The anesthesiologist caring for a patient and observing the monitoring instruments can become alarmed by what he hears, feels, or observes. Many physiologic monitors generate an alarm when a monitored variable traverses outside fixed, but adjustable limits. The electrical or mechanical devices serving the alarm function by generating a sound or signal, can help by offering a backup system to the already overloaded, but vigilant clinician. Unfortunately, in present form, many alarms are not perceived as helpful (Kestin 1988, Beneken 1989). This is clearly demonstrated by the frequency with which alarms are silenced and ignored by annoyed clinicians.

This chapter examines why current alarm technology falls short in providing an adequate backup system and why and how additional measures should be taken.

4.1. Current Alarm Technology

The alarm technology of the current generation of physiologic monitoring equipment has several inherent problems. The idea to generate an alarm when an individual variable exceeds static, but adjustable, thresholds is attractive in principle: one simply sets applicable thresholds for that variable, and the monitor will alert when these barriers are surpassed. However, with more variables being monitored and more variables being able to trigger an alarm, it has become impractical to set all these individual thresholds at the beginning, or during an anesthetic procedure. Many clinicians rely on the manufacturer default settings, although these levels may not be appropriate.

The second problem is that current alarms are not specific. For example, there is no unique, industry-wide blood pressure, heart rate, or oxygen saturation alarm. If only a single alarm could be triggered, there would be no question about which variable is out of bounds. With the increase in monitoring modalities though, the number of possible

alarms increases proportionally. This makes it much more difficult to identify which variable(s) triggered an alarm.

The third problem merely emphasizes the non-specificity. Each manufacturer of monitors has selected a tone, beep or buzz to get the clinician's attention. This means, that one not only has to search for the sources setting off the alarms, but when multiple alarms are generated the resulting mixture of sounds is very confusing.

Problem number four is the inability of the single variable alarm to point to possible causes. For example, in those instances where a flat electrocardiogram (ECG) causes an alarm, cardiac arrest, but also loose ECG electrodes, must be considered. This is the prelude to problem number five.

Since single variable alarms are triggered by values exceeding thresholds, any unwanted disturbance (artifact) in a signal can produce increases or decreases in the value of a variable without an underlaying physiological cause. Artifacts can trigger an alarm indiscriminately. The artifact category includes motion artifact (caused by patient movement or repositioning), sensor fault (loose electrode or faulty pressure sensor during noninvasive blood pressure measurement), calibration error (blood pressure transducer not zeroed properly), and electrical noise (electrocautery, light source interfering with sensor operation). Quality control of the physiologic signal, therefore, is crucial. The clinician currently bears this burden by having to observe the real time waveform of the signal.

Problem number six is the result of the "all or nothing" nature of almost all current single variable alarms. Either an alarm is triggered, unconditionally and in full force when a variable digresses outside the set thresholds or it is silent. When silent, no early warning on developing problems are offered by the majority of the current technology. (One example of an exception is the "bar display" described by Meijler based upon the principle of the "artificial horizon." It provides a global impression of the behavior of up to ten variables over a period of up to three hours (Meijler 1987 p:42)).

More important, no indication regarding the urgency of the alarms is provided. To judge the severity of the situation and to take appropriate action is left to the clinician.

This leads us to the final problem: how to set thresholds. If thresholds are set too wide, an early warning of a developing, possibly deteriorating, trend will not be possible. When an alarm finally is triggered, it could be indicative of an already serious problem. On the other hand, when thresholds are set closely around a variable, frequent unnecessary triggering of an alarm may result.

Combined, all these problems are responsible for the large number of false and worthless alarms encountered in anesthesia. This was illustrated by Meijler, who analyzed a total of 731 warnings generated by a statistical disturbance detection algorithm during six cardiac operations (Meijler 1987 p:67-75). She concluded that, at most, 7% of the detected disturbances generated useful warnings. Kestin et al. concluded that with 75% of auditory alarms classified as spurious, an unacceptable high incidence of these alarms occurred during anesthesia (Kestin 1988). False alarms cause the alarms on the monitors to be silenced semi-permanently (McIntyre 1985), and adrenalin levels in anesthesiologists to be elevated (Schmidt 1986).

4.2. Possible Improvements

There are a number of ways to improve current alarm technology. One idea is to reduce false alarms by intelligent signal processing. Automated trend detection, the use of redundancy, or other methods that exploit a combination of several variables are examples of possible approaches.

4.2.1. Dealing with Artifact

As mentioned in paragraph 4.1, one major problem is artifact. During the transition from physical variable into electrical signal, the transducer system can introduce substantial errors. With analog signal processing, but even more so with digital processing techniques and help from computers, more sophisticated signal processing has become possible. The development of sophisticated signal processing techniques that automatically detect artifact in signals is one approach to reduce false alarms caused by artifact.

4.2.2. Trend Detection

Slow unidirectional changes in signals (trends) can prompt the clinician to alter management of the patient. Trends are caused either by spontaneous changes in the patient, by the administration of drugs by the anesthesiologist, or by surgical intervention, such as blood loss. Early detection of trends is important because trends give information regarding the direction and rate of change in a variable. Unwanted trends should trigger an alarm. On the other hand, when drugs induce anticipated and expected changes, no alarm should be triggered. This leaves the dilemma of what to do if an anticipated trend does not appear. Although clinicians recognize a trend when they see one, automated trend detection and analysis are not without problems. This is because trends are obscured by noise or natural fluctuation in the variable.

4.2.3. Multi-Variable Tactics

While the methods for automated artifact and trend detection concentrate on one signal at a time, methods that use a combination of variables also show potential. Since clinical decisions are rarely based on a single variable, these newer methods are a logical step up. One essential element in the multi-variable techniques is the use of redundancy among signals. For example, during anesthesia a patient's heart rate is obtained from a number of independent monitors: the electrocardiograph, pulse oximeter and

(automated) noninvasive blood pressure monitor. Thus, three independent sources observe and measure the same variable. In instances, when one source of heart rate triggers an alarm, a quick cross check with the other two sources could confirm or reject a positive alarm. Other multi-variable techniques combine different variables, e.g., heart rate with changes in blood pressure.

Artifact rejection and multi-variable analysis make it possible to add intelligence to current alarms, thus enabling reduction of false alarms, but also specific alarm messages specifying what the problem is and where it is located, compared to the nonspecific, obtrusive beep or buzz.

4.2.4. Integration and Communication

Multi-variable analysis presumes integration, which in turn presumes at least communication between intraoperative monitoring equipment (if the variables are not inherently integrated). But relevant information also comes from other sources, including clinical laboratories, the preoperative evaluation, and radiology. For example, a documented allergic reaction to certain drugs in some patients rules out the use of these drugs. The patient's weight determines the initial selection of the minute volume (10-15 cc per kilogram bodyweight at a rate of 10 breaths per minute) (Dripps 1977, Gravenstein 1989a). Lower setting may result in hypoventilation. Existing cardiovascular problems may determine the rejection of blood pressure and heart rate values for specific patients, while similar reading would be considered acceptable for other patients. These examples show that alarms should be evaluated in their proper context.

4.3. Toward Intelligent Alarms

Clinicians think in concepts. They reject apparent artifact, integrate information from a wide variety of sources and are able to adapt to changes. If, for example, the patient's end tidal carbon dioxide pressure ($P_{et}CO_2$) increases, the clinician re-evaluates the adequacy of ventilation by considering weight of the patient, and takes into account

preexisting pathological deficiencies, as well as a possible increase in the patient's metabolic rate. If alarms are to be helpful, alarms must resemble this process.

In these terms, one could define intelligent alarms as any scheme providing helpful interpretation of 1) the condition of the patient, 2) performance and condition of monitoring and anesthesia equipment, 3) possible consequences of clinical actions and interventions while taking into account a-priori information. The clinician is presented with a helpful and meaningful message, that should include an indication of the possible cause, location, and severity of the situation.

4.3.1. Fantasy or Possibility?

The inadequacy of many of the currently implemented alarm approaches has been recognized, and in recent years, a number of schemes to improve alarm technology have been proposed. Thus, the question whether intelligent alarms are wishful thinking or a real prospect is academic: we can expect intelligent alarms in the future.

The fundamental problem of how to deal with artifact is being addressed. Approaches include statistical methods, filtering techniques, frequency domain analysis, and common sense (Jorritsma 1979, van Genderingen 1987, Rampil 1987, Beneken 1987).

Trend analysis methods have also been described (Blom 1985). Using microprocessors, signal processing in modern monitoring equipment has become quite powerful and sophisticated compared to the "older" analog technology. For example, modern ECG monitors are quite capable of dealing with high frequency electrocautery artifact and some also have build-in S-T segment analysis or arrhythmia classification routines. Other devices, such as some of the commercially available pulse oximeters, are capable of detecting whether the sensor probe has been connected properly or has subsequently become dislodged.

Redundancy and multi-variable techniques are being developed and used, although on a small scale. As early as 1968, Raison et al. described how to reduce the number of false alarms in an intensive care unit using the correlation of two variables (Raison

1968). Fukui described an intelligent alarms system in use during cardiopulmonary bypass, that used three independent signals (Fukui 1987). However, monitoring equipment has begun to appear on the market taking advantage of redundancy and multi-variable analysis only very recently. For example, the Critikon's integrated (Critikon Tampa, Fl.) pulse oximeter/non-invasive blood pressure monitor employs a scheme not to trigger an alarm when the pulse oximeter sensor is unable to pick up a signal secondary to cuff inflation during noninvasive blood pressure measurements on the same extremity.

Redundancy and the use of multiple signals have been proposed by others as a natural step toward the reduction of detrimental alarms (Kunz 1975, Osborn 1982, Gravenstein 1987 p:387-389, Beneken 1989).

Communication and integration is also being addressed. The definition of a medical information bus (MIB) that specifies a local area network to acquire data from monitoring equipment, anaesthesia equipment, and intravenous pumps is nearing completion (Shabot 1989). These standards are being developed by the Institute of Electrical and Electronic Engineers (IEEE) and prototypes based on the MIB are being implemented (Gardner 1989).

In addition, manufacturers of anesthesia and monitoring equipment are beginning to answer the demands for integrated anesthesia equipment. A number of these new generation anesthesia machines and monitoring devices are beginning to appear on the market from various vendors (American Draeger, Hewlett-Packard, and Ohmeda). These machines address the pressing needs of better intraoperative anesthetic management and alarms. It should be noted that these developments are a result of the numerous efforts by research teams (Cooper 1978a, Gardner 1982, Block 1985, Meijler 1987).

4.3.2. The Layered Approach

Intelligent signal processing that produces reliable and reproducible data is a fundamental prerequisite for intelligent alarm systems, as is the ability to integrate. Measurements are obtained from physical variables transduced into an electrical representation. But, the sheer amount of information in these continuous signals is unworkable. Thus, both qualitative and quantitative features have to be extracted from the original signal. Artifact rejection and multi-variable analysis (section 4.2) are the necessary and essential elements of attacking signal analysis.

To present the clinician with helpful intelligent alarms, the following layered approach toward intelligent alarms, which emphasizes data reduction without loss of essential information would provide the necessary framework (Figure 4.1).

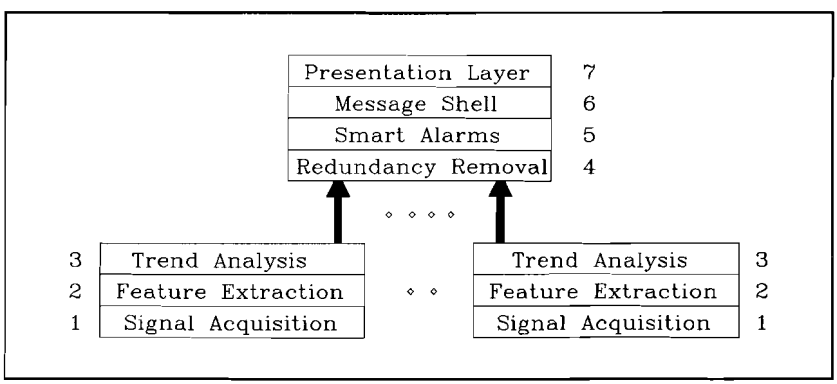

Figure 4.1 Possible Framework for a Layered Approach to Intelligent Alarms.

At the lowest level resides the transducer system with sensors, amplifiers, filters, and calibration components. These components transduce the physical variable into an electrical signal. At this level not only is the electrical signal available, but also status information about the transducer system. These include: transducer present/not present,

working/not working, calibrated/not calibrated, connected/not connected, etc. All this information is passed to the second level, feature extraction.

At the second level, signal features are extracted to reduce the amount of information; most commonly, a digital computer hosts signal processing software responsible for data reduction of the signal into a set of derived features. These features should describe the original signal as completely as possible. Examples include maximum, minimum, frequency spectrum, area under the curve, timing information, slopes. Signal validation is also performed at this level, which entails a comparison of the set of derived features with previous sets of features. These sets are learned over time and stored into local computer memory. They may be fixed, based on common knowledge about the signal, or adaptive, based on the behavior of the original signal. Other tests look at feature values in terms of absolute value (e.g. a systolic blood pressure of 500 Torr is non-physiologic) and rate of change. The results of analysis on this level both in terms of the set of features plus associated status information is transferred to the next level. It should be noted that not necessarily all features are passed to the next level; features extracted solely to aid in validation are omitted.

On the third level trend analysis per feature is performed. The time of onset and direction of the trend are calculated. Corresponding status information augments the trend information and are added to the feature information set. At this moment, all information that can be extracted from one signal expressed in features is extricated from the signal and available to be passed on to subsequent processing levels.

The previous three levels described work with only one signal and its derived features. The fourth level, receiving features and status information from the lower levels from different signals is the redundancy removal level. Here, superfluous data are omitted from the pool of feature information, before being passed to the next level. For example, of the three heart rate values, one value with status information regarding validity and quality is transferred to subsequent levels.

On the fifth level, where the heart of the intelligence resides, smart alarms are generated. This level looks at variable features and values, trends, combinations of variables, and determines if problems exist, where they occur, and their plausible cause(s); and, if applicable and appropriate, suggests how to solve the problem. In order to make this level as intelligent as possible, as much a-priori information as feasible should be made available. This includes patient demographic data (e.g. sex, age, height, weight), preoperative evaluation information (e.g. known allergies, cardiovascular and pulmonary historical data, smoking habits), and intraoperative information, including clinical interventions such as drug administration (e.g. what drug, amount, timing and pharmacokinetics of drugs given to induce and maintain anesthesia or therapy), readjustment in ventilation (changes in fresh gas flows, tidal volume), position of the patient (e.g. Trendelenburg, supine), and fluid balance (e.g. loss and input by amount, rate, timing, and composition).

Level six is the message shell, which determines what (if any) message to send to the clinician about the patient and the equipment: for example "Suspect Hypoventilation," "ECG lead disconnected," "Heart rate falling fast," and also "High end-tidal CO_2 values. Cause unknown." If more than one possible cause should be considered, the messages should preferably appear in order of likelihood. Much like a clinician would assess the situation, these messages are scored on a scale from "high priority" to "low priority," from "need to act" to "need to observe."

Level seven is the final layer: the presentation. This level receives its inputs from level six, but also might display real time signal waveforms, trend information, pertinent patient demographics, and other data on a central, integrated display used for interaction with the anesthesiologist.

4.4. Limits and Alarms

It was argued in this chapter that many of the prerequisites for an intelligent alarm technology are feasible, developed, or currently under development to allow the layered approach to be implemented, although the three top layers require additional work. To add intelligence, to select which is the most appropriate message and under what condition, and to define the man-machine interface requires imaginative solutions.

As Beneken points out, decisions made with signals, trend variables, and multi-variable analysis, are based upon comparisons with reference values; they are either static or variable over time (Beneken 1989). This means that too many reference values must be set for too many variables for too many patients under too many circumstances. While all problems have not been solved, it is reasonable to help the clinician as much as is currently feasible. When useful messages can be generated, we should and will do so.

5. IMPLEMENTING INTELLIGENT ALARMS

We have identified the clinical problems the anesthesiologist tries to solve through monitoring: 1) titrating the level of anesthesia, 2) untoward trend identification, and 3) patient safety (chapter 3). It was argued that current alarms do not help the clinician, and problem areas were identified. A layered approach to *intelligent alarms* (chapter 4) was subsequently presented as a possible framework for an implementation. In this chapter, arguments for concentrating on the patient's ventilation are discussed for the implementation of our version of intelligent alarms. Possible approaches are compared, and reasons for selecting the expert system approach are given. A frame work for the implementation concludes this chapter.

5.1. Monitoring for Patient Safety

The anesthesiologist's main concern for patient safety is irreversible damage to the brain, heart, lungs, liver, and kidneys. Insufficient oxygen supply to the organ is the primary concern. Tissue hypoxia can be the result of ventilatory, circulatory, metabolic or toxic effects. When clues indicate that patient safety might be in jeopardy, the anesthesiologist diagnoses the possible causes, assesses the implication for the patient, and selects and institutes a treatment. In the following discussion metabolic and toxic factors will be ignored. The focus will be on respiratory and circulatory factors.

5.1.1. Detecting Potential Problems

It takes only minutes before irreversible brain damage or even death can result due to deficiencies in, or a total lack of, ventilation or circulation. Therefore, the identification of a trend or a change in a variable, particularly those without the trigger of a clinical action, can be significant and must be detected. Patient monitoring, with or without the aid of instruments, enables the early recognition of changes in a variable or the detection of a trend (chapter 3). However, it is clinically nearly impossible and impractical to monitor the condition of the patient continuously and in every detail, even

with monitoring devices. That is why alarms should advise the clinician of untoward situations.

5.1.2. The Differential Diagnosis

When a potential problem arises, time can be essential, and the anesthesiologist must act swiftly to uncover and treat the cause, as the origin is either iatrogenic, related to equipment, produced from within the patient, or caused by artifact, much valuable time can be spent making a differential diagnosis of the problem. First, artifact must be ruled out. Then the anesthesiologist inspects the surgical field, evaluates actions of himself and of the surgeon. The anesthesia machine, the breathing circuit, and other anesthesia equipment are examined while evaluating monitored variables for clues of equipment failure or a problem within the patient. As an illustration, the differential diagnosis for hypoxemia is examined in more detail.

An Example

Hypoxemia can be limited to an organ, for example hypoxia of the brain after occlusion of the blood supply to the brain, it can affect all organs if blood flow in general becomes inadequate, or it can be the result of insufficient oxygen in arterial blood. The latter circumstance is of interest here; it can result from: 1) hypoxic inspired gas mixture, 2) hypo-ventilation, or 3) a mismatch of ventilation to perfusion (Gravenstein 1990). The primary indication of hypoxemia is provided by the pulse oximeter, assuming circulation is intact.

After determining that artifact is not the culprit of the lowered saturation reading, and that the monitor is functioning properly, the process of finding the cause begins. This searching process can be presented as the following list of questions (in a "pseudo language"). The sequence in the list indicates a priority.

Ad 1) Consider hypoxic inspired gas mixture.

Is the fraction of inspired gas (FiO_2) >= 21%? If not, consider:

? adequate oxygen (O_2) delivery
- Check O_2 gas supply pressures
- Check gas flow settings on anesthesia machine
- Check flow meter on anesthesia machine
- Check anesthesia machine for leaks
- Check for obstructed fresh gas supply line

? contaminated O_2 supply
- Check for misconnection(s) at the anesthesia machine
- Check for wrong gas in pipeline

Ad 2) Consider hypoventilation

Look at the capnogram. If no capnogram present consider:

? disconnection
- Check pressures in the breathing system
- Check all connecting points in the system

? esophageal intubation
- Check position of endotracheal tube (ET)

? mechanical ventilation present
- Check mechanical ventilator for proper operation

? occlusion
- Check for gas flow in breathing system
- Check unidirectional valves
- Check for presence of foreign body in the system
- Check pressures in the breathing system

If a capnogram can be observed, consider:

? leaks
- Check pressures in the breathing system
- Check all interconnections for leaks
- Check ET cuff for leaks

? obstructions
- Check pressures in the breathing system
- Check for a kink or other obstruction in the ET

? CO_2 rebreathing
- Check for valve insufficiency
- Check for exhausted CO_2 absorber
- Check possible rebreathing valve

? adequacy of ventilation
- Check tidal volume. Is it adequate for this patient?
- Check for increased dead space

? increased CO_2 production
- Check for hyperthermia/malignant hyperthermia

Ad 3) ventilation to perfusion mismatch

The partial pressure of O_2 in arterial blood is less than that in alveolar gas:

? Endobronchial intubation
- Check breath sounds
- Check position of ET

? Occlusion in the lung due to mucus or aspirated stomach contents
- Check for foreign bodies in the bronchia

? Patient's position has changed
- Check position of the patient

? Embolism
- Check for clues of embolism due to air, blood clot, fat, or tumor
- Check trend in end-tidal CO_2

? Pulmonary diseases
- Check patient history
- Check for partial occluded airway

? Surgical interference
- Check surgical field

5.1.3. Implications and Treatment

The example in section 5.1.2 not only illustrates the many potential causes to be evaluated in a short time period, it also hints at the range of implications for the patient, and at possible different treatment strategies. In both instances, differential diagnosis is the key that determines the next course of action. Immediate action is indicated in case of hypoxic gas mixture, while a change in the position of the patient could result in no treatment. As treatment is the territory of the clinician, an intelligent alarm system

should not interfere or even suggest treatment of the patient. It should however point out mechanical or instrumentation problems, or other probable causes.

5.2. Selecting the Area of Implementation

While illustrating the differential diagnosis process for hypoxia in section 5.1.2, the fact that current alarms technology does not help the clinician's diagnosis process was again highlighted. For example, concepts as hypoventilation, shunt, obstruction and leak are not incorporated into the current alarm technology and no clue regarding the location is available; e.g., within the patient, anesthesia machine, CO_2 absorber, and/or hospital supply lines.

The development of a device that helps the clinician with the differential diagnosis is our goal. Cataloging encountered problems is the first step toward an implementation.

5.2.1. The Major Cause of Injury

Several studies indicate that difficulties with the respiratory system are the primary cause of patient injury, brain damage and death during anesthesia (Cooper 1978, 1984, Davies 1984, Cheney 1988). Meijler tabulated the causes of injury listed by six surveys (Meijler 1987 p:146), and found that almost 50% of the causes of injury were respiratory-related, either the result of incorrect gas flow (22.6%), problems with in- and extubation (11.7%), inappropriate airway maintenance (7.7%), and misconnections (7.3%). Cheney more recently presented data on a preliminary analysis of 624 cases (Cheney 1988 p:14) and reported that in 30% of the cases, difficulties in the management of the respiratory system was the single cause of injury.

Error in drug administration (i.e. anesthetic overdose, wrong drug, drug omission), with 22.6% is the second major area cause of injury (Meijler 1987). Problems with fluid replacement, intra-venous (IV) equipment, and monitoring each account for approximately 4%. It is widely believed that the majority of the causes listed above are preventable (Davies 1984, Cooper 1984, Keenan 1985).

Not all injuries can be prevented, however. A poor physiological status of the patient, pathological causes, and other factors beyond control present inherent risks.

5.2.2. Suggested Improvements

With human error and equipment failure accounting for the majority of injuries, approaches to minimize their occurrence have been proposed (Cooper 1984). Additional training, more complete preoperative assessment, additional monitoring equipment, improvements in the man/machine interface, and better supervision were among the suggestions made toward detection and prevention. In the meantime, helpful monitoring modalities have become available and have been put to use. Minimal monitoring standards have been adopted, quality assurance programs have been instituted, and man/machine interface issues are being addressed (Cooper 1978a, ASA 1986, Meijler 1987, Eichhorn 1989, Schreiber 1989).

5.2.3. Scope of the Project

It must be clear from all that is mentioned so far, that the advanced monitoring facilities are brought on, in part, by the increased sophistication of surgery, and through advances in commercial equipment. Notwithstanding the additional monitoring modalities, the current alarm technology still proves to be a major weakness. The sheer vastness and complexity seems to have reached the limits of comprehension by the anesthesiologist. It is our intention, in the long run, to hide all monitoring details from the anesthesiologist and to present him (her) with a higher abstraction level of the patient. Essential, however, is the availability of all pertinent qualitative and quantitative information, in order to home in on the problem area. Toward this goal, integration of information and *intelligent alarms* are steps toward the detection of changes in the state of the patient and to aid in the differential diagnosis process.

With the identification of the area where most causes of injury are to be found, the stage is set to define the scope of the project: smart alarms concerning ventilating patients under anesthesia.

5.3. Project Approach

The fundamental idea is, that an analysis of clinical important decisions by clinicians (while making the differential diagnosis) during critical incidents concerning ventilation, constitutes the basis for the development of smart alarms. In selecting an approach for the implementation of the Intelligent Alarm (IA), a number of issues are important. This section describes design criteria, compares possible approaches and selects the approach of our project.

5.3.1. Design Criteria

There are several properties (or attributes) the IA system should possess, most of them discussed in chapter 4. Apart from reducing the number of false alarms and presenting the clinician with helpful messages identifying the encountered problem in terms of severity and location, the system should work in real time. For our application, real time means that the system should have recognized an external event and produced a response by the time it is required clinically. Real time in our context also requires the ability of the system to respond fast enough to external events, as the presence of new or updated data from front-end monitoring devices, or pressing a key on a keyboard. Finally, the IA system should provide both a practical and economical solution to the problem.

5.3.2. Possible Approaches

Even though the onset of a potential complication can be signaled by a change in only one monitored variable, the differential diagnosis is based on multiple signals and variables. Few approaches currently exist that interrelate different signals and variables. One approach suggested by Beneken and Gravenstein introduces the concept of fault models (Beneken 1987). In this approach, a three digit classification is associated with each variable indicating its static, dynamic and statistical properties. Each fault model (e.g. an arterial catheter flush, loose electrodes) is subsequently expressed in terms of combinations of these three-digit classifications. An algorithm identifying fault models would notify the clinician of a present or impending problem.

A variant of the fault model approach is to identify a potential problem as a pattern of "n" digits; one digit per variable or derived feature. Like Beneken's approach, concepts as: too high, elevated, normal, depressed, too low would be mapped into a digit. A potential problem would be expressed as an n-digit number, which could be compared with the current n-digit number of signals and features.

The methods above can be considered as examples of a more general pattern recognition approach. Pattern recognition generally entails, that a set of characteristic features is extracted from input signals. These features are operated upon such that each of the patterns to be recognized produces an output which is as unique as possible. The n-tuple input pattern is mapped to a m-dimensional output space. For "n" features there is an m-dimensional space in which normal and problem areas can be discriminated. Location of the feature set in one of the problem areas provoke associated alarms. Examples of the use of pattern recognition for displays have been made by Siegel, who suggested a circle diagram for physiologic states (Siegel 1983), and Meijler, who presented the "bar display" of up to ten patient variables (Meijler 1987 p:42).

Application of the Fuzzy Set Theory (Zadeh 1965) is another approach to consider. Fuzzy logic is used to model human reasoning which by nature is saturated with imprecise concepts. The Fuzzy Set Theory can be seen as a generalization of the

classical set theory, in which an element either belongs to a set or it does not. The key idea in the Fuzzy Set Theory is that an element belongs to a set expressed as a degree of membership. For example, consider the set of tall individuals. A person who is four feet tall would have a degree of membership of 0, while a seven feet tall person's degree of membership would be 1. Intermediate heights have a degree of membership between 0 and 1. Examples from the world of anesthesiology include: "heart rate is high," "ventilation is adequate," "this is a young patient," and "blood pressure is stable." The membership concept is related to the concepts of "probability" and "certainty."

The only other possible approach that will be mentioned here is the use of an expert system. Much like human experts, expert systems solve problems in a certain area of expertise. Expert systems differ from algorithms in that rather than a set of operations, procedures, and decisions, a *heuristic* is used. A heuristic is a rule of thumb, a trick, or a simplification of the problem to aid in finding a solution to the current problem. In addition, the knowledge about the problem to be solved (the knowledge base) is kept separately from the knowledge of how to solve problems (the inference engine). In algorithmic approaches, knowledge and procedural knowledge are integrated into the algorithm. Intuitively, smart alarms and expert systems are interrelated. Anesthesiologists, through increasing knowledge and experience that is gained over many years of practice, become experts in the field. The differential diagnosis process is an illustration of the expert at work. The expert systems approach will be looked at in more detail in the next section.

5.3.3. The Expert Systems Approach

Before embarking on the expert system approach, it is necessary to evaluate whether expert systems are appropriate for helping physicians determine the cause of problems. The most appropriate problems for expert systems are heuristic in nature which use symbolic reasoning. The problem area must be sufficiently narrow in scope, must be manageable and must have practical interest (Waterman 1986 p:131-134).

Shortliffe, one of the pioneers in the field of expert systems in the medical field, suggests a number of criteria (Shortliffe 1982), including: 1) physicians must recognize the need for assistance, in particular computer assistance, 2) medical expertise and experts must be available and accessible, 3) mechanisms must be in place to introduce the tool into the clinician's daily routine, 4) clinicians must maintain the final say in the decision process, 5) clinical participants in the project must be highly motivated, and 6) the problem to be solved must be well understood.

Using these criteria as a guide in our evaluation, led us to believe that the approach is appropriate. As mentioned before, physicians recognize that functional integration of information from monitoring devices, and integration of alarms in particular, is helpful. Alarms pertaining to ventilation of patients under anesthesia is an area of particular interest in the Department of Anesthesiology at the University of Florida (Beneken 1985, 1987a, van Genderingen 1987, Good 1988, Gravenstein 1989a, 1990).

Initially, the scope of the project concerns itself with a limited number of potential problems and concepts. The availability of an anesthesia simulator designed to reproduce the working environment of the anesthesiologist while reproducibly creating a number of undesired situations, specifically during mechanical ventilation, is particularly attractive during the development (Good 1988, Hekker 1989). Finally, laboratory and operating rooms are readily available and accessible.

Another important consideration favoring the expert systems approach over conventional programming is the separation of the knowledge from the reasoning techniques with that knowledge as it is inherent in expert systems (chapter 6). Keeping the knowledge separate facilitates concentration on the knowledge which makes it possible to represent the knowledge conveniently, to discuss the knowledge with the expert. This, in turn, can improve modularity, transparency and ease of maintenance.

Given these considerations, it is reasonable to embark on the expert systems approach for the intelligent alarm system outlined in paragraph 5.2.3. that assists the clinician with alarm management during anesthesia.

6. EXPERT SYSTEMS

Ever since ENIAC, the first digital computer, made its entrance in 1946, man has looked for ways to make computers behave like intelligent human beings. In 1956, John McCarthy organized the Dartmouth conference and introduced the term Artificial Intelligence. This conference is uniformly regarded as the birth of that part of computer science research concerned with intelligent computers: artificial intelligence (AI). One practical definition of AI was offered by Winston: "Artificial Intelligence is the study of ideas that enable computers to be intelligent" (Winston 1977 p:1). Tracing the path of AI in history, Jackson identifies three periods: the Classical period, the Romantic period and the Modern period (Jackson 1986). For the first ten years (the Classical period), AI research concentrated on the quest for a general purpose problem-solving algorithm that was the key to all human intelligence. Despite initial promising results (Feigenbaum 1965), researchers, in the following decade (the Romantic period) concentrated their efforts on making computers understand natural language and methods to represent knowledge in a computer. Methods to reason with the knowledge representations also gained much attention. Many papers from this period can be found in Winston (Winston 1975). Toward the end of the 1970s (the Modern period), researchers, somewhat disillusioned with the general problem-solving techniques, realized that it was impossible to develop a general purpose algorithm for the broad spectrum of problems. The conviction grew that problem-solving power of intelligent computer programs results from incorporated, explicit, relevant knowledge. According to Waterman: "To make a program intelligent, provide it with lots of high-quality specific knowledge about some problem area" (Waterman 1986). This realization led perhaps to the most exciting areas of Artificial Intelligence research in recent years: the expert system. Many useful and successful applications of expert systems in such areas as chemistry, medicine, geology, and computer hardware have resulted (Martin 1971, Shortliffe 1976, Fagan 1980, Lindsay 1980, McDermott 1980).

This chapter presents a brief introduction to expert systems, followed by a description of the expert system tool SIMPLEXYS that was used to implement the intelligent alarm application.

6.1. Introduction to Expert Systems

An expert system is a computing scheme that combines knowledge, facts, and an inference technique to solve problems in a well defined domain in a way human experts would (Waterman 1986). In layman terms, an expert system is a computer program that mimics an expert in a specific narrow field (domain) by applying a problem solving technique (the inference technique) to the knowledge gathered from the expert. Therefore, expert systems, like the human expert whose knowledge is implemented, make the same mistakes and do not guarantee a correct answer, but increase the likelihood to find a useable answer.

By capturing the expert's knowledge, which is generally expensive, perishable, scarce, and difficult to document and transfer, expert systems make this knowledge affordable, permanent, abundant, and easy to document and transfer. Consequently, expert systems are becoming cost effective alternatives in a variety of areas requiring experts to solve problems.

6.1.1. Expert System Components

The internal structure of an expert system consists of, the *knowledge base*, a *data base*, an *inference engine*, and a *user interface* (figure 6.1).

The Knowledge base

The knowledge base in an expert system contains facts and the domain knowledge (heuristics) for the decision making process. Note that the knowledge base is a separate entity. The domain knowledge can be represented using a number of approaches.

Widely used are representation schemes using rule-based methods, structured objects, and predicate calculus (Jackson 1986).

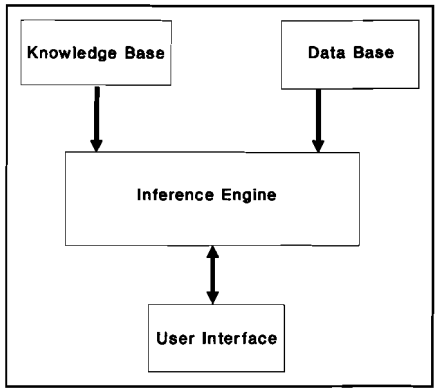

Figure 6.1 Components of an Expert System.

Rules (also called production rules) are of the form:

IF *premise 1* AND *premise 2* AND ...

THEN *action 1, action 2, ...*

If the premises of the rule are satisfied, the actions specified by the THEN part are performed. The action part may in turn invoke another rule, and so on. When the knowledge is stored using a rule-based method, the knowledge base is also referred to as the rule base. Many expert systems are rule-based, because these kind of rules are easily understood, and easy to implement.

Structured objects include a number of representations such as 1) semantic nets, a constellation of nodes and links in which a node stands for a specific concept and the links describe the relationships between the nodes, 2) frames, a network structure of nodes and hierarchical relationships in which each node is described by a collection of slots (attributes), and 3) decision trees, a hierarchical semantic network where the nodes represent goals, and the links represent decisions.

Predicate calculus consists of a language for expressing propositions, and rules that prescribe how to infer new propositions from existent ones. Possible inferences include deductions, abductions, and inductions. An example of a deduction:

Proposition 1: BASIL is a cat

Proposition 2: All cats are black

From these two propositions, we deduce that BASIL is a black cat.

The Data Base

For temporary storage of external inputs to, and intermediate results of the inference process, scratch-pad storage is provided by the internal read/write memory. Since expert systems are implemented using computers, the computer's internal memory usually serves that purpose.

The Inference Engine

The inference engine is the mechanism that contains the problem solving knowledge and performs the reasoning. The inference engine uses the knowledge in the knowledge base plus information provided by users (interactive applications), data acquisition equipment (process controllers), or databases to infer. Examples of reasoning strategies include forward chaining, backward chaining, pattern matching, or one of a variety of searching techniques.

The User Interface

The user interface is the part of the system that enables the user to communicate with the expert system and visa versa in a friendly and flexible way. Entering facts about a particular situation, questions within the system's subject domain, and responses to user requests are all handled by the user interface. Some expert system shells provide a graphics interface in the form of a lattice (a visual representation of the logic flow) to aid in the expert system development. For example the Automated Reasoning Tool

(ART) provides this mechanism (ART is a product of the Inference Corporation, Los Angeles CA.). The lattice can also be used to provide the user with visuals of the inferencing process. Examples of implemented user interfaces include natural language dialogue, graphics interface, menus, explain facilities, or a "window" environment with non-keyboard entry devices, such as a mouse or track-ball.

6.1.2. Building an Expert System

Designing and building an expert system is called *knowledge engineering*; the person performing the activity is called the *knowledge engineer*. The knowledge engineer interacts with the human expert, the *domain expert*, to obtain the knowledge to solve problems in a specific domain; this is called *knowledge acquisition*.

Knowledge is acquired from a number of sources, including textbooks, databases, and personal experience, but the main source is the domain expert. The knowledge transfer from the human expert into an expert system is the key element in development. Typically, a series of intense interviews between knowledge engineer and domain expert is the method of choice, although other methods have been attempted, including on-site observation, video-taping, and simulators. Building a knowledge system is an iterating, evolutionary process in which five major stages of identification, conceptualization, formalization, implementation, and testing can be identified (Hayes-Roth 1984). After initial sessions with the domain expert, the knowledge engineer will have identified the problem and after finding concepts to represent the knowledge and structures to organize it, he or she builds a prototype of the expert system. This prototype is tested and discussed with the domain expert and, over the course of many sessions, refinements are made, and new prototypes built and rebuilt, until all involved are satisfied.

6.2. Expert Systems Applications in Medicine

Since the birth of expert systems, medicine has provided a challenging field for applications, but the few applications currently in use deal with relatively simple tasks (Gardner 1986). Over the last twenty years, a number of investigators have developed medical AI systems to assist the clinician primarily in the area of consultation (Kulikowski 1988). The most renowned results are: MYCIN, which gives advice on the diagnosis and treatment of bacterial infections in the blood, and meningitis (Shortliffe 1976); INTERNIST, which given a patient's history, symptoms, or laboratory results assists in the diagnosis process in general internal medicine (Miller 1982); and PUFF, which aids in the diagnosis and assesses the severity of pulmonary disease (Aikins 1983). Other applications followed, such as ONCOCIN, which advises physicians who care for patients on chemotherapy protocols (Shortliffe 1984); and ATTENDING, a critiquing system that gives advice for anesthetic management (Miller 1983). These expert system applications are examples of systems in domains with static data, and no requirement for time critical responses.

More recently there is an interest in applications of real-time expert systems to reduce the cognitive load on users (Turner 1986). Specifically, in the process control domain operators are confronted with a large number of signals. In case of a problem the cognitive load on the operators while identifying the cause of the problem is considerable. PICON (Process Intelligent Control), developed by LISP Machine Inc.(LMI has been acquired by GigaMos Systems, Lowell MA.), is an example of an expert system shell that provides real-time monitoring and control of a process control system.

Real-time expert systems differ from the consulting type systems. First, the interface to the environment has sensors that provide data. Second, these data need not necessarily be static; hence, they can change during one run of the expert system. Third, these systems tend to run continuously, or until stopped by an operator's request; even continue to operate in some form with missing or disturbed data. Fourth, the system

must react to asynchronous, even unexpected external events. Fifth, temporal reasoning: the ability to reason with events from the past, present and future should be possible. Finally, the systems must come to a conclusion within a problem-dependent, guaranteed response time; although, one desires the best possible conclusion. The traditional expert systems, primarily programmed in the established list-processing programming languages LISP and PROLOG, are not suited for real-time performance: they are too slow because they spend much time searching. Thus, they have been used primarily for interactive applications. A number of expert system tools that have become available in the last 3-4 years allow for the development of real-time expert system applications (Laffey 1988).

In the medical application, one of the first examples in medicine is Ventilator Management (VM), which was designed to interpret on-line physiological data from patients in the intensive care unit (ICU) (Fagan 1980). This system provides the clinicians with suggestions about the patient state and therapy. Another example is BABY, which assists clinicians in the newborn intensive care unit (Rodewald 1984). It contains neonatology knowledge for interpreting clinical and demographic data. Another example is CAPS, an application based on the expert system EXSYS (Exsys Inc. Albuquerque NM.) for respiratory and anesthesia monitoring based on the capnogram (Rader 1987).

These examples of AI methods and expert system applications demonstrate the range of interest. With the increased performance obtained both with recent software improvements and the availability of more powerful, and economical, micro-computer platforms, an increase in small-scale dedicated expert system applications is envisioned. Our intelligent alarm application falls in this category.

6.3. Finding an Expert System Tool for Intelligent Alarms

One of the design criteria for our Intelligent Alarms system was that it should work in real time (paragraph 5.3.1) to prevent the clinician having to keep up with every detail. Real time expert systems are used to reduce the cognitive load on the user and

to enable them to increase their productivity (Turner 1986). Apart from the real time criterion, other requirements had to be met. First, data from a variety of front-end monitoring devices must be accessible to the expert system. These data can be obtained from serial interfaces, analog to digital (AD) convertors, or digital input/output lines. Secondly, the user interface should be dictated by the application, not by the expert system tool. Based on these two requirements, the expert system should provide for "hooks" to standard programming languages as FORTRAN, Pascal, or "C." Another important requirement calls for the ability to represent knowledge in a convenient way and thus to be able to discuss the knowledge with the expert. Finally, to meet our requirement that our system should be economical, the expert system should be small enough to run on a micro-computer; preferable a Personal Computer (PC).

The search for a suitable, existing expert system tool for the intelligent alarm application indicated only few available tools (paragraph 6.3). If one appeared to be able to handle our application, little or no documentation was available, and information on its worst-case performance was omitted. LISP was used commonly as the programming language making applications relatively slow, particularly on a PC (Rader 1987). Speed could be increased when expensive workstations were used, however. Also, the intelligent alarm application relies on data collected automatically from front-end monitoring devices; not through question and answer sessions. These were some of the reasons for J. A. Blom from the Dutch participating group to develop the real-time *SIMPL*e *EX*pert s*YS*tem tool: SIMPLEXYS. (Blom 1987, 1988, 1990, de Hair 1988). Another reason to pursue the SIMPLEXYS development stemmed from the desire to understand the insides of the expert system and to enlist all possible techniques to speed up the expert system's operation.

6.4. The Expert System Tool: SIMPLEXYS

As Blom points out, "SIMPLEXYS was not designed, it grew, out of a need" (Blom 1990). The SIMPLEXYS expert system tool was originally implemented using the Pascal programming language, a "C" language version is also available. For our application we elected to use the "C" version. In the next sections a detailed description of SIMPLEXYS is presented including the formal syntax of the language and examples on how to build applications with SIMPLEXYS.

6.4.1. Introduction

SIMPLEXYS is a toolbox with which real-time expert systems can be built. Knowledge entities are represented by rules, which in turn are linked in a *semantic network* that specifies how those chunks of knowledge interrelate. A rule is either *primitive* that represents an atomic concept (therefore, no other rules are needed for evaluation), or it is *composite*: a higher level concept, some type of combination of other rules. The rules that represent the conclusions to be evaluated are called the *goal rules* or simply goals.

SIMPLEXYS provides a number of tools for the implementation of expert systems:

1. The SIMPLEXYS language is designed for an easy translation of human knowledge into symbolic form. A program written in this language is called a *knowledge program*. Such a program is a formal description of the domain knowledge or knowledge base.
2. The SIMPLEXYS Rule Compiler, that translates this knowledge program into an internal representation that can easily be handled by the inference engine.
3. Several tools, implemented as additional passes of the Rule Compiler perform syntax, semantic, and consistency checks on the knowledge base.

4. The SIMPLEXYS inference engine implements the necessary "reasoning" ability. By combining the SIMPLEXYS inference engine and the internal representation of the knowledge generated by the rule compiler, a ready-to-run SIMPLEXYS expert system results.
5. Tools to examine the inferencing process performed by the expert system while the system is running or at the end of a run.

One important feature of SIMPLEXYS is the ability to include "C" code as an integral part of a SIMPLEXYS application. This ability provides the interface to the outside world such as data acquisition equipment, results from signal processing techniques, sense lines to external interrupts, or other externally supplied data (paragraph 6.3.4).

6.4.2. Building Applications with SIMPLEXYS

Building an expert system with SIMPLEXYS entails a number of steps. First, acquire the knowledge and translate it into SIMPLEXYS rules. Make a text file that contains these rules.

Next, use the SIMPLEXYS Rule Compiler to translate the rules into an internal representation. The Rule Compiler asks for the input file containing the rules that represent the domain knowledge. This source code is compiled into an internal representation of the knowledge: a number of "C" code sections and tables. The Rule Compiler checks the SIMPLEXYS text only. It halts at the first error it finds and shows the offending line with an error message. If the SIMPLEXYS Rule Compiler finds rules missing, it can automatically create code asking the user to provide the facts at run-time. Several auxiliary passes of the Rule Compiler perform extra (semantic) checks on the correctness of the knowledge base.

During the third step, a "C" language compiler is used to build the expert system. The compiler subsequently checks for any errors in code sections of the program not written

in the SIMPLEXYS language. The expert system is then ready to run. The forth and final step entails running the expert system on a number of test cases and use the built-in facilities to analyze its behavior.

6.4.3. SIMPLEXYS Rules

Conclusions of rules in SIMPLEXYS have the type *bool* (pseudo-boolean). type bool = (TR, FA, PO)

Where:

TR: the conclusion is true

FA: the conclusion is false

PO: the conclusion is unknown; it could be either false or true; PO is very different from UD (see next): PO is the result of an evaluation (which could not return a true or false answer)

In addition to these possible conclusions, a tag "UD" has been defined:

UD: is a tag indicating that the rule has not been evaluated yet; if the conclusion is needed, the rule must be evaluated.

The SIMPLEXYS syntax allows multiple conclusions from a single evaluation. Whenever a rule is evaluated, other conclusions of other rules may be given a value based on the previous evaluation. The keyword THEN is reserved to assign values when the conclusion of the rule evaluation is TR, ELSE is reserved when the evaluation is FA, while IFPO is reserved when the conclusion is PO. The THEN's, ELSE's, and IFPO's are collectively called THELSE's.

Primitive rules

There are 5 types of primitive rules:

1. FACT rules denote constant knowledge.
2. ASK rules ask questions from the user.
3. TEST rules test externally supplied data.
4. MEMO rules remember results.
5. STATE rules denote the current context.

When primitive rules are evaluated, the conclusion is assigned a value.

Composite rules

These are rules constructed from a combination of other rules and logical operators to form an expression. The logical operators include the binary operators AND, UCAND (unconditional and), OR, UCOR (unconditional or), and ALT (alternative), and the unary operators NOT, POSS (possible), and MUST. (The ALT operator indicates a logical equivalent in an expression. For example, in the expression rule1 ALT rule2, rule2 is evaluated if rule1 evaluates to PO, which is inconclusive.) Conclusions of composite rules are assigned a value by conditionally evaluating the expression from the left to the right.

Goals

Goals or goal rules are special only in that those rules are explicitly defined as goals. Primary goals are goal rules connected to a STATE rule; they are evaluated whenever that state is active (that STATE rule has evaluated to TR). Secondary goals are goal rules connected to other rules and are evaluated as a consequence of the evaluation of the rule with which they are connected.

The following are examples of rules, which also indicate the rule syntax. The syntax itself will be discussed in detail in the next section.

```
MALE: 'The person is a male'
ASK
THEN FA: FEMALE
ELSE TR: FEMALE

PRESSURE_NORMAL: 'The blood pressure is normal'
BTEST ( ( BP > BP_LOW_LIMIT) and (BP < BP_HIGH_LIMIT) )

MECH_VENT: 'The patient is mechanically ventilated'
STATE
INITIALLY FA
THEN GOAL: TEST_BREATHING_CIRCUIT

TEST_BREATHING_CIRCUIT: 'Find problems with the breathing circuit'
LEAKS UCOR OBSTRUCTIONS UCOR VALVE_PROBLEMS
```

6.4.4. SIMPLEXYS Programs

A SIMPLEXYS program consists of up to seven sections. The first five sections are optional and exist only if the rules must interface with "C" code to perform acquisition of data, print output, and so on. The syntax calls for the sections to appear in this order:

```
1 DECLS    declarations          |
2 INITG    global initializations |  These sections
3 INITR    run initializations    >    consist of
4 EXITR    run exit code          |     "C" code
5 EXITG    global exit code       |
6 RULES    the rules
7 PROCESS  the "script"
```

Declarations

Section 1 is optional. All variables, that will be used by initializations, exit code, TESTs and so on, must be declared and their type must be specified. Similarly, all procedures and functions that will be used must be declared. The "C" code in this section is included without changes into the SIMPLEXYS inference engine.

Initializations

Sections 2 and 3 are optional; they start with the keywords INITG and INITR respectively and contain "C" programming code. INITG precedes INITR. The statements in the INITG section are executed immediately after system start up; the statements in the INITR section are executed immediately after the start of each run. These sections consist of executable statements that are used to initialize data values or invoke procedures, e.g., to acquire data or provide a user interface.

In contrast, a rule conclusion can be initialized only by an INITIALLY statement; this initialization is done only at system start-up, immediately after execution of the INITG code. The "C" code in INITG and INITR sections is included without changes into the SIMPLEXYS inference engine.

Exit code

Sections 4 and 5 are optional and start with the keywords EXITR and EXITG respectively. EXITR precedes EXITG. These sections contain "C" programming code. The statements in the EXITR section are executed immediately after the completion of the evaluation of the goals of each run; the statements in the EXITG section are executed only once, at the end of the last run, when no more STATEs are active. These sections consist of executable statements used to change data values, invoke procedures, e.g., to store data or provide a user interface. The "C" code in these sections is included without changes into the SIMPLEXYS inference engine.

Rules

Section 6 starts with the keyword RULES. The SIMPLEXYS rules must be inserted here; they consist of:

Rule header; mandatory

First comes the symbolic name for the rule. This 'name' consists of alphanumeric characters (numbers are allowed but not recommended) and underlined characters (except in first position). Each rule has a unique name, followed by the character ":", followed by a text string that is used in questions to show results and for explanations. The text may be empty, but it must be surrounded by quotes.

Rule type; mandatory

This is the actual body of the rule. It specifies either one of the 5 primitive rule types, or a composite rule (paragraph 6.3.3). In case of primitive rules, the body starts with one of the following special symbols:

-. FACT, which returns the value of a previously acquired fact with value TR, FA or PO (note: the result of a FACT rule evaluation never changes). FACT rules have no arguments.

-. ASK, which returns the value of the answer of a question to the user, with value TR, FA or PO; ASK rules have no arguments.

-. TEST; TEST rules provide a 'hook' to "C" code. If the remainder of the line is not empty, it is used to specify one valid programming statement, which assigns a value of type bool (paragraph 6.3.3) to the reserved symbolic name TEST (return only TR, FA or PO). If the code is to consist of more than one statement or if a single statement is too long for a single line, as many lines as needed can be used if TEST appears on a line by itself; the code is then started on a new line and ended by a line with the

word ENDTEST. In order to keep the statements simple, the default result is FA. TEST rules provide for input from external devices and data sources (measurement equipment, data bases and such); or:

BTEST (for Boolean TEST); a BTEST rule is just a TEST rule with a simpler syntax. The remainder of the line is used to specify a valid boolean expression, which, if true, assigns a value TR to the symbolic name TEST; otherwise it returns the value FA.

-. MEMO, which returns the value that was defined in an INITIALLY or subsequently changed by a THELSE in a previous run [Note: THELSE's that assign a value to MEMO rule evaluations do not take effect immediately so that the conclusion of MEMO rules remain consistent during a run; the new value will actually be assigned at the end of the run]. MEMO rules have no arguments.

-. STATE, which returns the value that was defined in an INITIALLY or subsequently changed by a state change (ON statement). STATE rules provide a context memory and can have a value of only TR or FA. STATE rules have no arguments.

Apart from these primitive rule types, the rule body can also consist of a combination of rules:

-. An expression to use in the evaluation of a rule; the expression consists of rule names and operators and cannot be longer than a single line. These composite rules combine the results from the primitive rules and operations on them into more complex expressions.

Initial value; optional

The keyword INITIALLY followed by the initial value (TR, FA or PO) of the rule for the first run. STATE rules can be initialized to FA or TR only (it is not logical, and hence forbidden, not to know the analysis context). By default, unless

overridden by an INITIALLY, FACT and MEMO rules are initialized to PO, STATE rules to FA and ASK, TEST and composite rules to UD.

THELSE's; optional

The next part of a rule allows multiple consequences from a single rule evaluation. Each line starts with either THEN (applied if the rule evaluates to TR), ELSE (applied if the rule evaluates to FA) or IFPO (applied if the rule evaluates to PO). These THELSE's are followed by TR, FA, PO, DO or GOAL; THELSE's must be the first symbol on a line.

a. THELSE TR/FA/PO takes as argument(s) other rules, except FACT and STATE rules.

b. THELSE GOAL takes as argument(s) other rules, except FACT, MEMO or STATE rules.

c. THELSE DO provides a 'hook' to "C" code. It is followed by one or more legal statements that are executed if the rule is evaluated to TR (THEN DO), FA (ELSE DO) or PO (IFPO DO).

Process definitions

Section 7 is mandatory and starts with the keyword PROCESS. The Rule Compiler recognizes the start of this section by the keyword PROCESS, which must be first symbol on a line. Section 7 describes the dynamics of the process. State transitions are inserted here. Each has the format:

ON *tr* FROM *s1* TO *s2*

where *tr* is a rule (but not a STATE rule);
s1 is a non-empty STATE rule list;
s2 is a STATE rule list (A "*" denotes the empty list).

Rule *tr* is called the *trigger*. A state change takes place if all STATEs in *s1* are active **and** if *tr* evaluates to TR. On a change of state all STATEs in *s1* become inactive and all STATEs in *s2* become active. Note that *s2* can be the empty list. An empty list is denoted with a "*". When the system starts up, all STATE rules that have an INITIALLY TR are active. The expert system halts as soon as no STATEs are active.

Example

```
00    DECLS
01
02    real flw_min, low_threshold = 0.5;
03
04    void message( char mess_text )
05    begin
06      printf( "%s",mess_text );
07    end;
08
09    INITG
10    {put all the global initialization code here}
11    {executed only once}
12
13    INITR
14    {run initialization code here}
15    {executed every run}
16
17    RULES
18    EXIT: 'exit the expert system program'
19    BTEST keypressed
20
21    RUNNING: 'The breathing circuit expert system is running'
22    STATE
23    INITIALLY TR
24    THEN GOAL: INCOMP_EXP_VALVE
25
26    INCOMP_EXP_VALVE: 'There is an incompetent expiratory valve'
27    FLW_MIN_DOWN AND REVERSE_FLOW
```

```
28      THEN DO message('Incompetent expiratory valve');
29
30      FLW_MIN_DOWN: 'There is reverse flow'
31      BTEST (flw_min =< low_threshold)
32
33      PROCESS
34      ON EXIT FROM RUNNING TO *
35
```

line 00: The code in the DECLS part is "C" code with the procedures and "C" variables definition.

line 09: The "C" code in the INITG part is executed only when the expert system program is started.

line 13: The "C" code in the INITR part is executed when a new run of the expert system is started. The expert system program executes continuously until the exit rule evaluates to true.

line 17: The RULES part contains the SIMPLEXYS rules with the knowledge. If the conclusion of the exit rule evaluation becomes true the program stops looping. In the running rule the goal of the expert system is defined. The inference engine evaluates the goal rule.

line 19: BTEST is a boolean test which returns the evaluation of the test that follows.

line 23: Initially all the rules are tagged as UD. With the INITIALLY keyword a conclusion of a rule evaluation can be assigned an initial value rather than tagged as UD.

line 28: THEN DO is used if an action has to be performed when the conclusion of the rule is true.

line 33: The PROCESS section describes the dynamics of the rule evaluation process.

line 34: When conclusion of the exit rule is true, the system stops. The "*" denotes the empty list.

Much of the previous discussion was based on J.A. Blom's Ph.D. dissertation: (The SIMPLEXYS experience. Real Time Expert Systems for Patient Monitoring) (Blom 1990). For an in-detail description of SIMPLEXYS, we refer to his dissertation.

6.5. SIMPLEXYS and the Intelligent Alarm Project Requirements

SIMPLEXYS was designed to be as efficient as possible in order to allow implementation of real time expert systems in which a limited period of time is available for evaluation of the conclusions. The efficiency of SIMPLEXYS is due mostly to the facts that no searching is necessary and that the conclusion if the rules are calculated only once per run. As soon as the conclusion of a rule (a sub-conclusion) is known, this value is stored and used whenever the rule is called again.

6.5.1. Real Time Performance

The efficiency of SIMPLEXYS code is due to several factors. First, rules are evaluated only once per run. This means that each node of the problem network is traversed once at most, preventing an explosion of the search space. Evaluation takes linear time. Once a rule is evaluated, its consequence is stored and reused whenever the rule would otherwise need to be called again. Rules are evaluated only in their relevant context. The script specifies which rules are evaluated in which context. Rules can have multiple consequences, allowing the evaluation space to be effectively pruned. In addition, the use of the operators AND, OR and ALT in evaluation rules provide conditional evaluation preventing unnecessary work.

Data are stored into known memory locations, not lists; there is no searching for data. Also, the links between rules are compiled; there is no searching for rules to be evaluated next.

Compared to LISP and PROLOG, the usual expert systems implementation languages, "C" is a very efficient language.

6.5.2. Linkage with Other Software

SIMPLEXYS was designed for such real-time applications as monitoring. Data acquisition, interrupt-driven data communication, display of real time waveforms, and any type of user interface are integral capabilities of SIMPLEXYS. Data structures, procedures, and other valid statements in "C" can be incorporated. The DECLS, INITG, INITR, EXITR, and EXITG provide for this (paragraph 6.3.3). The utility of SIMPLEXYS in a real-time environment other than the intelligent alarm system was demonstrated in a rule-based blood pressure controller using SIMPLEXYS (Hoogendoorn 1989, Blom 1990).

6.5.3. Temporal Reasoning

A *static environment* is defined as an environment in which the data to be analyzed are fixed. Thus, the conclusion of all rules, when (or if) evaluated, will likewise be fixed and unique. In a static environment more than one conclusion (GOAL rule) may need to be evaluated. Each evaluation of a goal is called a sub-run, a complete set of sub-runs is called a run. Rule values cannot change during a run (except from UD into TR, FA or PO); thus, during a run the environment is static.

A *dynamic environment* is defined as an environment in which the data change and the conclusions of the primitive rules are not necessarily constant. For example, the conclusions of TEST and ASK rules can change when new data requiring analysis become available; the conclusions of MEMO or STATE rules can change if new facts need to be remembered or old facts obtain a new value. A new evaluation dictates a new run. A dynamic environment, thus, requires a sequence of runs.

The SIMPLEXYS inference engine is designed to work within a static environment for only in a static environment can we guarantee the consistency of the conclusions of all rules. Therefore a dynamic environment must be translated into a **sequence of *static* environments**. This is possible only if new data do not arrive too quickly, i.e., while previous data still are being analyzed. If the data arrive at irregular intervals, buffering of the data may provide a solution.

7. IMPLEMENTATION: PROTOTYPE I

Our goals to aid the clinician in the early detection and diagnosis of possible critical incidents concerning ventilation of anesthetized patients have been defined, and an approach toward a solution is selected. Now an analysis of complications by the clinician guides the implementation. This analysis of such concerns as hypoxemia, apnea, and hypoventilation point out that causes of respiratory system problems can originate inside the patient, or be iatrogenic or machine related. Problems with ventilation occur when difficulties arise with the delivery of a gas mixture to the lung, the gas exchange in the lung, or the transport of gas throughout the body. The differential diagnosis tells the clinician where to find the cause and how to correct the problem (Chapter 5). In this project, circulation is not the area of primary interest and we will assume, that circulation is intact. The delivery of a gas mixture to the lung requires that a sufficient volume of gas, with constituents in appropriate concentrations, can participate in the gas exchange. Inappropriate inspired gas mixtures can result from machine malfunctions or unsuitable gas concentrations. Insufficient lung ventilation in terms of inspired gas volumes can result from machine and equipment defects, misplacement of the endotracheal tube (ET), or an unsuitable selection of inspired volumes. Anesthetic equipment related defects include problems with the ET, breathing circuit, ventilator, anesthesia machine and gas supply. The recognition of machine-related defects requires knowledge and understanding of the equipment.

One strategy to manage the problem, is to partition the project into smaller, well-defined portions. This allows an incremental implementation, while preserving all essential phases of the implementation cycle: pertinent knowledge acquisition, data acquisition, and construction and evaluation of a working prototype.

The implementation of the prototype system, which concentrates on the integrity of the circle anesthesia breathing circuit during *mechanical* ventilation is described in this chapter. The implementation of this prototype demonstrates the applicability and feasibility of the approach, and supplies the platform for expansion.

7.1. Knowledge Acquisition

This section describes possible problems with the circle anesthesia breathing circuit and means to monitor the breathing circuit toward detection of the problem (Refer to figure 2.2).

7.1.1. Breathing System Problems

Possible problems with the circle anesthesia breathing circuit have been well described. Because of the large number of connections integral to the system, there is always a risk of incorrect assembly (Sellery 1972, Goldman 1987). The number of connections also increases the possibility of disconnections, which disrupt ventilation of the patient.

Leaks have been described (Colavita 1985, Ferderbar 1986, Lamarche 1985, Ripp 1985, Raja 1986, Cooper 1987). Most frequently, a leak develops at a point where parts of the system are interconnected. A connector may crack and develop a leak, the inflatable plastic cuff at the end of the ET tube may be inflated insufficiently or, particularly in rubber hose, a crack may develop over time. A small leak may not have serious consequences, but is nevertheless undesirable: a leak may eventually become a disconnection. Another concern is that a leak may result in hypoventilation either because part of the tidal volume (V_T) is not delivered to the patient, or because expired gas is allowed to bypass the carbon dioxide (CO_2) absorber, effectively reducing ventilation.

In the circle breathing system, CO_2 is removed chemically with the CO_2 absorber. Inadequate absorption caused by an improperly packed absorber allows the gas mixture to pass through the absorber without complete absorption of CO_2 (this is also called channeling) (Dorsch 1975). Also, an exhausted absorbent can result in CO_2 retention in the breathing circuit. In either case, the resulting inspired CO_2 levels affect the patient's partial pressures of arterial CO_2 and alter the requirements for ventilation. Another

cause of increased inspired CO_2 levels is valve insufficiency (Pyles 1984). The most commonly observed problem with the unidirectional valves is incompetence, in which flow reverses trough the valve. Valve incompetence can be the result of electrostatics, foreign material, or humidity in the circuit. As with inadequate absorption or exhausted absorber, valve insufficiency can lead to rebreathing of CO_2.

Kinked, or otherwise obstructed inspiratory or expiratory limbs of the breathing circuit have been reported (Frankel 1983, Roelofse 1984). If excessive pressures are allowed to develop as a result of obstructions or defective valves in the breathing circuit, pneumothorax, pneumoperitoneum, and subcutaneous emphysema may result (Gravenstein 1959, Henzig 1982, Roth 1986). Obstructed tubes also can impair the free flow of gas to or from the patient, making it virtually impossible to ventilate the patient (Springman 1986).

Problems with the anesthesia machine as a whole have also been reported (Childres 1982, Klein 1982, Abraham 1987). Leaks can develop, and mechanical failure impairing the delivery of fresh gas flow (FGF) to the breathing circuit or allowing hypoxic mixtures to exit from the machine have been observed.

The mechanical ventilator is yet another source of potential problems (Ripp 1985, Myerson 1986). Failure to cycle because of an electrical or mechanical failure, and failure to occlude the ventilator pop-off valve thereby allowing part or all of the V_T to escape, are some examples.

Finally, a number of untoward events can be attributed to human error. In this category, we include inadequate fresh gas flow (FGF) settings, selection of hypoxic mixtures, wrong gas in the hospital piping system, and failure to check for adequate amounts and composition of gas in the backup tanks.

7.1.2. Monitoring the Breathing System

In a system where gases flow under the influence of pressure differences and gas exchange takes place, it seems reasonable to measure the pressure, flow, and gas composition in the breathing system during the respiratory cycle. Currently accepted monitoring standards and clinical practice require measurement of the capnogram. Capnographs display maximal exhaled and minimal inhaled values in addition to the waveform, which is a desirable feature (Block 1988b, Gravenstein 1989a). The gas sampling site of choice is close to the patient's mouth, most commonly between the ET tube and the Y-piece (Gravenstein 1989a).

Airway pressure is also commonly monitored, both to prevent excessive pressure from developing in the breathing circuit and as an indicator of a lack of pressure in the circuit (which could signal a possible disconnection). An airway pressure waveform is not commonly displayed, however.

Measurement of gas volumes delivered to and exhaled by the patient could indicate adequacy of ventilation. Expired volume values are considered an adequate indicator that at least the expired volume was delivered to the patient; however, during ventilation using small tidal volumes a disconnection may go undetected (Gravenstein 1990a). In current clinical practice, expired volumes are monitored not frequently, while monitoring of the flow waveform is very uncommon.

The adequacy of the oxygen (O_2) concentration is assessed with an O_2 analyzer. The majority of the commercially available units are based on principles that have a response time of, typically, 90% of the total change in O_2 concentrations in many seconds, which makes it impossible to monitor breath by breath both inspired and expired concentrations. Mass spectrometers have been used to measure O_2 as well as CO_2, nitrous oxide (N_2O), nitrogen and halogenated agents. However, cost has made time sharing of the device among several operating rooms a necessity (Severinghaus 1978). Advances in technology are making available dedicated monitoring units, that allow measurement of both inspired and expired concentrations (Van Wagenen 1986).

A typical setup of monitors measuring the capnogram at the end of the ET tube, airway pressure and inspired O_2 concentrations in the inspiratory hose of the circuit, and expiratory volume (expiratory flow integrated over time) in the expiratory hose, will produce waveforms as shown in figure 7.1.

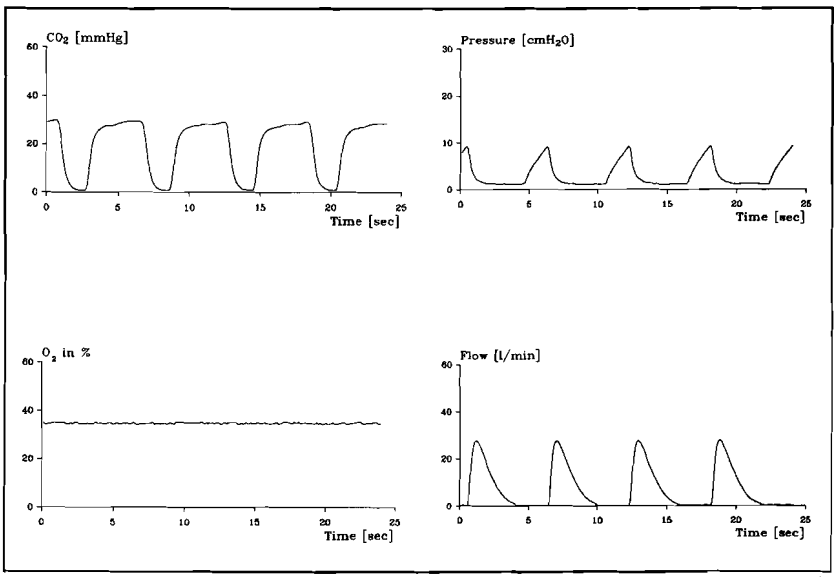

Figure 7.1 Real time waveform of CO_2 (top left), Airway Pressure (top right), Inspiratory O_2 (bottom left), and expiratory Flow (bottom right).

During forced mechanical inhalation, a pressure higher than lung pressure causes gas free of CO_2 to flow through the inspiratory hose toward the patient's lungs (figure 2.2). The build-up of airway pressure depends on the characteristics of the lung. As a first approximation, the lungs can be seen as a series resistor/capacitor network, with a time constant of about one second. During inspiration, the pressure increases linearly with a constant flow pattern generated by the ventilator. When the positive pressure is removed,

the lungs are allowed to empty passively as the lungs elastic recoil forces gas out of the lungs (Figure 7.1 top right). First gas not participating in the gas exchange (dead space gas) that is free of CO_2 will flow through the expiratory limb toward the ventilator and be followed by the appearance of CO_2. Quickly, the CO_2 concentrations increases to a plateau approximately equal to alveolar CO_2 concentration (figure 7.1 top left). The shape of pressure and flow waveform is determined by the time constant which depends on the lungs and breathing circuit characteristics. Much like the discharge of a capacitor via a resistance, an exponential decay is observed. During the entire respiratory cycle, the O_2 analyzer indicates constant inspiratory O_2 concentrations (Figure 7.1 bottom left).

During mechanical malfunctions of the breathing system, the shape of the CO_2, pressure and flow waveform is affected. The examination of the waveforms can be automated. Our thesis is, that the combination of shape changes are indicative of both the type of malfunction and its location.

7.1.3. Summary

The emphasis in the development of the first prototype is on the early detection of malfunction in the circle anesthesia breathing circuit from the CO_2, pressure, and flow signals. These common, yet infrequently, observed malfunctions include obstruction, leak, disconnect, valve insufficiency, and exhausted CO_2 absorber (Table 7.1).

Malfunctions alter the shape of signals monitored in the circle breathing circuit. Feature extraction from these signals followed by feature analysis and intercorrelation of features in real time is the method of detection.

7.2. From Knowledge to Signals

Detecting breathing circuit malfunctions from the CO_2 waveform has been attempted before. Smalhout described in his atlas a number of typical waveforms under a variety of circumstances (Smalhout 1981). Van Genderingen et al. showed that some

Table 7.1 List of Possible Malfunctions in the Circle System (refer to fig 2.3)

1. Leaks and Disconnections at the following locations:

   Ventilator hose
   Inspiratory hose
   Expiratory hose
   Y-piece/ET tube connection
   ET tube cuff
   Fresh Gas Flow inlet

2. Obstructions at the following locations:

   Inspiratory hose
   Expiratory hose
   Endotracheal tube
   Scavenger System

3. Valve malfunctions:

   Incompetent Inspiratory Valve
   Incompetent Expiratory Valve
   Ventilator Pop-off Valve

4. Exhausted CO_2 absorber

malfunctions can be detected automatically with a computer-based data acquisition and signal analysis system based solely on an analysis of the capnogram. However, they recommended that other signals, such as airway pressure, also be included (van Genderingen 1987).

Rader et al. developed a prototype expert system CAPS that classifies capnograms most likely to arise during surgery into categories (normal, equipment malfunction, rebreathing, and so on) but does not elaborate on a possible cause (Rader 1987). They also recommended pressure and flow be included in concert with real time respiratory gas analysis.

Takami and van der Aa developed a computer model of the circle anesthesia breathing system to allow the study of its behavior during normal operation and during a number of malfunctions (Takami 1987, van der Aa 1989). Based on this computer model and laboratory experiments, a system using the CO_2, pressure, and flow waveforms measured simultaneously with an integrated sensor at the Y-piece was developed to evaluate the integrity of the circle system (van der Aa 1987). A total of 12 malfunctions were investigated including obstruction, disconnection, incompetent valve, exhausted CO_2 absorber, and leaks in different locations. This analysis showed that it was possible to distinguish 5 clusters of malfunctions: 1 cluster with 3 malfunctions, 2 clusters with 2 malfunctions, and 2 clusters with a single malfunction. Despite the fact that it was not possible to differentiate among malfunctions within a cluster, this study showed that useful messages can be generated that not only reveal the existence of a problem but also help localize it. Using a different signal analysis and feature extraction technique developed specifically in the framework of this research, Bastings reported similar results also with an integrated CO_2, pressure, and flow sensor at the end of the ET tube (Bastings 1989).

Although the use of one integrated sensor is considered to be an advantage, results from previous studies suggest alternative sensor placement. In addition, a small, inexpensive, lightweight, integrated sensor is not yet within reach given current technology. Ideally, one would like to locate pressure and flow sensors in both inspiratory and expiratory limbs to maximize the amount of information, but adding additional sensors may not be practical or cost effective; plus, adding sensors increases the possibility of a sensor failure. Experience gained during the development of the Gainesville Anesthesia Simulator (Good 1988, Hekker 1989) indicates that the utility of the "standard" sensor placement (CO_2 at the end of the ET tube, airway pressure in the inspiratory limb, expired volume in the expiratory limb) during clinical practice is suitable to detect malfunctions in the breathing circuit. Given these arguments, we chose to use to measure CO_2 at the end of the ET tube, airway pressure at the patient site of the inspiratory valve, and flow at the patient site of the expiratory valve. In addition, to minimize

additional cost and maximize clinical utility, we elected to use commercially available monitoring equipment.

7.3. Implementation

Schematically, the implementation is divided into data acquisition, signal processing, feature extraction and rule evaluation (figure 7.2). After each run of the expert system, a message, possibly an alarm message, is generated. This design was proposed and implemented (van Oostrom 1989, 1989b) based on signal processing routines developed earlier (Bastings 1989).

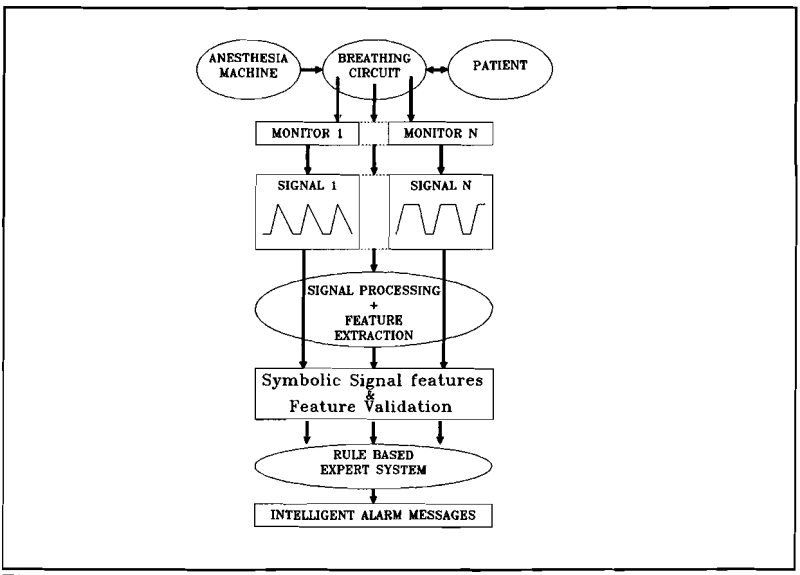

Figure 7.2 Data flow in prototype I of the Intelligent Alarm System.

The three real time signals measured in the breathing circle, airway pressure, expiratory flow, and the capnogram (see paragraph 7.2) are processed and translated into features. Subsequently, these features are transformed into symbolic values and passed on into the

real time expert system at the end of each respiratory cycle. The expert system evaluates and combines the feature data derived from the different signals, identifies changes in this data set, reaches a conclusion about the status of the breathing circle, and presents an indication about mechanical malfunctions that have occurred, together with their most probable site.

7.3.1. Data Acquisition and Signal Processing

Table 7.1 defined a list of malfunctions that could occur in the circle system and, thus, need to be detected by the alarm program. Standard monitors are used to obtain the waveforms. The analog signals from the airway pressure monitor and the capnograph are converted by an analog to digital (AD) convertor into sampled versions of the signals. A real time flow signal is created by counting the number of revolutions of a vane, which is part of a commercial available volume monitor, is inserted into the path of the flow in the expiratory limb of the breathing circuit. The expiratory flow causes the vane to rotate and with each revolution an electrical pulse is generated which can be counted. With each pulse representing approximately 3 ml. of gas, and the number of pulses per time unit the flow waveform can be represented (van Oostrom 1989a). A sampling frequency of 20 Hz is used for each signal. The samples serve as input to the signal processing software.

7.3.2. From Signals to Signal Features

A breath detection and feature extraction algorithm is implemented for all three signals, which divides one (respiratory) period of each signal into individual "phases." The concept is illustrated using the airway pressure signal as an example (figure 7.3).

The pressure signal is divided into four phases, up stroke, maximum, exponential expiratory decay, and end-expiratory pressure value. The algorithm uses adaptive upper and lower threshold values to detect when a signal switches from one state to another (Bastings 1987). With each sample, the algorithm checks the signal state and updates

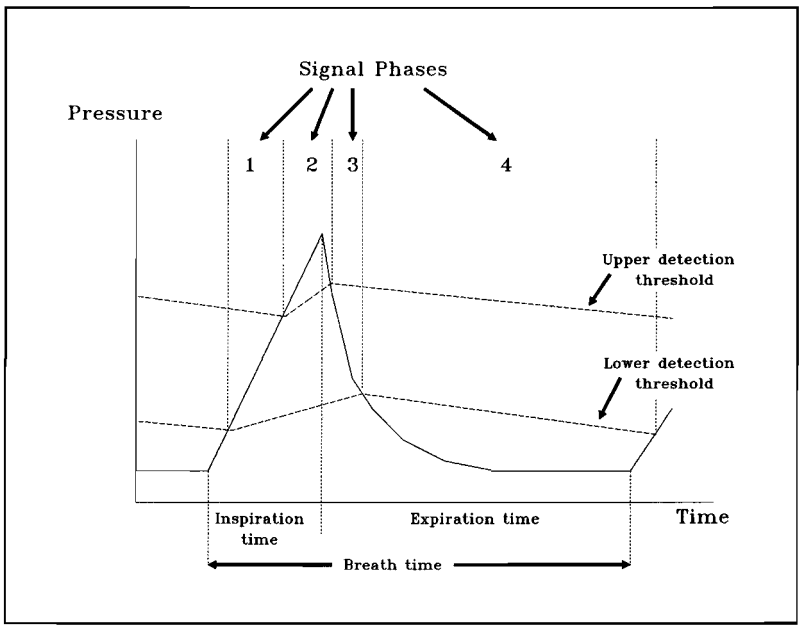

Figure 7.3 The pressure signal divided into several phases.

one or more variables that characterize the signal during the appropriate signal state. For the pressure signal, the features that are updated include; in state 1, the pressure derivative (P_{slope}); in state 2, the maximum pressure (P_{max}); in state 3, the time constant of the down stroke (T_P); and in state 4, the minimum pressure (P_{min}). Other calculated features include inspiratory time, expiratory time and total breath time (figure 7.3). Similar analysis is performed on the CO_2 and flow signals.

When a new breath is detected for each of the three signals, a complete set of numerical "features" is available for each signal. The features for the CO_2 signal include inspired CO_2 level (P_iCO_2), end-tidal CO_2 level ($P_{et}CO_2$), timing features, values of the expiratory up slope and inspiratory down stroke and the "plateau" time. Apart from

timing features, the flow features are, maximum flow (F_{max}), minimum flow (F_{min}), the time constant of the expiratory down stroke (T_F), and V_T. The latter variable is calculated by integrating the positive part of the flow curve during one respiratory period. All available features are summarized in table 7.2.

Table 7.2 List of Extracted features

CO_2:		
CO_2_INS	Inspired CO_2 partial pressure	[mmHg]
CO_2_EXP	Expired CO_2 partial pressure	[mmHg]
CO_2_B_TIME	Respiratory time	[sec]
CO_2_DO_TIME	Inspiration time	[sec]
CO_2_EXP_T	Expiration time	[sec]
CO_2_UP_STR	CO_2 up stroke	[mmHg/sec]
CO_2_DO_STR	CO_2 down stroke	[mmHg/sec]
Airway Pressure:		
PRS_MIN	Minimum airway pressure	[cmH_20]
PRS_MAX	Maximum airway pressure	[cmH_20]
PRS_B_TIME	Respiratory time	[sec]
PRS_INS_T	Inspiration time	[sec]
PRS_EXP_T	Expiration time	[sec]
PRS_SLOPE	Pressure up slope	[cmH_20/sec]
PRS_T_CONST	Time constant down stroke	[sec]
Flow:		
FLW_MIN	Minimum expiratory flow	[Liter/min]
FLW_MAX	Maximum expiratory flow	[Liter/min]
FLW_B_TIME	Respiratory time	[sec]
FLW_INS_T	Inspiration time	[sec]
FLW_EXP_T	Expiration time	[sec]
FLW_EX_VOL	Expired volume	[Liter]
FLW_T_CONST	Time constant down stroke	[sec]

Many of the derived features are subject to a validation process. For example, slopes and time constants are valid only if the calculation is based on a minimum of six samples. The current time for one respiratory cycle must be within ± 20% of the previous cycle. If no new breath is detected within this time span, the signal is declared invalid and a time-out flag ("no breath detected") is set. Also, all of its features are considered invalid for that respiratory period.

When all the numerical feature values are available the inspiration and expiration times of the three signals are compared. If data from one signal vary more than 20% from the variables from the other two, the signal and corresponding features are retroactively declared invalid (see also 7.3.3).

7.3.3. From Features to Symbolic Data

The expert system uses symbolic rather than numeric data. Therefore, the calculated numerical features are translated into a symbolic format. In his description of Ventilator Manager (VM), Fagan introduced concepts as acceptable, stable, abnormal, and so on (Fagan 1980). Our translation of feature values into a symbolic format is less extensive. Features are either not valid (NV), unchanged (UC), up (UP), or down (DN). Features are considered invalid, when the signal processing routines are unable to calculate correctly a feature, or when the input signal contains artifacts making it impossible for the signal processing routines to identify correctly the signal phases (paragraph 7.3.2). Invalid features are assigned the symbolic value "NV" (Not Valid). Valid feature values are assigned a symbolic value based on a comparison with a "feature baseline." The feature baseline is a running average of the feature value when the signal is accepted as normal. In the first prototype implementation, the feature baseline is set with a "RESET BASELINES" button. This button must be pushed when the operator considers the signals stationary and acceptable as normal. At that moment all baselines will be reset to the current running average of the feature value, assuming that no

malfunction is present. Subsequently, deviations from these baselines are identified and classified.

A separate low and high threshold is defined for every feature. The zone between upper and lower threshold is called the normal band for that feature. For example, assume a default baseline value for the maximum flow of 600 ml/sec. When the low and high thresholds for the maximum flow feature are set to 30% and 20% respectively, the normal zone will be the band between 420 and 720 ml/sec. To prevent the normal band from becoming too small, an absolute minimum value of this band is defined for each feature. This is particularly useful for features inherently close to zero, like minimum flow or inspired CO_2.

Each valid feature is assigned a symbolic value that is based on the low and high thresholds. These values range from "UC" (UnChanged) when the feature value is within the normal band, to "UP" (Up) with the feature value above the upper threshold, to "DN" (Down) when the feature value is less than the lower threshold. The set of symbolic values ("UP", "DN", "UC", "NV") serves as input to the expert system after each respiration.

7.3.4. From Features to Rules

For every malfunction in the breathing circle to be detected, a SIMPLEXYS (see Chapter 6) rule describes how different feature values behave, compared to their baselines, when this malfunction occurs. To analyze this behavior during normal operation and during mechanical malfunctions, recordings were made using the Gainesville Anesthesia Simulator. The extracted signal features during a malfunction were compared to the malfunction-free situation. For example, the change in a number of features during an incompetent inspiratory valve is examined (figure 7.4). The rule set used in the first prototype was built based on the feature analysis and discussions with anesthesiologists, who indicated the behavior of a unique combination of features defining a mechanical malfunction.

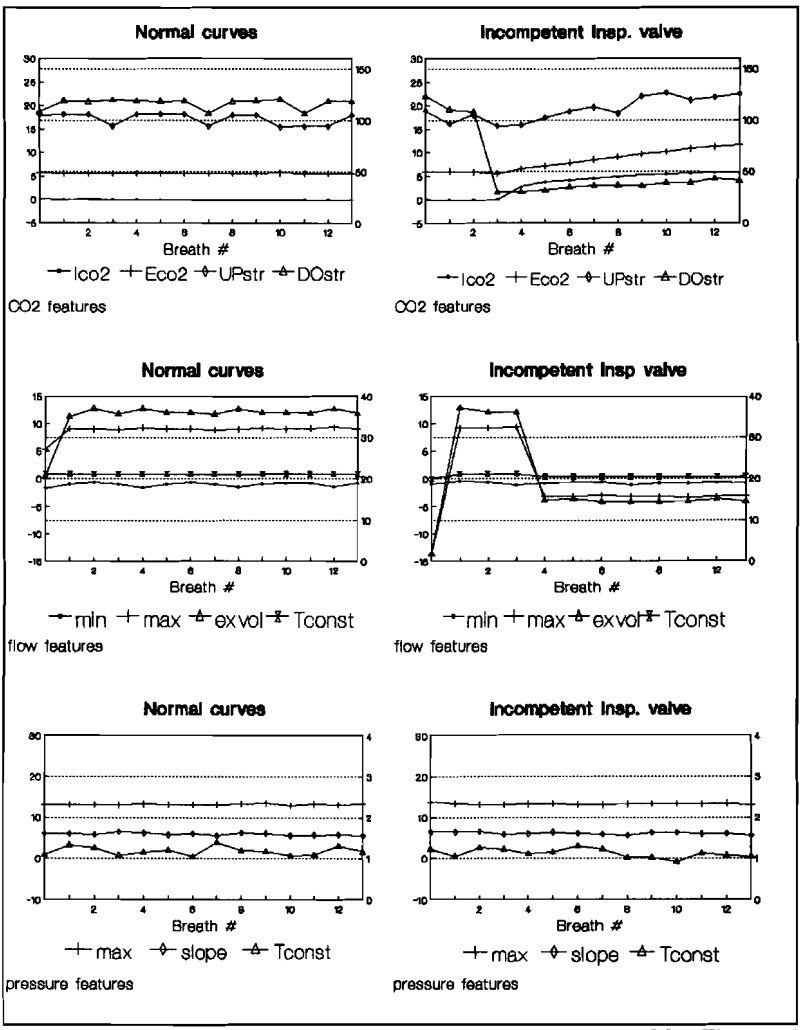

Figure 7.4 Normal vs Incompetent Inspiratory Valve features of CO_2, Flow, and Pressure.

As an example, the rule for the incompetent inspiratory valve will be examined in more detail. First, changes in features during the valve insufficiency compared with the normal situation reveal a decrease in the slope of the CO_2 down stroke, no affect on the pressure features, and a marked decrease in both peak expiratory flow and expired volume (figure 7.4). The decrease in peak flow and expired volume is explained easily realizing that an alternative path for the expiratory flow through the inspiratory limb has opened up (figure 2.2). The CO_2 down stroke change is explained realizing that part of the (CO_2 rich) expired volume will invade the inspiratory limb, which, with the next inspiration, will be part of the inspired volume. The CO_2 rich content of the inspiratory limb causes the prolonged downstroke in the CO_2 waveform and rebreathing of CO_2 during inspiration. Since no gas escapes from the closed system, no change in pressure waveform features can be observed. Thus, the rule for the incompetent inspiratory valve can be phrased as: a decrease in peak expiratory flow and expired volume combined with a prolonged down stroke of the CO_2 waveform. Translated into SIMPLEXYS, the incompetent inspiratory valve rule could be implemented like this:

```
INCOMP_INSP_VALVE: 'Rule for incompetent inspiratory valve'
EXPIRED_VOLUME_DOWN AND PEAK_EXPIRED_FLOW_DOWN AND
CO2_DOWNSLOPE_DOWN
```

This rule, in its present form is not suitable to detect the intended malfunction, however. A leak on the patient site of the inspiratory valve where the inspiratory limb connects to the valve, will also reduce the expired volume, the peak expiratory flow, and cause a prolonged CO_2 down stroke. However in case of the leak, the peak airway pressures is reduced. Our extendeded inspiratory valve malfunction rule takes the unchanged airway pressure into account:

INCOMP_INSP_VALVE: 'Rule for incompetent inspiratory valve'
EXPIRED_VOLUME_DOWN AND PEAK_EXPIRED_FLOW_DOWN AND CO2_DOWNSLOPE_DOWN AND PRS_MAX_NORMAL

In the first prototype the complete rule for the incompetent inspiratory valve adds the feature that the direction of the expiratory flow is not affected during this malfunction to assure uniqueness. The implemented rule looks like:

INCOMP_INSP_VALVE: 'Rule for incompetent inspiratory valve'
EXPIRED_VOLUME_DOWN AND PEAK_EXPIRED_FLOW_DOWN AND CO2_DOWNSLOPE_DOWN AND PRS_MAX_NORMAL AND NOT REVERSE_FLOW

A complete example of the inspiratory valve malfunction rule base concept implemented in SIMPLEXYS rules is presented in table 7.3.

7.3.5. From Software to Hardware

The data acquisition, signal processing, feature extraction and validation, and expert system were implemented on an IBM, Personal Computer (PC) AT compatible (Tandy 3000) running at a clock frequency of 8 MHz with a numerical co-processor and an EGA high-resolution monitor. The analog signals from the capnograph and the airway pressure monitor are converted to digital numbers using a Data Translation 2811 Analog to Digital (A/D) converter board. The resolution of the A/D converter is 12 bits. All real time analog signals were sampled with a frequency of 20 Hz. Table 7.4 lists the monitoring equipment and the anesthesia ventilator equipment used in the implementation.

The software routines responsible for the data acquisition, signal processing, feature extraction, data presentation, and so on are written in the Microsoft "C" programming language. The expert system used in the implementation was the "C" version of the

Table 7.3 Examples of Expert Systems Rules

```
INCOMP_INS_VALVE: "Incompetent inspiratory valve"
FLW_EXP_VOL_DOWN AND FLW_MAX_DOWN AND
CO2_DO_STR_DOWN
AND PRS_MAX_NORMAL AND NOT FLW_REVERSE

FLW_EXP_VOL_DOWN: "Expired volume down"
BTEST (FLW_EX_VOL.stat == DN)
THEN FA: FLW_EXP_VOL_NORMAL

FLW_EXP_VOL_NORMAL: "Expired Volume normal"
BTEST (FLW_EX_VOL.stat == UC)
THEN FA: FLW_EXP_VOL_DOWN

FLW_MAX_DOWN: "Maximum peak expired flow down"
BTEST (FLW_MAX.stat == DN)

FLW_REVERSE: "Reverse Expiratory Flow"
BTEST (FLW_MIN.stat == DN)

CO2_DO_STR_DOWN: "CO2 downstroke prolonged"
BTEST (CO2_DO_STR.stat == DN)

PRS_MAX_NORMAL: "Maximal airway pressure unchanged"
BTEST (PRS_MAX.stat == UC)
```

SIMPLEXYS toolbox.

7.3.6. About Software, Hardware, and Rules

Prototype I was implemented using the "C" programming language and the SIMPLEXYS toolbox. The SIMPLEXYS rule base consisted of a grand total of 102 rules. Less than 50% of the rule base (46) consisted of composite rules (paragraph 6.3.4), while the remaining 60 rules provided a "hook" to the "C" code through TEST rules (paragraph 6.3.4). Tests conducted with this system using a respiratory rate of 10

Table 7.4 Hardware Used.

Computer	:	IBM AT compatible, 8 MHz, co-processor installed
Monitor	:	EGA or VGA High Resolution Graphics Monitor
AD-board	:	Data Translation 2811
Anesthesia machine	:	Ohmeda Modulus II
Ventilator	:	Ohmeda 7810 Mechanical Ventilator
Flow signal obtained from	:	Ohmeda 5410 Volume Monitor
Pressure signal from	:	Ohmeda 5500 Airway Pressure Monitor
CO_2 signal from	:	Ohmeda 5200 CO_2 Monitor

breaths/min indicated that our PC, running at 8 MHz, but equipped with a numerical co-processor, occupied the available processing power for about 14%. This result was obtained by assessing the time spent, per breath, executing signal processing code, and in evaluating rules. Since these totals were obtained with recorded data, these numbers do not include overhead for AD data acquisition and serial communication. Time required for screen output was also not included in these results.

Figure 7.5 shows the test results per sample obtained with a respiratory rate of 10 breaths/minute. From these results we deduce that one expert system run takes about 160 msec.

The memory requirements of the system for the prototype totalled 112 KBytes (1 Kbyte = 1024 bytes) of available memory.

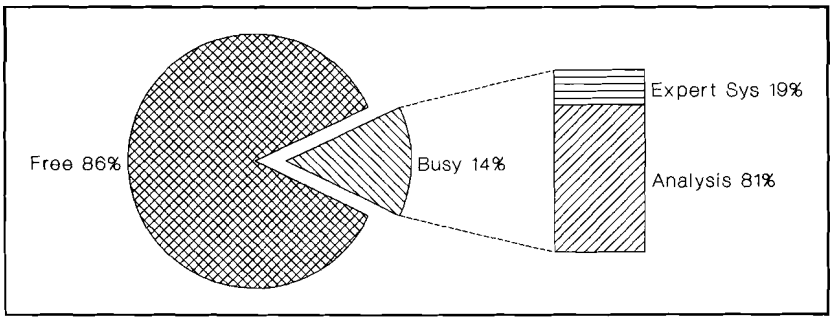

Figure 7.5 Processor load per sample

7.4. Tests and Evaluation

The system described in paragraph 7.3 has been tested in a clinical environment as well as with the Gainesville Anesthesia Simulator. The protocol and the test results are presented in the next sections.

7.4.1. Simulator Testing

Before testing the system in the operating room (OR), its performance was tested on the Gainesville Anesthesia Simulator (GAS) (Good 1988, Hekker 1989). The GAS reproduces the working environment of the anesthesiologist while a number of anesthesia machine and breathing circuit malfunctions can be introduced reproducibly. Toward this end, a regular anesthesia machine (Ohmeda Modulus II) was equipped with actuators, bypass valves, and sensors, that can be manipulated under computer control to introduce a malfunction. A mechanical lung was ventilated using a standard breathing circuit and ET tube (Nederstigt 1989). CO_2 is introduced into the lung to simulate the CO_2 production of the patient. Since the malfunctions our prototype is to detect cannot be introduced during real anesthesia without endangering the patient, the simulator is the ideal (safe) testing ground for the Intelligent Alarm System.

The simulator setup and locations of the sensors used by our system are schematically pictured in figure 7.6.

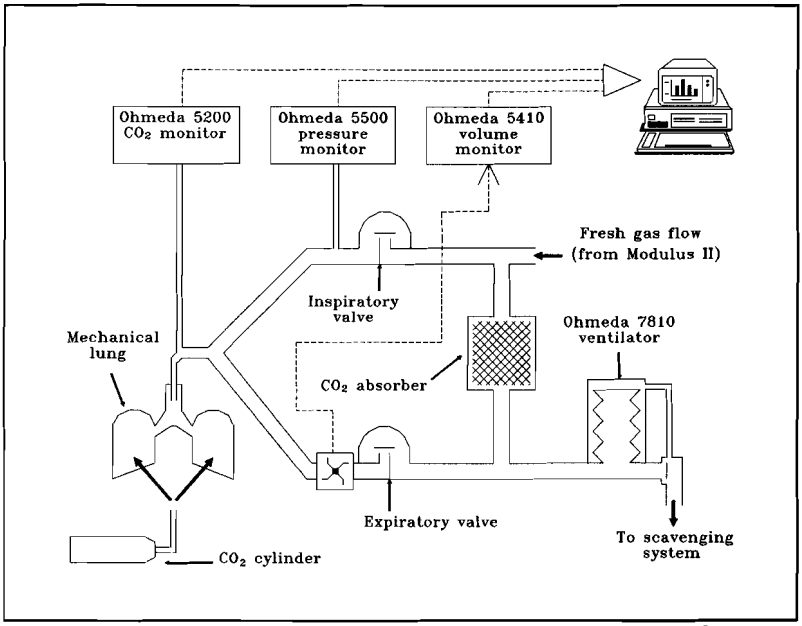

Figure 7.6 Schematic of the test setup with the Gainesville Anesthesia Simulator.

7.4.2. Test Protocol and Results

Using four different combinations of ventilator and FGF settings, a number of malfunctions were introduced, one at a time. During a maximum of 30 seconds or five respirations, whichever came first, the alarm system was expected to detect the introduced malfunction and to generate the correct alarm message. Before the next critical event was introduced, the system was subsequently allowed to return to the "no-malfunction"

state. Whenever settings were changed, the system was allowed to adapt to the new settings by setting the feature baselines to their new running average value (paragraph 7.3.3). The different combinations of ventilator- and FGF settings are presented in table 7.5 (Nederstigt 1989). The compliance of the mechanical lung was set to 0.1 l/cmH_2O, which resembles the normal lung compliance value of an adult patient.

The malfunctions introduced by the simulator were: incompetent expiratory valve, incompetent inspiratory valve, exhausted CO_2 absorber, disconnection of the ventilator hose, CO_2 canister leak, and leak in the ET tube cuff. Leaks in different hoses, obstructions of different hoses and disconnections of hoses other than the ventilator hose were manually introduced.

Table 7.5 Setting combinations used during the tests at the simulator.

Setting no.	V_T (ml)	RR (breaths/min)	I:E	FGF (l/min)
1	500	12	1:2	6
2	500	12	1:2	3
3	750	6	1:2	6
4	750	6	1:2	3

Leaks of 1.5 mm (small leak) and 3 mm (large leak) in diameter were introduced in the various sites. In the expiratory hose the leaks were introduced on either side of the flow sensor. In table 7.6 the "1" indicates a leak *before* the sensor, while the "2" indicates a leak between sensor and expiratory valve. Obstructions were simulated by pinching the hoses.

For the first combination of settings from table 7.5, the mechanical malfunctions were repeated four times to test the consistency of the system. All test results are listed in table 7.6. In this matrix an "X" indicates that the most appropriate alarm message was generated within the 30 seconds, an "N" means that no alarm was triggered at all, while an "F" indicates the triggering of false alarm messages. When more alarm messages

appeared, thereby indicating that the system detected more than one possible malfunction, and the correct message was one of them, the reaction of the system was still considered correct.

From table 7.6 it can be seen that from the total of 189 events simulated, 167 were detected correctly, while 20 were not detected and 2 false alarms were recorded. This means that 88% of the mishaps were detected correctly within 30 seconds. The two false alarms consisted of an "incompetent inspiratory valve" message, when both a small and a large leak in the ET tube was introduced.

Of the 20 undetected malfunctions, 13 were leaks introduced directly downstream of the flow monitor but upstream of the expiratory valve. Because loss in expired V_T through the leak took place downstream of the flow sensor, the flow signal detected no volume loss, and no leak message was generated. An integrated fixture of the expiratory flow and expiratory valve would alleviate this problem.

7.4.3. Tests in the Operating Room

A second test of the system took place in the OR with the objective to evaluate the behavior of the prototype and its robustness in an uncontrolled environment prone with artifacts (Nederstigt 1989). During 11 different surgical cases CO_2, pressure, and flow monitors were connected to the breathing circuit in the same way as pictured in figure 7.6, using an Ohmeda Modulus II anesthesia machine. The operations included pediatric, ear-nose-and throat, abdominal, cardiac, liver, orthopedic, and eye surgery. The ages of the patients varied from 12 months to 75 years; 8 female and 3 male patients were involved. Data from the three monitors were recorded and the system's performance was evaluated for alarms.

During the OR tests, no false positive alarms were generated and a number of correct alarm messages were generated. When the surgeon pushed or leaned on the patient's abdomen the correct "decreased compliance message" was generated. During

Table 7.6 Matrix with test results of IASA prototype I on the Gainesville Anesthesia Simulator.

Malfunction	Setting 1	Setting 2	Setting 3	Setting 4
Stuck exp. valve	X X X X	X	X	X
Stuck insp. valve	X X X X	X	X	X
Exh. CO_2 absorber	X X X X	X	X	X
Obstr. insp. hose	X X X X	X	X	X
Obstr. E.T. tube	X X X X	X	X	X
Obstr. exp. hose	X X X X	X	X	X
Obstr. vent. hose	X X X X	X	X	X
Small leak E.T. tube	F X X X	X	X	X
Small leak Y-piece	X X X X	X	X	X
Small leak insp. hose	X X X X	X	X	X
Small leak 1, exp. hose	X X X X	X	X	X
Small leak 2, exp. hose	N N N N	N	N	X
Small leak vent. hose	N N N X	N	X	X
Large leak E.T. tube	F X X X	X	X	X
Large leak Y-piece	N X X X	X	X	X
Large leak insp. hose	N X X X	X	X	X
Large leak 1, exp. hose	N X X X	X	X	X
Large leak 2, exp. hose	N N N N	N	N	N
Large leak vent. hose	X X X X	X	X	X
E.T. tube cuff leak	X X X X	X	X	X
CO_2 canister leak	X X X X	X	X	X
Disc. FGF hose	X X X X	X	X	X
Disc. vent. hose	X X X X	X	X	X
Disc. insp. hose	X X X X	X	X	X
Disc. exp. hose	X X X X	X	X	X
Disc. Y-piece	X X X X	X	X	X
Disc. E.T. tube	X X X X	X	X	X

one case, were a device was inserted between the Y-piece and the ET tube to moisten the inhaled gases, water partly obstructed the airway. This resulted in the correct "obstruction ET tube" message. A partly deflated ET cuff was recognized as "small leak ET tube/Y-piece." The OR tests did confirm that, as on the simulator, the system could be fooled by changes in ventilator settings and/or FGF. As expected, messages indicating

a leak appeared when the clinician reduced the V_T, or the total volume of FGF, while increases produced messages indicating an obstruction.

The most important result was, not counting alarm messages caused by setting changes, the prototype system produced no false positive alarm messages. In the pediatric cases, the system easily kept up with respiratory rates in excess of 20 breaths per minute, and the signal processing routines under these circumstances were able to continue to perform in real time.

7.4.4. Conclusions about the First Prototype

Prototype I worked as expected on simulator data as well as on patient data in the OR (Nederstigt 1989). The tests showed that the complete system consisting of data acquisition, signal processing, feature extraction, and the SIMPLEXYS expert system worked in real time on an 8 MHz IBM AT compatible computer with a co-processor and an EGA video card. Improvements still have to be made, however.

The most important limitation of the first prototype is the fact that feature baselines have to be reset after every change in ventilator or FGF settings. Without the reset, the system is "fooled" when ventilator settings or the FGF are changed. A decrease in these settings without baseline reset results in "Leak" rules being triggered. Therefore, a major goal for the second version is to implement an automatic baseline reset. This should prevent false alarms and missed detections due to setting changes.

Another issue is the fact that the first prototype does not consider a "flat" signal and an "invalid" signal as fundamentally different. An extra "signal flat" status will also be implemented in the second prototype.

8. IMPLEMENTATION: PROTOTYPE II

An important disadvantage of prototype I is the need to manually reset the feature baselines whenever the clinician changes ventilator settings, the amount of fresh gas flow (FGF) from the anesthesia machine, or changes positive end-expiratory pressure in the breathing circuit. Failure to reset results in false alarm messages or missed critical events. The main upgrade of prototype II is an automated feature baseline reset whenever a setting change requires it.

This chapter defines the requirements for the automatic baseline reset routine and describes the implementation of the automatic reset in the intelligent alarm software of prototype I.

8.1. Knowledge Acquisition

Feature baselines are the basis during the detection of changes in features. When the volume of gas delivered to the patient is changed, when the timing of the mechanical ventilation is altered, or when pressures in the breathing circuit are altered by the clinician, the baseline of affected features must be recalculated. The mechanical ventilator's controls adjust tidal volume (V_T), respiratory rate (RR), and ratio of inspiration to expiration time (I:E). A decrease in V_T results in smaller expired volume and decreased peak expiratory flow and airway pressure, while an increase in V_T results in higher volume, flow and pressure. Without a change in waveform timing, derived temporal features will not change in this instance, however.

A change in FGF entering the breathing circuit affects the delivered V_T (Gravenstein 1987a) and, thus, flow and pressure-related features. Again, timing features are not affected.

The clinician can also alter the gas composition of the FGF from the anesthesia machine. A change in gas composition will not measurably affect the features from pressure and flow in the breathing circuit.

For therapeutic reasons, the pressure against which is expired is sometimes raised. This causes a sustained positive airway pressure at the end of the expiration (PEEP). As a result, the patient's lungs remain partially inflated after expiration, which improves arterial oxygenation (Ashbaugh 1967, Gregory 1971). PEEP can be accomplished by inserting a spring-loaded valve or water column in the circuit at the patient side of the expiratory valve. Some PEEP valve models can be mounted on top of the expiratory valve and allow for a continuous adjustment of the PEEP level through a control knob. A change in applied PEEP influences minimal and maximal airway pressure features.

In conclusion, changes in V_T, RR, I:E, FGF, and PEEP must be detected. Since the rule base is evaluated at the end of each respiratory period, it is sufficient to detect these changes at the end of each breath.

In the next section the effects of volume and timing changes are studied.

8.1.1. Which Features Change

Changes in the timing of the mechanical ventilation changes the timing features derived from the capnogram (inspiratory time T_{insp}, expiratory time T_{exp}, and respiratory time T_{br}). A change in alveolar ventilation affects alveolar carbon dioxide (P_ACO_2) levels and, thus, end-tidal concentrations ($P_{et}CO_2$) measured by capnography. Since changes in ventilation take multiple breaths before affecting the capnogram, it can be assumed, in a first approximation, that the upstroke, downstroke, and end-tidal plateau value ($P_{et}CO_2$) are not influenced by a change in V_T, composition of FGF, or PEEP. The expected value for inspired CO_2 pressures (P_iCO_2) will always be zero in the circle breathing circuit, independent of the setting values, assuming that the CO_2 absorber in the breathing circuit scrubs the CO_2 from all gas, no malfunctions are present, and no CO_2 is present in the FGF. Prototypes I and II deal with mechanical malfunctions in the breathing circuit. However, a simple patient model could be incorporated in the alarm system to calculate new estimates for $P_{et}CO_2$ after, for example, the gas composition is changed (see chapter 9).

In contrast with CO_2 features, setting changes alter flow and pressure features more pronounced. The feature baseline for the timing features (inspiratory time T_{insp}, expiratory time T_{exp}, and respiratory time T_{br}) is similarly affected. In addition the minimum pressure (P_{min}), the pressure slope value (P_{slope}), maximum pressure (P_{max}), maximum flow (F_{max}), and the measured expired V_T (V_{Tmea}) all have to be recalculated after setting changes. Since the flow sensor is mounted in the expiratory hose close to a competent expiratory unidirectional valve which allows flow only during expiration, the expected value for minimum expiratory flow (F_{min}) will always be zero, independent of the setting values. The features pressure and flow down stroke time constant depend on the resistance of the connecting hoses, the hose compliance, airway resistance, and the compliance of the lungs. The first two factors are equipment related and can be assumed to be constant. Lung compliance changes during surgery, for example when the chest is opened or if the surgeon leans on the chest. In prototype II, the automated feature baseline reset is performed after setting changes, not when a change in the patient's condition is suspected. It is the clinician' s responsibility to reset the feature baselines to their running average value in that case. This means that we can consider the time constant of the flow (T_F) and pressure signal (T_P) as constant.

8.1.2. How to Change the Feature Baseline

Formulae for the anticipated change in features mentioned in the previous section can be derived. The basis for the derivations is a simple first order electrical model for the pressure and flow signals in the breathing circle. In figure 8.1 the electrical model for the inspiration is pictured, while figure 8.2 shows the expiratory model.

During inspiration the ventilator forces a constant flow, F_I, into the lungs through the inspiratory hose, while the expiratory flow, F_E, is zero. At the onset of expiration, the driving force of the ventilator is removed, the flow through the inspiratory hose F_I

equals zero, and the lungs empty passively through the expiratory hose until the pressure in the lungs equals the PEEP value.

In figures 8.1 and 8.2 the following abbreviations are used:

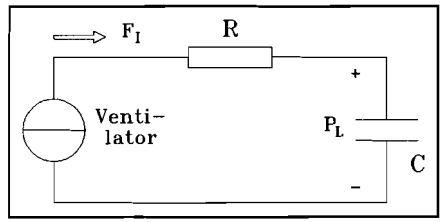

Figure 8.1 Electrical model for inspiration.

R: airway resistance combined with resistance of the inspiratory, respectively the expiratory tubing and the unidirectional valves,
C: combined compliance of lungs and tubing,
F_I: inspiratory flow,
F_E: expiratory flow,
P_L: the pressure in the lungs.

Defining the peak pressure in the lungs as P_{max} and assuming the resistance of the inspiratory tubing to be equal to the resistance of the expiratory tubing in a no-malfunction situation, the following formulae can be derived:

$$P_{min} = PEEP \quad (1)$$

$$F_{max} = V_{Tmea} / RC \quad (2)$$

$$P_{max} = (R \times F_{max}) + P_{min} \quad (3)$$

$$P_{slope} = V_{Tmea} / (T_{insp} \times C) \quad (4)$$

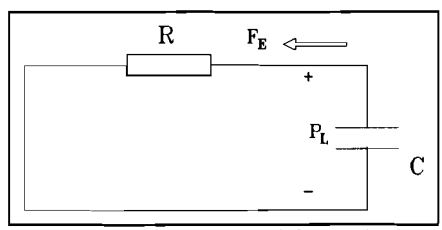

Figure 8.2 Electrical model for expiration.

The above formulae use the expired volume measured in the expiratory hose (V_{Tmea}). This expired volume equals the V_T delivered (V_{Tdel}) to the patient, assuming a respiratory quotient equal to one. In turn, V_{Tdel} can be determined from the V_T set on the ventilator (V_{Tset}), plus a contribution from the FGF, minus a volume of gas lost due to gas compression and the breathing circuit compliance. The FGF contribution to

the total volume of inspired gas, assuming that the FGF is completely added to the V_T during the inspiratory time, can be calculated. This contribution of FGF to V_{Tset} is equal to (FGF x T_{insp}) (Gravenstein 1987a).

The portion of the V_T lost to gas compression and circuit compliance can be estimated as:

$$V_{Tlost} = (V_{Tset} + (FGF \times T_{insp})) \times C_{bc}/C_{Total}$$

where C_{Total} is the total compliance of and compression in the breathing circuit plus patient, and C_{bc} is the compliance of and compression in the breathing circuit alone (Elliott 1989). From this we derive:

$$V_{Tmea} = (V_{Tset} + (FGF \times T_{insp}) \times (1 - C_{bc}/C_{Total}) \qquad (5)$$

With (1) to (5) we are able to derive expected feature values when no malfunction is present as a function of the setting values V_{Tset}, RR, I:E, FGF and PEEP, and the constants R, C, and K (= 1 - C_{bc}/C_{Total}):

P_{min} [cmH_2O]	= PEEP	(1)
F_{max} [ml/sec]	= V_{Tmea} / RC	(2)
P_{max} [cmH_2O]	= (R x F_{max}) + P_{min}	(3)
T_{br} [sec]	= 60.0 / RR [breaths/min]	(6)
T_{insp} [sec]	= ((I:E) x T_{br}) / (1.0 + (I:E))	(7)
T_{exp} [sec]	= T_{br} - T_{insp}	(8)
V_{Tmea} [ml]	= K x (V_{Tset} + (FGF x T_{insp}))	(9)
P_{slope} [cmH_2O/sec]	= V_{Tmea} / (K x T_{insp} x C)	(10)

This set of formulae is used to calculate new feature baselines when one or more settings change.

Our assumption was that R, C, and K are constants. However, during the course of anesthesia, the patient's airway resistance and lung compliance may change. We have argued that these changes are slow changes, except for the fast changes caused by the surgeon. However, these fast changes trigger the rule set, or will alter the shape of the waveform and invalidate the signal. At the end of each breath, the signal processing routines calculate CO_2, pressure, and flow features. With the current ventilator and FGF setting, formulae (1) through (3) and (6) through (10) can be solved for the unknown R, C, and K, and these values can be updated.

8.2. Implementation

Prototype II incorporating the automatic feature baseline reset was implemented based on the prototype I design (Nederstigt 1989). An interface to the anesthesia ventilator and an instrument to measure the FGF was added as well as a graphics user interface.

8.2.1. Data Acquisition

The mechanical ventilator settings can be obtained electronically from an Ohmeda 7810 ventilator. This model provides a serial RS-232 interface to inquire for the settings selected by the user. Data on settings are requested from the ventilator at the start of each respiratory period. The incoming string of characters is stored in a buffer and processed when a breath is detected on the CO_2, pressure and flow signals. Thus, an updated set of ventilator settings is available before every expert system run.

A second volume monitor (Ohmeda 5410), inserted into the fresh gas hose, measures FGF. Similar to the expiratory flow signal (paragraph 7.3.1), this monitor generates a pulse for approximately every 3 ml. of gas that passes the sensor. After the detection of a breath, the number of FGF pulses is multiplied by 3 ml. and divided by the respiratory time to get the average FGF during one respiration. The FGF result is corrected for non-linear sensor error by means of a look-up table of correction factors

as a function of the average FGF value. The necessary information was obtained in laboratory experiments.

These new settings for V_{Tset}, RR, I:E, PEEP (from the ventilator) and FGF (from the second flow device) are compared to the settings from the previous baseline reset. If the relative difference is 10% or more, and if FGF > 0 ml/sec (a negative measured FGF value means a disconnect of the fresh gas hose rather than a setting change), new feature baselines are calculated and the current setting values are stored as the new reference values.

The constants R, C, and K are updated with a moving average algorithm at the end of a breath following each expert system run. These updates are performed only if 1) no setting change was made, 2) all numerical features are declared valid, and 3) no malfunction is detected in the breathing circle. The updated moving average values are obtained by filling in the values of V_{Tmea}, F_{max}, P_{max}, P_{slope}, and T_{insp} calculated by the signal processing routines, and the new setting values, into formulas (1) to (3) and (6) to (10) from section 8.1.2.

8.2.2. The User Interface

The basic purpose of the user interface is to present the status of the anesthetic system to the clinician (figure 8.3). The screen includes real time signal waveforms, numerical data, and messages generated by the intelligent alarm software. The left half of the screen displays the most recent 25 seconds of the CO_2, pressure, and flow waveforms. On the right half of the screen an indication of the current status of the anesthesia breathing circuit is displayed. This is implemented as a "traffic light" in the upper right corner of the screen giving the clinician a quick insight in the state of the anesthesia system. The box is either green (everything "OK"), yellow (a "CAUTION" message is generated by the expert system), or red (an "ALARM" condition is detected). Similarly, the status of the CO_2, pressure, and flow signals is displayed in "traffic light" fashion (figure 8.3). When the signal is "OK" the message is given in green, an invalid

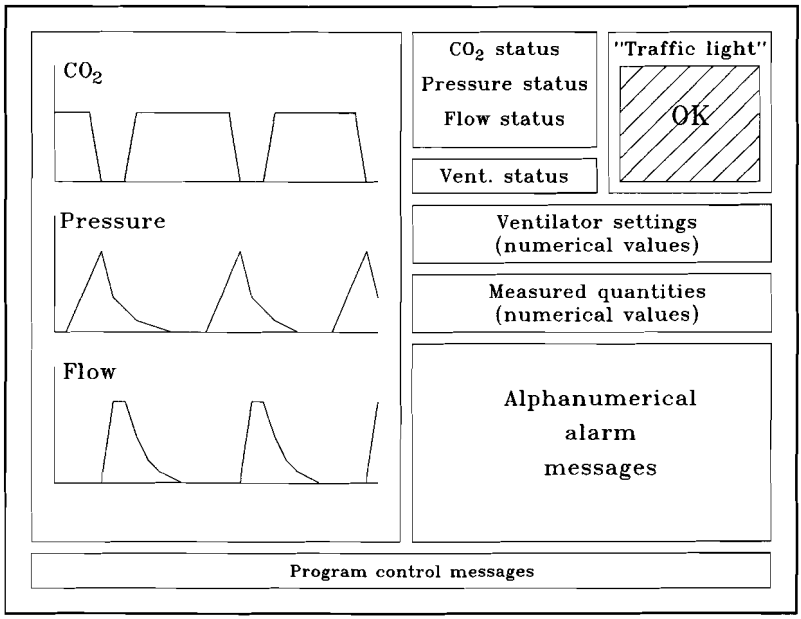

Figure 8.3 User interface display screen.

signal is represented by a yellow message and a red notice means that there is no signal detected at all (signal is called "FLAT" (see below)).

When the system status is "ALARM", an alphanumerical alarm message indicates the derived malfunction(s), and its (their) suspected site.

Other information including the system setting values (V_T, RR, I:E, FGF, and PEEP), and measured quantities like inspired O_2 percentage (F_IO_2) and minute volume (MV) is presented numerically.

The clinician controls the system by the push of a button. The "RESET BASELINES" button overrules any automatic baseline reset and accepts the current running average value of all features as new baselines. Other buttons allow the prototype

to start and stop recording the signal samples on hard disk, suspend the program temporarily, or abort the program.

8.2.3. Software Additions

Toward the goal to centralize alarms from different monitors, prototype II combines alarm messages from the Intelligent Alarms software with messages generated by the ventilator. Ventilator alarms include messages about low gas supply pressure, low and high airway pressure, failing O_2 or V_T sensor, low F_IO_2, and internal electrical failure. To prevent a large number of alarm messages from being generated in case of emergency, a "message shell" is implemented. In prototype II, every alarm message is assigned a priority. At the end of each expert system run, only the triggered alarms with the highest priority are selected and displayed on the screen. (All triggered alarm messages are written in a file, however, to evaluate the expert system's behavior afterward.)

An extra signal status ("FLAT") is implemented for the three signals as suggested by Bastings (Bastings 1989). The expert system differentiates between a flat signal ("FL") where there is a signal, however due to disconnections or apnea the signal amplitude is equal to zero, and an invalid signal, for example due to artifacts ("NV"). The symbolic data that serve as input to the expert system now have a value of either "UP", "DN", "UC", "NV", or "FL".

Finally, the modular software structure was updated in which machine dependent data acquisition and user interface routines are separated from the expert system and signal processing routines to allow for ease of portability (figure 8.4). For example, the system can be implemented into an anesthesia machine by only reprogramming the routines that interface the main module with the low level input/output (I/O) routines.

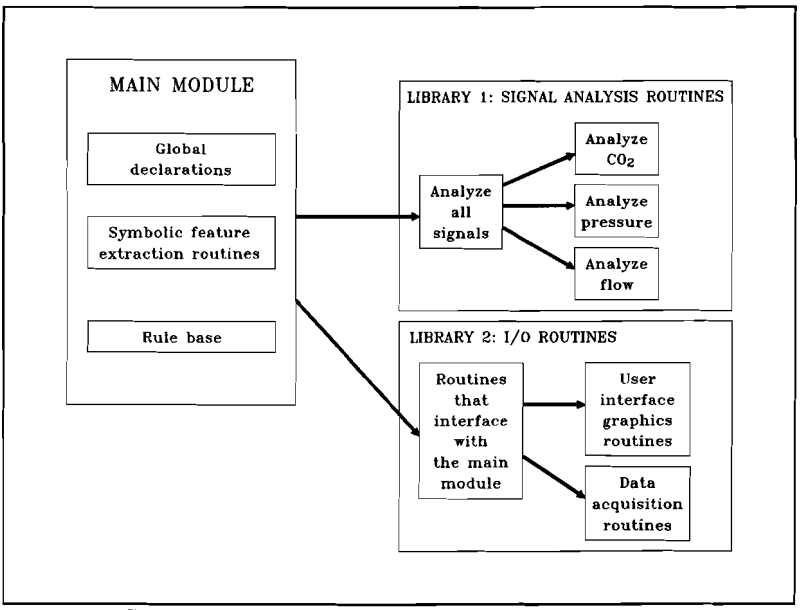

Figure 8.4 Configuration of the IASA prototype II software package.

8.3. Tests and Evaluation

Prototype II has been tested on the Gainesville Anesthesia Simulator (GAS). The testing procedures and the results are summarized in the next sections.

8.3.1. Single Malfunctions

The test setup with GAS (Chapter 7) was augmented with a second flow device (inserted into the fresh gas hose) and communications to the mechanical ventilator. To test the system's performance, two test sequences were executed. During each sequence, a number of malfunctions were introduced at different combinations of V_T, RR, I:E ratio,

FGF, and PEEP settings. Baselines were reset to their current mean only at system start-up. The compliance of the mechanical lung was set to 0.1 l/cmH_2O.

At the start of the first sequence, these were the following setting values: V_T = 750 ml, RR = 10 breaths/min, I:E = 1:2, FGF = 5 l/min, and PEEP = 0 cmH_2O (setting 1a). After introducing a number of malfunctions, FGF was lowered to 2 l/min and the experiments were repeated (setting 1b). Finally, V_T was decreased to 350 ml, RR increased to 20 breaths/min, and I:E increased to 1:2.5 (setting 1c) (table 8.1). "X" indicates that the correct message was generated within 30 seconds or 5 respirations, "F" indicates that false alarm messages were generated, and "N" means that no malfunction message was triggered at all (table 8.1).

Table 8.1 Results of test sequence 1 for Prototype II at the simulator.

Malfunction	**Setting 1a**	**Setting 1b**	**Setting 1c**
Obstr. E.T. tube	X	X	X
Obstr. insp. hose	X	X	X
Obstr. exp. hose	X	X	X
Obstr. vent. hose	X	X	X
Stuck insp. valve	X	X	**F**
Stuck exp. valve	X	X	X
Exh. CO_2 absorber	X	X	X
Disc. FGF hose	X	X	X
Disc. Y-piece	X	X	X
Disc. vent. hose	X	X	X
Small leak insp. hose	X	X	X
Small leak exp. hose	X	X	X
Disc. CO_2 sampling line	X	X	X

The only false alarm recorded was a "small leak" message when the inspiratory valve was stuck. At the high RR setting of 20 breaths/min (setting 1c), the increase in the down stroke of the CO_2 signal did not trigger the "incompetent inspiratory valve" message. The automatic baseline reset worked as expected during the first test.

The setting combinations of the second test sequence are given in table 8.2. Again, no manual baseline reset was performed after transitions from setting 2a to 2b, 2b to 2c, and 2c to 2d. The test results are presented in table 8.3.

Table 8.2 Settings during the second test sequence for Prototype II.

Setting	V_T (ml)	RR (br/min)	I:E	FGF (l/min)	PEEP (cmH_2O)
2a	300	15	1:2	3	0
2b	500	12	1:2	5	0
2c	750	10	1:2	8	0
2d	750	10	1:2	8	20

Table 8.3 Results of test sequence 2 for Prototype II at the simulator.

Malfunction	Setting 2a	Setting 2b	Setting 2c	Setting 2d
Large leak insp. hose	X	X	X	X
Large leak exp. hose	X	X	X	X
Disc. CO_2 sampling line	X	X	X	X
Small leak insp. hose	X	X	X	X
Small leak Y-piece	X	X	X	X
Small leak exp. hose	X	X	X	X
Disc. FGF hose	X	X	X	X
Stuck insp. valve	X	X	**F**	**F**
Obstr. insp. hose	X	X	X	X
Obstr. E.T. tube	X	X	X	X
Obstr. exp. hose	X	X	X	X
Obstr. vent. hose	X	X	X	X

The automatic baseline reset in this case, again, worked without error and false alarm message.

Two false alarm messages were recorded: a "small leak" message at setting 2c, and an "apnea" alarm at setting 2d, both when the inspiratory valve was stuck. At a high

FGF value (setting 2c), the CO_2 down stroke feature did not increase sufficiently after introduction of the malfunction, ergo, the correct alarm message was not triggered. Because the expiratory volume decreased, a small leak was incorrectly identified as the cause. In another situation, when the inspiratory valve was rendered incompetent in the presence of a PEEP value of 20 cmH_2O (setting 2d), the expiratory flow returned completely (not partly, as when there is less PEEP) through the inspiratory hose. In this case, the stuck valve provided a "short circuit" from the lungs to the part of the breathing circle located on the machine side of the valves, where no PEEP was present. As a result, the expiratory flow signal was flat, no breath detection could be performed on this signal, and the flow features were declared invalid. Because, again, the CO_2 downstroke was insufficiently affected and since the pressure signal remained unchanged, no intelligent alarm was generated. The only alarm that remained was the "apnea" alarm caused by the flat flow signal.

The rule for the incompetent inspiratory valve uses predominantly changes in the flow signal combined with a decrease in the downstroke of the capnogram and an unchanged peak inspiratory pressures. An improved rule could make use of the presence of PEEP, combined with a "flat" (Note: not invalid) expiratory flow signal. An improvement will be proposed in the next prototype.

8.3.2. Multiple Malfunctions

Although, theoretically, the probability of multiple malfunctions occurring at the same time is extremely small, we tested the system for a few combinations of malfunctions. The goal of these tests was to make sure that the alarm scheme generated reasonable messages during multiple malfunctions, and that no "nonsense" messages are presented (table 8.4). The settings were the same as 1a (table 8.1).

The results indicate that in nearly all cases, at least one of the triggered alarm messages was correct (table 8.4). The combination of a stuck inspiratory valve and a

Table 8.4 Test results for Prototype II during multiple malfunctions.

Malfunctions	**Triggered alarm message(s)**
Small leak exp. hose + Obstr. exp. hose	* Obstruction exp. or vent. hose
Stuck insp. valve + Obstr. exp. hose	* Incompetent inspiratory valve * Small leak, site unknown **or** (when complete occlusion) * Apnea
Stuck insp. valve + Small leak exp. hose	* Incompetent inspiratory valve * Small leak, site unknown
Stuck insp. valve + Stuck exp. valve	* Incompetent expiratory valve
Obstr. exp. hose + Obstr. insp. hose	* Obstruction E.T. tube/Y-piece

complete obstruction of the expiratory hose triggered the incorrect "apnea" message, however. This situation can be compared to the stuck inspiratory valve in combination with a high PEEP setting. Since the flow signal becomes completely flat, this alarm is generated by the ventilator. Because no other intelligent alarm message is triggered, the ventilator message is copied by the smart alarm system and subsequently displayed on the screen.

When the inspiratory and the expiratory hose are obstructed simultaneously, the logical result is an "Obstruction ET tube/Y-piece" message. Inspiratory and expiratory resistance increases in both cases, so the pressure and flow signals do, too.

8.3.3. Conclusions about the Second Prototype

The detection of the inspiratory valve malfunction in prototype II is not satisfactory, and the current rule, which is based on the change in the CO_2 down stroke needs attention.

Apart from the issues mentioned above, overall detection performance for single malfunctions was judged to be good. Of 87 malfunctions introduced, 84 were detected correctly within the 30-second time span. This means that 96% of the faults were recognized by the system.

When multiple malfunctions were introduced, the second prototype implementation was able to identify at least one of the malfunctions introduced. The general result of the preliminary tests of the system behavior during multiple malfunctions is satisfactory. More testing is planned, however (chapter 9).

9. IMPLEMENTATION: PROTOTYPE III

When the clinician notices abnormal end-tidal tensions of carbon dioxide ($P_{et}CO_2$), an abnormal arterial saturation of hemoglobin (S_aO_2), or an abnormal pattern of ventilation in the anesthetized patient with mechanical ventilation, (s)he searches for a cause (chapter 5). Checking the anesthesia breathing system for flaws, prevents inappropriate and potentially harmful treatment of the patient when no pathophysiologic process is at work. With the breathing circuit without leak, disconnection, obstruction or incompetent valve, the flow and composition of the fresh gas acceptable, and the patient alveolar ventilation deemed suitable, the clinician turns to the patient for the cause. Ventilation may no longer be adequate because of improper airway management or increased carbon dioxide (CO_2) production, oxygenation may no longer be sufficient in the light of increased oxygen (O_2) consumption, or a ventilation to perfusion mismatch developed. For example, the endotracheal tube (ET) may have slipped in a mainstem bronchus.

Assessment of *adequacy* of ventilation and oxygenation requires knowledge about the patient. During anesthesia and mechanical ventilation a tidal volume (V_T) of 10 to 15 ml. per kilogram of body weight combined with a respiratory rate (RR) of about 10 breaths per minute are often selected initially for adults (Gravenstein 1989a). Subsequently these settings are titrated to obtain a desired $P_{et}CO_2$. On the basis of the patient's weight, height, gender, and temperature, one can estimate the CO_2 production and end-tidal CO_2 concentrations of the patient. From inspired O_2 levels, combined with effective alveolar ventilation ($\dot{V}_A$), the level of arterial O_2 tensions (P_aO_2), and saturation (S_aO_2) can be estimated. Although estimated values are based on nomograms or empirical formulae and do not take into account many patient-specific factors that can change the ventilatory requirements, the estimated values should not differ dramatically from measured values. A close examination for a probable cause is warranted when there is a large discrepancy.

In this chapter, the prototype II platform is expanded to detect malfunctions in the O_2 supply system, and to evaluate adequacy of ventilation and oxygenation assuming the breathing circuit without malfunctions. Estimates for $P_{et}CO_2$ are compared with measured variables, and in cases where there is a discrepancy, differential diagnosis options are developed to aid the clinician in the early detection of clinical concerns concerning ventilation and oxygenation.

9.1. Knowledge Acquisition

Failure to deliver O_2 to the patient resulting in hypoxemia (reduced P_aO_2) is a recognized concern during anesthesia. Four major causes of arterial hypoxemia can be identified: inadequate inspired O_2 levels, hypoventilation, ventilation-to-perfusion ($\dot{V}/\dot{Q}$) mismatch, and impaired diffusion.

Toward detection, a number of monitors are clinically helpful. O_2 analyzers are inserted into the breathing circuit to measure O_2 concentrations in the inspired gases. Capnography monitors inspired and expired CO_2 concentrations (paragraph 3.4.2). A decrease in P_aO_2 causes a decrease in arterial oxygen saturation (according to the O_2 dissociation curve) (West 1979). The S_aO_2 can be assessed noninvasively with a pulse oximeter (paragraph 3.4.3). More precisely, pulse oximetry estimates the oxygen saturation of hemoglobin (S_pO_2) in arterial blood. The subscript "p" indicates that oxygen saturation was obtained with a pulse oximeter (Gravenstein 1990).

When the clinician observes an unexpected decrease in S_pO_2, or S_pO_2 readings lower than some expected or established baseline, or an abnormal capnogram with either abnormal inspired or expired CO_2 concentrations or a distinctly different shape of the capnogram compared to an earlier capnogram, or a decrease in F_IO_2 without a corresponding change in ventilation or inspired gas concentrations, the search for the potential cause for the abnormal reading(s) is started.

9.1.1. Inadequate Oxygenation

A number of reasons for inadequate inspired O_2 concentrations other than caused by anesthesia breathing circuit malfunctions have been reported. Hypoxic inspired gas mixtures can result from 1) an inadequate O_2 supply during anesthesia due to empty or depleted O_2 cylinders, 2) crossing of hospital gas supply lines to the operating room, 3) erroneous filling of the central O_2 supply or O_2 cylinder with other gases, 4) insufficient fresh gas flow (FGF) to the breathing circuit, 5) substitution of a non-O_2 cylinder at the O_2 yoke, 6) leaks or obstructions in the anesthesia machine, and 7) faulty flow meters. The second prototype of our system (Chapter 8) has no means to determine the composition of the FGF, nor can it detect if a decrease in FGF is caused by an adjustment of the flow settings by the clinician or is due to a leak or a blockade in the anesthesia machine. Thus, the prototype can be fooled. Attaching sensors to the control knobs of the flowmeters on the anesthesia machine can detect setting changes. Incorporating an O_2 sensor (or any other analyzer capable of measuring O_2) in the inspiratory limb allows measurement of inspired O_2 concentrations.

Hypoxic inspiratory gas mixtures can also develop over time despite O_2 concentrations in the FGF of 21% or more, if the volume of O_2 added to the breathing circuit by the FGF fails to satisfy the O_2 consumption of the patient. The O_2 concentration will decrease progressively when with each breath the breathing circuit is depleted from a volume of O_2. Leaks in the anesthesia machine, or an increase in O_2 requirement by the patient without an adjustment in FGF can produce these instances. The O_2 sensor in the breathing circuit will detect the hypoxic mixture, but not the volume of O_2 delivered into the circuit.

9.1.2. Hypoventilation

When the blood removes more O_2 from the lungs than is replenished by alveolar ventilation, the alveolar O_2 partial pressures decrease. This is called hypoventilation (West 1979). The minute volume (MV), or total ventilation, is the total volume entering the lung each minute. Dead space (V_D) is that part of the airway not participating in gas exchange. The total dead space has an anatomical component that consists of the upper conducting airways, and a component referred to as alveolar dead space. The latter component accounts for those part of the lungs that are well ventilated, but poorly perfused (paragraph 9.1.3). Because of V_D, only part of V_T contributes to the gas exchange in the alveolar gas compartment. We can calculate the alveolar volume V_A from:

$$V_A = V_T - V_D$$

Multiplying each side by the respiratory rate (RR) we obtain:

$$V_A*RR = V_T*RR - V_D*RR$$

or

$$\dot{V}_A = MV - \dot{V}_D$$

$\dot{V}_A$ is called alveolar ventilation, $\dot{V}_D$ dead space ventilation. From this formula can be seen that V_T must be chosen large enough to assure adequate alveolar ventilation. A tidal volume of 10 to 15 ml. per kilogram bodyweight is often selected with a respiratory rate of 10 breaths per minute. When malfunctions in the breathing circuit result in a smaller V_T, or when V_T is too small because of a setting error, hypoventilation will be the result. Note that MV, which is the product of V_T and RR may *seem* adequate when the patient is ventilated with a high RR, but a small V_T may only ventilate dead space

and not provide proper alveolar ventilation. An estimate for the dead space can be obtained with the modified Bohr equation (West 1979):

$$V_D = \frac{P_ACO_2 - P_ECO_2}{P_ACO_2} * V_T$$

where P_ACO_2 and P_ECO_2 refer to alveolar and mixed expired CO_2 partial pressures, respectively. A useful rule of thumb is the dead space volume in ml. is approximate equal to the body weight in pounds.

9.1.3. Ventilation to Perfusion Mismatch

Ventilation is responsible for the transport of O_2 into the lung, while removing CO_2. Blood delivers CO_2 to the lung, while O_2 is transported to the cells. When ventilation matches perfusion, an optimum exchange of gases is obtained, and the ratio of ventilation to perfusion ($\dot{V}/\dot{Q}$) equals 1. A mismatch occurs when parts of the lung are better perfused than ventilated, or conversely, better ventilated than perfused. It is impossible to confirm a $\dot{V}/\dot{Q}$ mismatch by capnography or pulse oximetry alone. The $P_{et}CO_2$ may appear to be normal and some time may pass before a decrease in S_pO_2 is observed. Only a comparison of the arterial and the alveolar CO_2 and O_2 partial pressures will reveal the $\dot{V}/\dot{Q}$ mismatch.

Increased Ratio

When perfusion of the lung is partially blocked while ventilation is unhampered, gas from ventilated but not perfused areas of the lung mixes with gas from ventilated and perfused areas. No gas exchange takes place in the un-perfused areas; this CO_2 free gas dilutes the CO_2 rich gas from the perfused segments. The $P_{et}CO_2$ will fall, while the P_aCO_2 of arterial blood must increase. More pronounced is the drop in P_aO_2, which in

turn, may lower the O_2 saturation of the blood depending on the position on the O_2 dissociation curve.

During surgery, clamping of some vessels can (temporarily) obstruct pulmonary blood flow. Emboli (air), blood clots, or tumor can obstruct blood flow to the lung and thus increase alveolar dead space, i.e., ventilated but not perfused areas of the lung.

Decreased Ratio

When a bronchus is blocked, ventilation of that part of the lung decreases. If perfusion of that part continues, an increase of the $\dot{V}/Q$ ratio is observed. Many clinicians refers to this type of mismatch as pulmonary shunt. Another common example is the intubation of a mainstem bronchus either during placement of the endotracheal (ET) tube, or as the result of a change in the patient's position which causes the placed ET tube to slip into a bronchus; ventilation will be limited to one lung. The arterial CO_2 tension will increase, possibly resulting in a reduction in arterial oxygen saturation. While the $P_{et}CO_2$ may only be small and clinically easily overlooked, the carbon dioxide content of arterial blood will show an increase. Analysis of an arterial blood sample will reveal the gradient between arterial and alveolar concentrations.

Sometimes, during intubation, the ET tube inadvertently may have been placed in the esophagus. Since the stomach does not produce CO_2, misplacement is readily detected by capnography, where over a number of breaths a rapid decline of end-tidal values can be observed and the movement of gas in and out of the patient fails to produce the familiar capnogram (paragraph 3.4.2).

A change in metabolism changes O_2 consumption and CO_2 production. With an elevated CO_2 production (QCO_2), hypercarbia may result if no change is made in V_A to compensate for the increased QCO_2. The consequence is that $P_{et}CO_2$ rises. In some patients, metabolism (primarily in skeletal muscle groups) may increase dramatically triggered by the anesthetic agent halothane, or succinylcholine. The temperature of the patient increases as the result of the increase in metabolism; often as fast as 1°C per

minute. This clinical syndrome is referred to as malignant hyperthermia. Monitoring $P_{et}CO_2$ concentrations show the increase in $\dot{Q}CO_2$ and indicate the possibility of malignant hyperthermia before an increase in temperature can be observed.

9.1.4. Diffusion Abnormality

Diffusion abnormalities prevent hemoglobin from becoming fully saturated with oxygen in the patients with severe lung disease where the alveolar wall is thickened. Only rarely does a diffusion abnormality develop acutely during anesthesia. In clinical practice, the diffusion abnormality will play a role in the development of intraoperative hypoxemia only when the abnormality existed preoperatively and with low F_IO_2 concentrations. In the following discussion diffusion abnormalities will be ignored.

9.2. Estimating $P_{et}CO_2$

To estimate $P_{et}CO_2$, estimations of the O_2 consumption and CO_2 production must be made. Basal Metabolic Rate (BMR), O_2 consumption, and CO_2 production can be derived from the patient's weight, height, and gender.

Gravenstein reported that body surface area (BSA) depends on height and weight in accordance with the following formula (Gravenstein 1987 p:140):

$$BSA = W_{kg}^{0.425} \times Ht^{0.725} \times 0.007184 \quad [m^2]$$

where

W_{Kg}: weight in Kg

Ht: height in cm

Based on metabolic data provided by Fleisch (Fleisch 1951), Wilmore proposed formulae to calculate metabolic rate per square meter body surface area as a function of age and gender (table 9.1) (Wilmore 1977). These functions are plotted in figure 9.1.

Table 9.1 Metabolic Rate as a function of Age and Gender

Group	Age	Mathematical Expression	r^2
Males	1-19	y = 52.96 - 0.77x	0.9651
Males	20-75	y = 37.50 - 0.079x	0.9366
Females	1-19	y = 53.35 - 1.01x	0.9816
Females	20-75	y = 37.50 - 0.079x	0.9366

x = Age in Years
y = Metabolic Rate [kcal/m^2/hr]

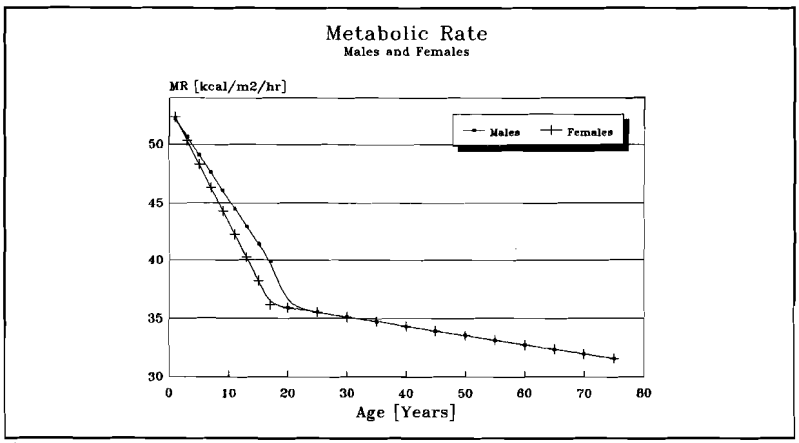

Figure 9.1 Prediction of Metabolic Rate for Males and Females at various ages

In humans, the Mean Metabolic Rate (MMR) at normal body temperature (37°C) (MMR37) is calculated as:

MMR37 = BMR x BSA

The metabolic rate is temperature dependant. Guyton found that the metabolic rate increases by 120% for every 10°C rise in body temperature (Guyton 1986). This is

equivalent to approximately 8% per °C (increase = $2.2^{1/10}$ - 1). Using this we can derive the following formula:

$$MMR(T) = MMR37 \times (1.08)^{T-37}$$

where:

T: body temperature in °C.

In figure 9.2 the mean metabolic rate as a function of body temperature is plotted for a 70 Kg (150 lb), 180 cm (6 ft) male.

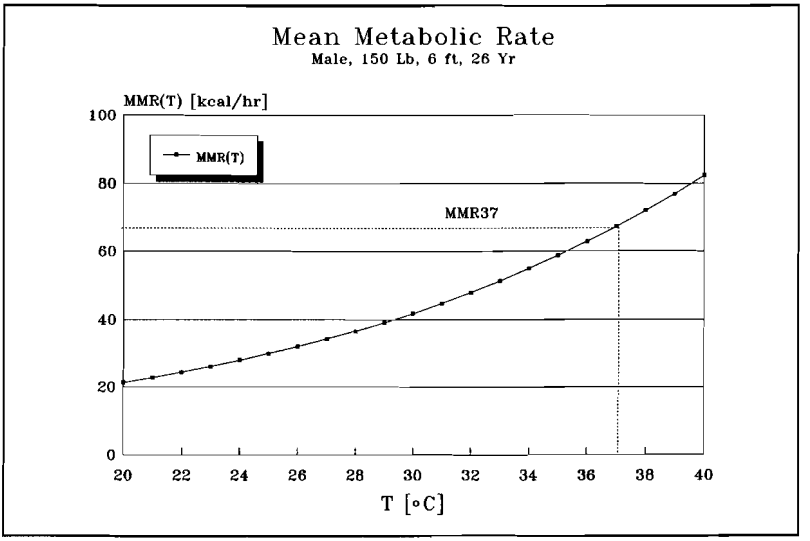

Figure 9.2 MMR adjustment for body temperature

On an average diet the body liberates an average of approximately 4.825 Kilocalories of energy per liter of oxygen (Guyton 1986). Based on this, an approximation for the oxygen consumption can be made as follows:

$$O_2 \text{ consumption} = MMR(T)/(4.825*60) \text{ [l/min]}$$

The ratio of CO_2 production and O_2 consumption is called the respiratory quotient (RQ). A typical value for RQ is 0.85. An estimate of CO_2 production can be made:

CO_2 production = O_2 consumption * RQ

To arrive at $P_{et}CO_2$, the estimate for CO_2 production must first be translated into alveolar tensions (P_ACO_2). Comroe describes the relationship between alveolar ventilation ($\dot{V}_A$) and P_ACO_2 (Comroe 1962):

$$\dot{V}_A = QCO_2 \times 863 / P_ACO_2$$

$\dot{V}_A$ and QCO_2 are in ml per minute.

Having QCO_2 together with an estimation for $\dot{V}_A$, we can obtain the P_ACO_2 tension. Comroe provides a nomogram for the relationship between body weight and both V_T, and RR (Comroe 1962). In figure 9.3 these values are plotted.

The curves can be approximated by the following formulae (van Oostrom, Personal Communication 1989):

V_T	= 4 * lbs	[ml]
RR	= 237/lbs + 7.56	[breath/min]

Alveolar ventilation is subsequently obtained with V_T and the estimate of the patient's V_D (most frequently an estimate of 1 ml/lb is used for V_D) as follows:

$$\dot{V}_A = RR*(V_T - V_D)$$

With P_ACO_2 known, $P_{et}CO_2$ is obtained by assuming that the end-tidal CO_2 concentrations obtained per capnography equal the P_ACO_2 tensions. Conversely, from a known QCO_2, one can calculate the $\dot{V}_A$ required to obtain a desired P_ACO_2.

Alveolar tensions of O_2 (P_AO_2) can subsequently be calculated using the alveolar gas equation (West 1979):

$$P_AO_2 = F_IO_2 * 713 - P_ACO_2*(F_IO_2 + (1 - F_IO_2)/RQ)$$

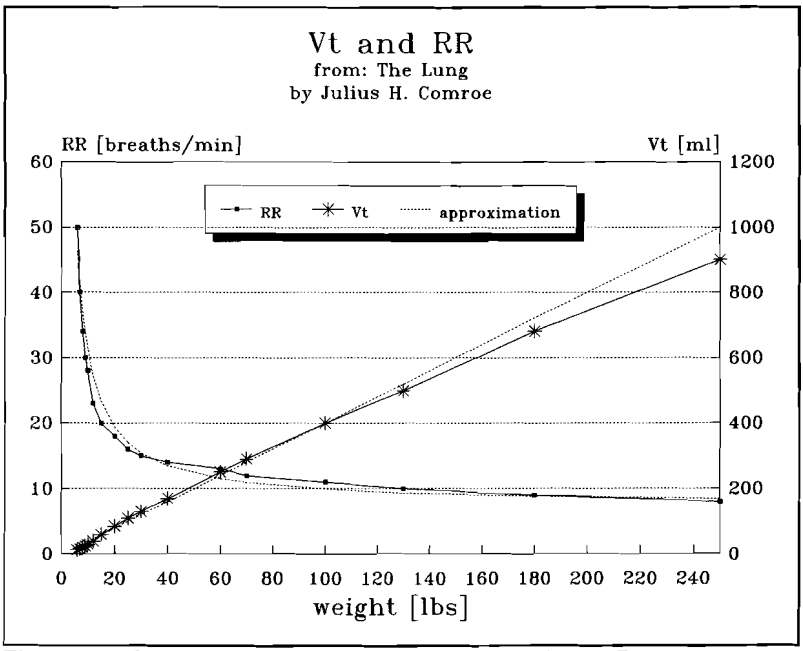

Figure 9.3 Normal values for Tidal Volume and Respiratory Rate.

9.3. From Knowledge to Rules

A significant decrease in O_2 saturation of arterial blood is called desaturation, with V/Q mismatch the most common cause. In case of desaturation, first rule out hypoxic inspired gas mixtures, than look at mechanical problems, gas delivery, and minute ventilation (Gravenstein 1990). Having addressed mechanical malfunctions in prototypes I and II, we now concentrate on hypoxic inspired gas mixtures, gas delivery, and ventilation.

9.3.1. Oxygenation

In this text an hypoxic inspired mixture is defined as a gas mixture containing less than 21% of O_2. As outlined in paragraph 9.1.1, a number of causes for hypoxic mixtures can be identified.

In our prototype, desaturation is defined as:

1) S_pO_2 readings of less than the lower alarm limit selected and set by the clinician on the pulse oximeter,
OR
2) a decrease of more than 3% from either the S_pO_2 baseline or from the S_pO_2 running readings (see paragraph 9.4.2).

We refer to this definition from now on as DESAT.

With F_IO_2 and $\dot{V}_A$, the volume of O_2 delivered to the patient can be calculated, whereas the O_2 consumption is estimated (paragraph 9.2). If the O_2 delivery is less than 50% of the estimated O_2 consumption, our system suspects inadequate O_2 delivery. Hypoxic inspiratory gas mixtures can develop over time, if the volume of O_2 added to the breathing circuit by the FGF with O_2 concentrations in the FGF of 21% or more was fails to satisfy the O_2 consumption of the patient (paragraph 9.1.1). In all these instances, a change in $P_{et}CO_2$ levels may, or may not result. Therefore, the $P_{et}CO_2$ is not included in the rules for oxygenation, but is an integral part of the rules for ventilation.

9.3.2. Ventilation

$P_{et}CO_2$ in clinically monitored as a guide for adequacy of ventilation assuming $P_{et}CO_2$ reflects the arterial PCO_2 recognizing its limitations. With a breathing system free of mechanical malfunctions either hypoventilation, hyperventilation, or some form of $\dot{V}/Q$ mismatch is suspected when a difference between the estimated $P_{et}CO_2$ and the

measured $P_{et}CO_2$ is observed. Three quantities are defined toward the correct identification. We define abnormal high $P_{et}CO_2$ values (HIGHCO2) as:

1) $P_{et}CO_2$ readings in excess of 50 mmHg
AND
2) either a 15% or a 5 mmHg increase in $P_{et}CO_2$ pressures from baseline.

The difference between the measured and calculated $P_{et}CO_2$ is determined (DIFF). The measured MV (MV_{mea}) is determined from the expired V_T (V_{Tmea}) and the set RR.

On the basis of MV_{mea} and $P_{et}CO_2$, the patient' s CO_2 production (QCO_2) can be estimated, assuming $P_{et}CO_2$ reflects P_ACO_2 and that alveolar tensions reflect arterial. QCO_2 in turn is used to calculate a V_T (V_{T_est}) with which a $P_{et}CO_2$ of 35 mmHg can be obtained. Accordingly, we define a low MV as a MV less than 30% of the estimated MV (MV_{est}) at the set RR, while a high MV is defined as a MV in excess of 30% of MV_{est}. With these three quantities we define:

Hypoventilation:	HIGHCO2 AND LOW_MV
Primary Hypercarbia:	HIGHCO2 AND DIFF > 10 mmHg
V/Q mismatch:	Normal $P_{et}CO_2$ AND DIFF > 10 mmHg

When the measured $P_{et}CO_2$ is < 30 mmHg in combination with a high MV, hyperventilation is suspected.

Adequacy of V_T is assessed in a similar manner. A low V_T is defined as a V_T less than 30% of the V_{T_est}, while a V_T larger than 30% of V_{T_est} is considered a high V_T. In our calculations V_T is corrected for the estimated dead space (paragraph 9.2).

9.3.3. Other Causes

When the ET tube slips into a mainstem bronchus due either to a position change of the patient, or to motion, a sudden drop in $P_{et}CO_2$ possibly combined with DESAT and an increase in peak inspiratory pressure is observed, without a change in the set MV.

In the event that the ET tube enters the esophagus, the $P_{et}CO_2$ will decrease dramatically, and the capnogram will disappear altogether within 3 to 5 breaths. In both cases, the repositioning of the ET tube will result in a change in compliance, thereby changing peak inspiratory pressures.

When the $\dot{V}/\dot{Q}$ mismatch is caused by pulmonary emboli, there will be no change in inspiratory pressures, but a rapid decrease in $P_{et}CO_2$ partial pressures can be observed.

The final issue we concern ourselves with is bronchospasm. When there is constriction of lung segments, an uneven emptying of the lung takes place. This typically causes the plateau of the capnogram to be sloped upward. Also, the decrease in compliance and the increase in airway resistance caused by the bronchospasm result in elevated airway pressures and a prolonged down stroke of the capnogram (beginning of inspiration).

The incidents mentioned in this paragraph have been translated into SIMPLEXYS rules and incorporated into our rule base.

9.4. Implementation

The prototype III additions were integrated into the prototype II design. Two changes were made. First, a pulse oximeter interface was added. Second, the signal analysis routines derived the slope of the CO_2 plateau.

9.4.1. Data Acquisition

The Ohmeda 7810 mechanical ventilator contains an integrated galvanic cell O_2 analyzer. The anesthesia machine used in the prototype (Ohmeda Modulus II) has a port specifically designated for mounting the O_2 sensor probe in the inspiratory limb. The data string transmitted from the ventilator to the prototype III computer per serial RS-232 interface contains a field for the O_2 reading. Data on settings is requested from the ventilator at the start of each breath period, and the incoming string of characters is stored in a buffer and processed when a breath is detected on the CO_2, pressure, and

flow signals. This information is then made available before each expert system run (Chapter 8).

A pulse oximeter (Ohmeda 3710) is used to estimate arterial hemoglobin saturation. This monitor provides both analog and digital outputs for S_pO_2 and the heart rate. This device is also designed to detect the presence of a probe and if the probe is connected to a patient. The device detects the presence of interference caused by ambient light, and a poor quality plethysmogram signal. Since these status messages are only available on the digital output, and the validity of the S_pO_2 signal is an essential and integral part of the intelligent alarm system, we elected to use the digital output of the monitor. Every two seconds, the monitor transmits S_pO_2 and heart rate values to the prototype III computer using RS-232 serial communication. When a breath is detected on the CO_2, pressure, and flow waveforms, the S_pO_2 data are evaluated and passed onto the expert system. Currently, prototype III makes no use of the available heart rate data.

9.4.2. Software Additions

From the CO_2 waveform one additional feature was extracted: the slope of the plateau. The slope of the CO_2 waveform is determined by fitting a line to the data using the least squares technique. This method has the advantage of yielding an accurate value for the slope in spite of noisy signals. The method fits a line of the form

$$y = ax + b$$

The solution of the least squares method yields (Cheney 1985):

$$a = 1/d \left(m \sum_{k=1}^{m} X_k Y_k - \sum_{k=1}^{m} X_k \sum_{k=1}^{m} Y_k \right)$$

$$b = 1/d \left(\sum_{k=1}^{m} X_k^2 \sum_{k=1}^{m} Y_k - \sum_{k=1}^{m} X_k \sum_{k=1}^{m} X_k Y_k \right)$$

where

$$d = m \sum_{k=1}^{m} X_k^2 - \left(\sum_{k=1}^{m} X_k \right)^2$$

For the CO_2 waveform the slope is calculated using the above equations where time is 'x' and the CO_2 samples are 'y'. Since only the slope is needed, only the 'a' term is calculated. The program maintains the summations in the above calculation by adding the appropriate value at each sample time then calculating the slope upon completion of the breath. The slope is declared valid if it is based on more than ten samples.

The S_pO_2 data analysis is performed at the end of a breath and is based on the six most recent readings received from the pulse oximeter. These six readings translate into twelve seconds of S_pO_2 data. The data are divided into two groups of three. Each reading in the most recent first set is compared with the average of the readings in the second set (these constitute the S_pO_2 running readings) and keyed to signal a 3% decrease, or a 3% decrease compared to the S_pO_2 baseline. This baseline is established the moment the "RESET BASELINES" button is pushed by storing the average of the S_pO_2 readings at that instant.

9.4.3. About Software, Hardware, and Rules

Prototype III was implemented using the prototype II platform. To accommodate the serial communication with the pulse oximeter, an 8 channel RS-232 expansion board was added to the Personal Computer (PC). The SIMPLEXYS rule base for prototype III consisted of a grand total of 189 rules. Ninety-nine of these rules consisted of composite rules (paragraph 6.3.4), while the remaining 90 rules provided the "hooks" to signal processing code. Tests conducted with this system using a respiratory rate of 10 breaths/min indicated that a little over 15% of the available processing power of our PC was used. This result was obtained by measuring the time spent, per breath, executing

signal processing code and in evaluating rules. Excluded were screen output and overhead for data acquisition and serial communication.

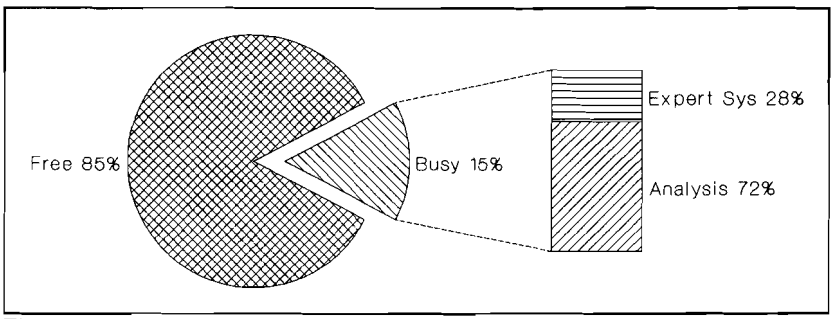

Figure 9.4 Processor load per sample

In figure 9.4 the test results are presented. All numbers are per sample. With a sample frequency of 20 Hz (50 msec) and a respiratory rate of 10 breaths/minute, one expert system run takes about 240 msec.

The memory requirements of Prototype III totalled 150 KBytes (1 Kbyte = 1024 bytes) of available memory.

9.5. Tests and Evaluation

Prototype III was tested on the Gainesville Anesthesia Simulator (GAS) using an animal (sheep) model. The test procedures and results are presented in the next sections.

9.5.1. Simulator Tests in the Animal Model

In four male sheep ranging in weight from 40 to 65 kg., an endotracheal (ET) tube was placed following induction of anesthesia with intra-venous (IV) thiopental. Anesthesia was maintained with a titrated thiopental drip. Mechanical ventilation was commenced, following the injection of a muscle relaxant, with a tidal volume of 10 ml/kg

and a respiratory rate of 10 breaths per minute. The fresh gas flow (FGF) was set to 4 liters/min of 100% O_2. The inspiratory to expiratory (I:E) ratio was 1:2. The experimental setup, apart from the mechanical lung, was identical to the setup described in paragraph 7.4 (figure 7.6). Oxygen saturation data were obtained through use of the probe of the Ohmeda 3710 pulse oximeter connected to the (well perfused) tongue of the animal. To test the performance of the system, both mechanical and non-mechanical (patient related) malfunctions were introduced.

With the help of the simulator the following mechanical malfunctions were introduced: incompetent unidirectional valves, exhausted CO_2 absorber, and CO_2 canister leak. Leaks of 2 mm (small) and 3 mm (large) as well as disconnections were introduced manually at a number of locations. Obstructions in the various hoses of the breathing circuit were obtained manually by reducing the initial diameter of the hose to one-half, and to one-fourth. The mechanical malfunctions were introduced, one at the time, using the V_T and RR deemed adequate by the clinician for the animal. The results of these tests are presented in table 9.2. An "X" indicates that a correct message appeared within 30 seconds or 5 respirations, "F" indicates that a false message was generated, while "N" marks those instances in which no message was triggered. A message was considered correct when the malfunction and its location were identified correctly, or if the identification of the nature of the malfunction was correct.

The introduced non-mechanical problems addressed oxygenation and ventilation, as well as causes such as endobronchial intubation, esophageal intubation, pulmonary emboli, and primary hypercarbia. An hypoxic mixture was created by utilizing a FGF consisting of 20% O_2 and 80% nitrous oxide resulting in a F_IO_2 of less than 21%. Adequate O_2 delivery was tested using a FGF of 0 liter/min, combined with a set delivered V_T of 80% of the calculated required V_T. Episodes of DESAT were created by respiratory arrest and/or hypoxic inspired mixtures.

Adequacy of alveolar ventilation ($\dot{V}_A$) depends on the two variables V_T and RR (paragraph 9.1.2). Evaluating adequacy of $\dot{V}_A$ first was executed with a tidal volume

Table 9.2 Matrix with test results of IASA prototype III on the Gainesville Anesthesia Simulator (GAS) during mechanical malfunctions.

Malfunction	Animal1	Animal2	Animal3	Animal4
Stuck exp. valve	X	X	X	X
Stuck insp. valve	X	X	X	X
Exh. CO_2 absorber	X	X	X	X
Small Obstr. insp. hose	N	N	N	N
Small Obstr. E.T. tube	X	N	X	X
Small Obstr. exp. hose	N	N	N	N
Small Obstr. vent. hose	N	N	N	N
Obstr. insp. hose	X	X	X	X
Obstr. E.T. tube	X	X	X	X
Obstr. exp. hose	X	X	X	X
Obstr. vent. hose	X	X	X	X
Small leak E.T. tube	X	X	X	X
Small leak Y-piece	X	X	X	X
Small leak insp. hose	X	X	X	X
Small leak exp. hose	X	X	X	X
Small leak vent. hose	X	N	X	X
Large leak E.T. tube	X	X	X	X
Large leak Y-piece	X	X	X	X
Large leak insp. hose	X	X	X	X
Large leak exp. hose	X	X	X	X
Large leak vent. hose	X	X	X	X
Y-piece leak	X	X	X	X
CO_2 canister leak	X	X	X	X
Disc. FGF hose	X	X	X	X
Disc. vent. hose	X	X	X	X
Disc. insp. hose	X	X	X	X
Disc. exp. hose	X	X	X	X
Disc. Y-piece	X	X	X	X
Disc. E.T. tube	X	X	X	X

increase and decrease of 40% of the calculated V_T to obtain a $P_{et}CO_2$ of 35 mmHg, while RR was adjusted to sustain the required MV. This would trigger the rules for the detecting high and low tidal volumes. Subsequently, hyper- and hypoventilation were introduced with an increase/decrease of 40% in MV by adjusting RR while maintaining V_T based on the calculated required value.

A mainstem intubation was simulated by advancing the ET tube into a mainstem bronchus following a period of stable anesthesia. The esophageal intubation was realized by placement of a second ET tube into the esophagus. After a two-minute period of a

stable course of anesthesia, the breathing circuit was disconnected from the ET tube, and quickly reconnected to the esophageal tube.

Air in quantities of 0.25 cc/kg was injected into the central venous catheter to cause pulmonary emboli, while primary hypercarbia was simulated by introducing a gas mixture containing 10% CO_2 into the lung. The results of these tests are summarized in table 9.3. An "X" indicates that a correct message appeared within 1 minute or 10 respirations, while "O" indicates an appropriate message. In all cases generated prototype III a message, while no false messages were triggered.

Table 9.3 Matrix with test results of IASA prototype III during "patient-problems"

Introduced Problem	**Animal 1**	**Animal2**	**Animal3**	**Animal4**
Main Stem Intubation	O	X	X	X
Esophageal Intubation	O	O	O	O
Pulmonary Emboli	O	X	X	X
Primary Hypercarbia	O	X	X	X
Hypoxic mixture	X	X	X	X
Low O_2 delivery	X	X	X	X
DESAT	X	X	X	X
Low V_T	X	X	X	X
High V_T	X	X	X	X
Hyperventilation	X	X	X	X
Hypoventilation	X	X	X	X

9.5.2. Conclusions Regarding the Third Prototype

Prototype III performed similarly to prototypes I and II in detecting mechanical malfunctions, since the rule set for the mechanical malfunctions was practically unchanged compared to evaluating the previous prototypes using GAS and a test lung (Compare with table 7.6). Also, the 116 mechanical malfunctions introduced in the animal

experiments were almost identical to the mechanical malfunctions introduced during the evaluation of prototype I. Of these 116 malfunctions, 110 were detected correctly, 14 malfunctions were not detected, almost all small malfunctions that minimally affect the signal features (table 9.2). This means that 88% of the mechanical malfunctions was detected correctly.

The major addition to the rule base (87 new rules were added) was for dealing with the identification of primary causes leading to hypoxemia. These additional rules enabled prototype III to detect flawlessly inadequate inspired O_2 concentrations using the O_2 sensor in the breathing system (table 9.3). Rules evaluating adequate O_2 delivery to the patient (sheep in our laboratory tests) triggered the correct message when the estimated O_2 consumption of the animal exceeded the delivered volume of oxygen. Prototype III's implementation of DESAT (paragraph 9.3.1) picked up rapid changes in saturation and classified these changes as desaturation before the alarm limit set on the monitoring device was exceeded. However, artificially low readings caused by placement of the probe over poorly perfused areas, or by a dislodged probe, continue to interject spurious alarms. Additional efforts by manufacturers of the pulse oximeter to improve its ability to distinguish artifacts from true signals are needed.

Where hypoventilation was the potential cause for hypoxemia, prototype III picked up successfully the introduced incident. The tidal volumes of 40% less than the calculated V_T to produce a $P_{et}CO_2$ of 35 mmHg, were also identified correctly ("Low Tidal Volume"). Similarly, during hyperventilation and V_T's of 40% larger than the calculated volumes to produce a $P_{et}CO_2$ of 35 mmHg, correct messages were presented ("High Tidal Volume"). The correct "Suspect Hypercarbia" message was generated, when the animals were ventilated with adequate MV settings, while the simulated increase in CO_2 production produced elevated $P_{et}CO_2$ tensions.

In the $\dot{V}/Q$ mismatch category, prototype III was able to detect the mainstem intubation and to generate the correct message "Suspected pulmonary emboli" after injecting the central venous catheter with air. The "Suspected Esophageal Intubation"

message was not triggered during our test sequence. The esophageal intubation did trigger messages identifying an obstruction at the Y-piece and desaturation, however, which are certainly not incorrect. The rule for the esophageal intubation used the disappearance of CO_2 as a trigger. However, in the animals the capnogram was not recognized as a valid signal by our signal processing routines. In addition, and the expected disappearance of CO_2 within the time allotted for this test was not observed, probably due to the high CO_2 content of the sheep's stomachs. After repeated attempts to intubate the mainstem bronchus in one sheep, the capnogram showed a typical waveform indicative of an uneven emptying of the lungs. Promptly the message "Suspect Bronchospasm" was triggered.

We recognize that the integrity of the breathing circuit is a crucial element in the evaluation of the patient-related problems during the development of prototype's III rule base. Most rules dealing with the patient related problems include a test assuring the integrity of the breathing circuit for a number of subsequent breaths. Changes in ventilator settings affect patient variables though not instantaneously. No changes in ventilator or FGF settings for a number of breaths was therefore another pre-requisite before examining the patient for the cause of a suspected problem.

In summary, the clinical team was quite satisfied with the performance of prototype III in detecting and recognizing 100% of the patient-related perturbations that were introduced in the animal model. The next step would be to test prototype III intra-operative. Since it is unacceptable to introduce malfunctions in non-animal tests, prototype III can only be evaluated in the operating room as a "passive" observer. Tests of its performance in the clinical arena as well on improvements in its ability to prevent false alarms are planned for the near future.

10. DISCUSSION AND CONCLUSIONS

By nature, anesthesia is not without risk. The drugs used in anesthesia produce side effects and the clinical actions of surgeons and anesthesiologists can jeopardize an already endangered patient. Monitoring devices are intended to protect the patient from devastating situations by allowing the clinician to monitor the patient's condition and, through alarms, be warned of potential problems before harm is done. We have argued that the current alarm strategy is flawed and does not help the clinician. The quest for helpful, smarter (intelligent), alarms enticed us to explore the utility of a real time expert systems approach to intelligent alarms. Now, after three years and three prototypes, numerous lines of programming code, many discussions amongst the project team, pounds of paper, and countless gallons of coffee, it is time to sit back and reflect.

There is a problem with the current alarm technology. The de facto standard for alarms seems to have been: loud, obtrusive, easily fooled by artifacts, nonspecific, not integrated, and not helpful. It was merely a matter of time before the problem just **had** to be addressed. Did we provide a solution for the problem? And if so, how did our solution stand up during the evaluation?

The Intelligent Alarms (IA) prototypes I and II through integration of the capnogram, airway pressure, and expiratory flow detect and locate mechanical malfunctions in the circle anesthesia breathing circuit during mechanical ventilation. Messages indicating the detected problem and possible location are presented in 88% of tests performed in prototype I with the Gainesville Anesthesia Simulator (GAS) using both an artificial lung and an animal model. During 11 surgical procedures, prototype I was evaluated for feasibility, while connected in parallel to existing monitoring devices in the operating room. The signal processing routines proved to be robust enough to handle the noisy, and often disturbed, patient signals. Prototype II augmented the capabilities of the previous prototype, by adding the ability to adjust automatically to setting changes. Prototype III increased the capabilities of the previous prototypes by messages intended to help the clinician in the identification of potential problems with

oxygenation and ventilation. This was demonstrated during our tests in the animal model. The third prototype identified correctly 88% of the introduced mechanical malfunctions comparable to malfunctions introduced in prototype I, while in 100% of the introduced patient perturbations helpful messages were generated.

Providing the clinician with useful alarms was one of the design goals. Showing what is NOT a useful alarm is simpler than defining the useful alarm. Repositioning of the patient by a clinician can cause artifacts in signals which in turn can trigger an audible alarm. These alarms are as annoying as those caused by electrical interference (e.g. 60 Hz interference on the ECG leads). The question of useful alarms is intertwined with the question of where to set alarm limits, or more precisely, how to set alarm limits in this patient confronting the clinician. Very quickly one recognizes that the question on how to set alarms does not originate in the operating room. It is crucial to feed the "alarm" system with as much a-priori information as possible (Beneken 1989). This requires that a complete assessment of the patient (preoperative assessment including a complete workup including laboratory tests, ECG analysis, complete physical and history on the patients background, and possible previous intraoperative data) be available to the clinician. A detailed examination was beyond the scope of our project, but we believe that extensive research will be required before solutions will be available on how to preset appropriate alarm limits.

Within the context of intelligent alarms, we consider an alarm triggered by a signal traversing a threshold and causing a beep to sound to be equally as useful (actually, useless) as a verbose message of the same occurrence. Our IA system does incorporate some of these messages, however, in the event no other messages can be generated. Our thesis is that, through integration and the use of redundancy, the clinician can be presented with a "higher" level of abstraction indicating a probable cause. To evaluate our system in this context, we tabulated both the occurrences of alarms on the front-end monitors (the alarm limits were set appropriately by a clinician) and the messages presented by our prototype system during the animal experiments for the mechanical and

Table 10.1 Comparison of usefulness of messages from the prototype III vs front-end monitors

Front-end Monitors alarms	**Prototype III messages/alarms**	**Type of Malfunction Introduced**
None	Small Leak	Small Leak
	Low Tidal Volume	Inadequate Tidal Volume
	High Tidal Volume	High Tidal Volume
High $P_{et}CO_2$	Incompetent Insp Valve	Incomp Insp. Valve
	Exhausted CO_2 absorber	Exhausted absorber
	Hypoventilation Low Respiratory Rate	Hypoventilation
	Hypercarbia	Hypercarbia
High $P_{et}CO_2$ Apnea (Ventilator)	Large Leak	Large Leak
High $P_{et}CO_2$ Reverse Flow (Volume)	Incomp Exp. Valve	Incompetent Exp. valve
Low $P_{et}CO_2$	Hyperventilation	Hyperventilation
Apnea (Ventilator, Capnograph, Volume)	Disconnect	Disconnection
Low F_IO_2	Hypoxic Mixture	Hypoxic mixture
	Low O_2 delivery	Inadequate O_2 delivery
Low S_pO_2	Low S_pO_2	Desaturation
	Pulmonary Emboli DESAT	Pulmonary Emboli

non-mechanical malfunctions. The results are tabulated in table 10.1. We submit that our prototype III generated messages at least equal to the alarms from the front-end monitors, but more often messages perceived as more helpful. We have not tested prototype III in the operating room for occurrences of "false positive" alarms, as of yet.

Based on the presented data we postulate that it is indeed possible to present the clinician with intelligent and helpful alarm messages by relying on changes in features derived from the capnogram, airway pressure, and expiratory flow waveforms, combined with known information such as ventilator settings and the patient's weight, height, and gender.

SIMPLEXYS was designed to respond to the need for a real time expert systems tool, since there was no suitable and economical commercially products available to fill that need. Through our prototypes, we have established that complex real time knowledge based systems can be implemented with SIMPLEXYS. Our current prototype implementation consists of 189 rules, half of which provide for the needed interface to incoming data. Performance measurements indicated that one rule base evaluation of prototype III takes about 240 msec with an 8 MHz 80286 processor. Prototype I, which contained 102 rules, took about 160 msec per run using the same processor. Blom demonstrated that the time required for a rule base evaluation in SIMPLEXYS is increasing approximately linear with the number of rules (Blom 1990). Our results confirm his assessment.

The translation of knowledge into SIMPLEXYS rules proved to be straightforward. The SIMPLEXYS rule syntax was easy to learn and understand. This was demonstrated by the swiftness by which new team members were able to master SIMPLEXYS and begin to contribute in the various phases of the development. Furthermore, the SIMPLEXYS rule syntax made it simple to discuss the implemented knowledge with the clinical team.

The IA system adds an extra layer on top of existing monitoring equipment. The clinician still examines waveforms and other data from the front-end monitors just as (s)he always does, but now an extra backup system is available in the background. This backup system also examines the data and by combining signals from different sources intents to reduce the number of false alarms and produce helpful messages when a problem is suspected, thus reducing the time to make a differential diagnosis.

Compared to the front-end monitors the IA layer has a distinct advantage. One knows how the IA system arrives at conclusions: the necessary knowledge is explicit, expressed in rules, and thus transparent and discussable.

Artifacts continue to plague alarms. When signals contain artifacts, features derived from these signal most likely will be affected, and erroneous values are presented. During the signal processing in many of the front-end monitors available today, much information about the original signal is lost and many times a clinician resorts to observing the waveform (if available), when derived features are not trusted. Any intelligent alarm system that relies on front-end monitoring equipment for data must be fed data that are reliable and valid. Quality control of the signals must start at those levels where the analog waveform, or a sampled version of the waveform, is still available and must continue throughout all levels of signal and feature processing. It is therefore necessary that the front-end monitors of tomorrow should provide for some form of indicator (Quality Index), signaling the quality of the outgoing data. This quality index should be accessible to subsequent layers of data processing.

Recently a number of reports have appeared providing alternate solutions to the problem of alarms. How does our solution measure up to other solutions? So far we have not been able to compare the different approaches. Westenskow and his group at the University of Utah have also addressed the integrity of the circle anesthesia breathing circuit, but have taken a Neural Network approach to alarm recognition (Orr 1989).

Their system was able to detect correctly 89.3% of thirteen introduced events in testing using seven mongrel dogs after their alarm system was trained on two mongrel dogs. Their system was also evaluated during spontaneous breathing and was able to detect 76% of the introduced malfunctions. Other expert system approaches are able to detect automatically such events as intubation and artifacts in the data from monitoring equipment (Watt 1989), or aid in the recognition of untoward events and artifacts during closed-loop blood pressure control (Fukui 1989). Others report the implementation of a diagnostic system for patient monitoring based on statistical data and probabilistic reasoning (Beinlich 1989). This prototype considers a differential diagnosis for hypovolemia, light anesthesia, main-stem intubation, esophageal intubation, and others for a patient dependent on a mechanical ventilator. A correct diagnosis in 71% of the test cases was reported with this system. After the different approaches have been compared, We suspect that a combination of the different approaches will emerge, which exploits individual strengths. This combination may well be able to deal with the complex integrated problem of how best to utilize alarms when taking care of anesthetized patients.

The development of our prototype has concentrated on *ventilation* aspects of the anesthetized patient. This is but one important aspect. During anesthesia, changes in the cardiovascular system are as important. We believe that the developed prototype is suited to serve as a platform for a cardiovascular extension.

SUMMARY

The patient undergoing surgery or a painful diagnostic procedure is anesthetized. During the procedure, the patient is monitored to titrate the level of anesthesia, detect potentially untoward changes in the condition of the patient, and prevent human error or equipment failure from producing catastrophic events. Alarms aim to help in the early detection of potentially dangerous situations. But the current alarms do not help the clinician much. Intelligent alarms are intended not only to reliably detect potentially dangerous situations, but also to help the clinician in the differential diagnosis. This dissertation describes the development of a real time expert system approach to intelligent alarms for patients under anesthesia during mechanical ventilation with the circle anesthesia breathing circuit.

The task of the anesthesiologist is to induce anesthesia in patients undergoing surgery, maintain life support and vital organ functions during the procedure, and allow the patient to awaken upon completion without complications. Anesthesia is administered through a typical sequence of events combined with the use of anesthesia equipment and the administration of drugs given intravenously and/or by inhalation (Chapter 2).

Anesthesia, by nature, is not without risk. Drugs used to induce anesthesia produce side effects. In addition, actions and clinical interventions by both anesthesiologists and surgeons sometimes may endanger the patient. Also, preexisting diseases may already put the patient at risk. Monitoring for safety and control of the anesthetic helps the clinician minimize the risk (Chapter 3). When information overload, a busy period, or lack of vigilance impedes the clinician, alarms draw attention to potential problems before the patient is harmed. The current threshold alarms do not help the clinician, because the alarms are not specific, not integrated, easily fooled by artifacts, and are loud and thus obtrusive. In addition, the clinician must set the limits triggering the alarms, which has become impractical because of their sheer number. Possible improvements include methods to set limits easily, strategies that deal with artifacts, and programs that use redundancy between signals and integrate and interrelate

these signals. Subsequently, helpful and meaningful messages that indicate the possible cause of the problem, its location, and severity are presented to the clinician (Chapter 4). The current deficiencies of the threshold alarms and possible improvements were illustrated with an example of the differential diagnosis process detailing hypoxemia (Chapter 5). Smart alarms detect changes in the state of the patient and help in the differential diagnosis process.

An analysis of the primary causes of patient injury indicated that difficulties in management of the respiratory system are most frequently the cause of patient injury. This suggested that the greatest benefit was to be realized by identifying possible causes of respiratory system difficulties in a prototype implementation. The expert system approach was chosen because the clinician's differential diagnostic process very much relies on expert knowledge. The expert makes decisions based on specific and on experience gained over many years of practice (Chapter 5).

The essentials of expert systems are described. The search for an appropriate expert system tool discovered few real time expert systems. The real time expert system tool SIMPLEXYS grew out of this. SIMPLEXYS is a toolbox with which real time expert systems can be built. It has a language, a rule compiler, tools for semantic and consistency checks, and an inference engine (Chapter 6).

The feasibility and applicability of the expert system's approach for smart alarms was illustrated with the staged development of a prototype that deals with monitoring the respiratory system of patients under general anesthesia with mechanical ventilation using the anesthesia circle breathing circuit. Maintaining adequate oxygenation and ventilation is essential to prevent clinical concerns as hypoxemia or hypoventilation from developing. Many causes can interfere with oxygenation and ventilation. One is a malfunction of the anesthesia breathing circuit. In the first stage of the development, a prototype system capable of monitoring the integrity of the circle anesthesia breathing circuit was developed (Chapter 7). Signal processing routines derived features from the capnogram, airway pressure, and expiratory flow waveforms. Based on the identification

of changes in derived features, the first expert system-based smart alarm prototype was able to detect correctly 88% of the malfunctions introduced with the Gainesville Anesthesia Simulator (GAS) within 30 seconds of the introduction. This prototype showed the utility of the SIMPLEXYS toolbox and that it is, indeed, possible to detect obstructions, incompetent valves, leaks, disconnections, and exhausted carbon dioxide (CO_2) absorber as well as the malfunction's location by combining the analysis of features from three waveforms. Moreover, when the prototype was connected in parallel to monitoring devices routinely used in our operating rooms during 11 surgical cases, the evaluation of the system revealed that, other than being hampered by artifacts, no false positive alarm messages were triggered. The feasibility of the approach was sufficiently demonstrated from this evaluation and subsequently prompted the development of a second prototype.

To compensate for the deficiency of the initial implementation in that it could be fooled when the clinician changes the settings of the mechanical ventilator, or the fresh gas flow (FGF) of the anesthesia machine, a second prototype with improved utility was developed. It is capable of automatically adapting to setting changes in the anesthesia machine and the mechanical ventilator (Chapter 8). Changes in the volume of FGF were detected with a volume monitor, while changes in ventilator settings were obtained from the ventilator itself per serial communication. The second prototype had a 96% correct detection performance during selected tests with GAS, but more important, no errors due to incorrect adaptation to a setting change. With GAS, multiple malfunctions were introduced simultaneously, and the prototype was able to identify at least one of the malfunctions in the breathing circuit.

Assuming that the breathing circuit is free of malfunctions, adequacy of ventilation and oxygenation must be evaluated with additional knowledge about the patient. In the third prototype, this concept was pursued. Based on the patient's weight, height, and gender and existing ventilation parameters, an estimate for the end-tidal CO_2 concentrations ($P_{et}CO_2$) is compared with the measured variable. A large discrepancy

triggered a differential diagnosis to aid the clinician in the early detection of perturbations in the patient's ventilation (Chapter 9). The third prototype was evaluated with GAS in an animal model (sheep). Both mechanical malfunctions, similar to malfunctions introduced in prototype I, and physiologic perturbations were introduced. Prototype III identified the nature of the introduced mechanical malfunctions during the animal experiments in 88% of the cases. During physiologic perturbations prototype III presented helpful messages in 100% of the introduced perturbations, many times before the other monitoring equipment had sounded an alarm. In addition, the messages that prototype III presented were perceived by the clinical team as more helpful compared to the beeps and sounds generated by the other monitoring equipment.

The final chapter discusses the developed prototypes. A preliminary comparison of the Intelligent Alarm system and non-integrated front-end monitoring equipment is presented. Recommendation for possible improvements are made, and future developments expanding the utility of the developed smart alarm system beyond the respiratory system are discussed (Chapter 10).

SAMENVATTING

Voor operaties en pijnlijke procedures wordt een patiënt onder narcose gebracht. Tijdens de anesthesie wordt de patiënt bewaakt om het anesthesienivo te regelen, ongewenste veranderingen in de toestand van de patiënt te onderkennen en ter herkenning van eventuele menselijke fouten of mechanische problemen, voordat deze tot catastrofale gevolgen kunnen leiden. Het aktiveren van een alarm heeft dan ook tot doel om vroegtijdig een mogelijk probleem te signaleren. Helaas zijn de huidige alarmsystemen nauwelijks van enig klinisch nut: ze zijn te beperkt. Een intelligenter alarmsysteem hoeft zich niet alleen te beperken tot het kunnen herkennen van mogelijke gevaarlijke situaties, maar kan daarnaast ook de anesthesist behulpzaam zijn in de lokalisering van het probleem en het bepalen van de urgentie ervan. In deze dissertatie wordt de ontwikkeling beschreven van zo'n intelligent alarmsysteem, bedoeld voor patienten onder narcose, die beademd worden met een ventilator.

Het is de taak van de anesthesist om de patiënt onder narcose te brengen voor een operatie, zo goed mogelijk onder narcose te houden en hem erna weer te doen ontwaken. In de Verenigde Staten van Amerika wordt een patiënt voornamelijk onder narcose gebracht met behulp van door specifieke apparatuur toegediende gassen en dampen, plus intra-veneuze narcotica (Hfdst. 2).

Anesthesie is niet zonder mogelijke nadelige gevolgen. De verdovende middelen, die gebruikt worden, hebben bijwerkingen. Daarnaast kunnen zowel chirurg als de anesthesist de patiënt in gevaar brengen door de klinische interventies. Bovendien kunnen bestaande ziektes het risico van de patiënt vergroten. Met het gebruik van patiënt-bewakingsapparatuur kunnen een aantal van deze nadelige gevolgen vroegtijdig ontdekt of voorkomen worden (Hfdst. 3).

Een alarm heeft tot doel om een mogelijk probleem onder de aandacht van de anesthesist te brengen, die mogelijk overbelast of afgeleid kan zijn. Maar dikwijls helpt het huidige alarmsysteem de anesthesist niet: de alarmen zijn niet specifiek, nauwelijks geïntegreerd, gevoelig voor artefacten en erg luidruchtig. Naast deze beperkingen moet

de anesthesist alle alarmgrenzen van de patiënt-bewakingsapparatuur instellen. Dit is op zichzelf al een aanzienlijke taak, als gevolg van het aantal grenzen. Mogelijke verbeteringen in deze situatie zijn te verwachten van benaderingen die het makkelijk maken om de alarmgrenzen in te stellen, die ongevoelig zijn voor artefacten, die de redundantie tussen signalen weten te gebruiken en die signalen van verschillende bronnen weten te correleren. Dit resulteert vervolgens in een boodschap voor de anesthesist, welke niet alleen de mogelijke oorzaak aangeeft, maar ook de mogelijke lokatie en urgentie (Hfdst. 4). De gebreken in de huidige alarmsystemen en de mogelijke verbeteringen worden beschreven met behulp van een uitgewerkt voorbeeld betreffende hypoxie (Hfdst. 5). Een intelligent alarmsysteem ontdekt niet alleen veranderingen in de toestand van de patiënt, maar assisteert bovendien in het vinden van de mogelijke oorzaak.

Een analyse van gedocumenteerde oorzaken van nadelige gevolgen van anesthesie voor de patiënt gaf aan, dat problemen met de kunstmatige beademing de meest frequente oorzaak waren. Dit suggereerde dat een systeem, dat gespecialiseerd zou zijn op het onderkennen van deze problemen, het meeste profijt zou opbrengen. Dit werd verder uitgewerkt en voor de implementatie werd de expertsysteem-benadering gekozen. Immers, ook de anesthesist wordt, bij het zoeken naar de oorzaak van problemen, geleid door zijn expertise verkregen door jarenlange praktijkervaring (Hfdst. 5).

De basisbegrippen van expert-systemen worden vervolgens beschreven. Omdat er geen geschikt commercieel real time expertsysteem gevonden kon worden waarmee het intelligente alarmsysteem kon worden ontworpen, is SIMPLEXYS ontwikkeld, dat nu is uitgegroeid tot een compleet en essentieel stuk gereedschap, waarmee real time expertsystemen gecreëerd kunnen worden. SIMPLEXYS bezit een eigen syntax voor het opstellen van regels, een compileer-programma voor de SIMPLEXYS-regels naar "C"-programmeercode, ingebouwde testen voor consistentie en semantische geldigheid, en een "inference engine" (Hfdst. 6).

Dat het inderdaad mogelijk is om een expert systeem te creeren dat in staat is om alarmering op een intelligenter peil te brengen, is aangetoond door de ontwikkeling (in fasen) van een prototype voor de detektie van abnormale en potentieel gevaarlijke situaties bij de kunstmatig beademde patiënt onder narcose. Zo kunnen er een aantal oorzaken aangegeven worden voor deze problemen, zoals hypoxie, onderbeademing of problemen met het beademingscircuit. In de eerste fase van het projekt is een prototype ontwikkeld, dat in staat was foutencondities in het beademingscircuit te ontdekken. Dit was gebaseerd op de verwerking van signalen, welke op drie verschillende plaatsen in het beademingscircuit gemeten werden: partitiële CO_2-druk bij het T-stuk, druk in het inademingsgedeelte van het beademingscircuit en de gasvolumestroom in het uitademingsgedeelte van het circuit (Hfdst. 7). Dit eerste prototype was in staat om 88% van de foutencondities welke geïntroduceerd waren met behulp van de Gainesville Anesthesie Simulator (GAS), te ontdekken binnen 30 seconden. Dit prototype demonstreerde ook de inzetbaarheid van SIMPLEXYS en toonde bovendien aan dat het inderdaad mogelijk is, op basis van een analyse van de verandering in de signaalvorm van de gemeten signalen, fouten in het beademingscircuit te onderscheiden, zoals: niet-werkende inademingsklep, niet-werkende uitademingsklep, een verzadigde CO_2-absorber, en verstoppingen van het T-stuk, de inademings- of de uitademings buis. De resultaten van tests, die uitgevoerd waren tijdens operaties, gaven aan dat het prototype geen valse alarmeringen produceerde.

Een tekortkoming van het eerste prototype was, dat het, wanneer de anesthesist de instelling van het beademingstoestel of de gasvolumestroom veranderde, dit niet kon waarnemen en daarom deze veranderingen ten onrechte aan de toestand van de patiënt toeschreef. Het tweede prototype detecteert automatisch veranderingen in de gasvolumestroom met behulp van een opnemer, terwijl veranderingen die op het beademingstoestel worden aangebracht, ontdekt worden door aan het eind van een ademteug de huidige instellingen te vergelijken met de vorige instellingen. De ventilator is hiertoe uitgerust met de mogelijkheid om met de computer de instellingen op te vragen

(Hfdst. 8). Dit tweede prototype detecteerde 96% van de met GAS geïntroduceerde foutencondities, maar belangrijker, het prototype reageerde correct op aangebrachte veranderingen in de instellingen. Het gedrag van dit prototype is vervolgens onderzocht, terwijl gelijktijdig twee foutencondities werden geïntroduceerd. In alle gevallen werd minstens één van de fouten correct ontdekt.

Wanneer vast staat dat er geen foutencondities in het beademingscircuit voorkomen, dan moet een mogelijke oorzaak voor bijvoorbeeld een onvoldoende beademing gezocht worden in het licht van een mogelijke optredende veranderingen in de patiënt. Zo kunnen onder meer de verwachte eindexpiratoire CO_2-concentraties ($P_{et}CO_2$), berekend op basis van gewicht, de lengte en het geslacht van de patiënt vergeleken worden met de gemeten waarden. Wanneer de berekende en de gemeten waarden niet overeenstemmen, dan moet naar een mogelijke oorzaak voor deze discrepantie worden gezocht. Dit is uitgewerkt in een derde prototype (Hfdst. 9). Het derde prototype is geëvalueerd met GAS in dierproeven (schapen). Tijdens de evaluatie werden zowel foutencondities in het beademingscircuit (vergelijkbaar met Prototype I), alsook fysiologische verstoringen geïntroduceerd. Dit prototype identificeerde de geïntroduceerde foutenconditie in het beademingscircuit in 88% van de gevallen. Bij de fysiologische verstoringen werd in 100% van de gevallen een boodschap gegenereerd, die correct was voor de onderkenning van het probleem. Deze boodschap werd veelal gegenereerd voordat de traditionele patiënt-bewakingsapparatuur een alarm genereerde.

De drie ontwikkelde prototypes worden met elkaar vergeleken. Ook wordt een vergelijking getrokken tussen het intelligent alarmsysteem en bestaande patiënt-bewakingsapparatuur, welke nu routinematig in operatiekamers wordt aangetroffen. Aanbevelingen en suggesties voor verbeteringen worden tenslotte aangegeven, die de inzetbaarheid van het systeem zouden vergroten (Hfdst. 10).

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About The Author

Jan J. van der Aa was born in Aarle-Rixtel (Noord-Brabant), the Netherlands, May 23, 1952. After graduation from secondary school at the Sint Joris Lyceum in 1970, he attended Eindhoven University of Technology in Eindhoven, the Netherlands. During his last year of study, he worked in the Medical Electrical Engineering group headed by Prof. Jan E.W. Beneken, where he was exposed to medical applications, specifically in anesthesia. He obtained his "Ingenieur" degree (M.S.) in August 1978. After graduation he joined Hoogovens IJmuiden B.V. in the Netherlands as a software engineer, where he was involved in the installation of a continuous steel casting machine.

In June, 1980 he came to the United States to work as a biomedical engineer in the Department of Anesthesiology at the University of Florida in Gainesville, USA under the supervision of Dr. J.S. Gravenstein. Here he worked on a number of research projects pertaining to various aspects of monitoring patients during anesthesia. In December, 1987, he obtained a M.E.(EE) degree from the Department of Electrical Engineering at the University of Florida. He is married and has two children. He is a member of the Institute of Electrical and Electronics Engineers (IEEE) and of the Association for Computing Machinery (ACM).

STELLINGEN

I.

Anesthesiologie: een vruchtbare voedingsbodem voor ingenieurs.

II.

Als de huidige trend in de gezondheidsverzekering in de Verenigde Staten zich voortzet, kan het probleem "wie zal leven, wie niet?" opgelost worden door het verkregen antwoord op de vraag: "Bent U verzekerd?"

III.

De bruikbaarheid van de huidige alarmering in patiënt-bewakingsapparatuur wordt duidelijk, wanneer men zich realiseert dat deze alarmeringsmogelijkheid routinematig wordt uitgezet.

IV.

Alarmeringen gebaseerd op het overschrijden van statische grenzen zijn begrensd door deze grenzen.
(dit proefschrift)

V.

Door de toegenomen komplexiteit van de apparatuur die gebruikt wordt tijdens anesthesie, zal in de toekomst het gebruik van een "anesthesie simulator" sterk toenemen.

VI.

Het gebruik van een "real time" expertsysteem tijdens patiënt-bewaking resulteert in een duidelijke verbetering van het alarmsysteem.
(dit proefschrift)

VII.

Een geïntegreerd anesthesie werkstation wordt niet gebouwd door bewakingsapparatuur op elkaar te stapelen.
(Jan E.W. Beneken, Anesthesia and ICU record Keeping: Present and Future Developments. Proc 9th Int Symp on Intensive Care and Emergency Medicine. Brussels March 20, 1989)

VIII.

De verwachting dat de installatie van Personal Computers in een kantoor het papierverkeer zal doen afnemen, is een illusie.

IX.

Het verdient aanbeveling om voor bepaalde artsen-opleidingen een voltooide technische opleiding als voorwaarde te stellen.
(dit proefschrift)

X.

'An alarm system should be designed to maximize the time available to correct a potential problem before injury begins'
(Peter J. Schreiber & Joachim Schneider, J Clin Monit 1989;5:201-204)

XI.

'A Carbon Dioxide Monitor that does not show the Waveform is Worthless'
(Frank E. Block, Jr, J Clin Monit 1988;4:213-214)

XII.

'The recent emphasis on instrument-assisted monitoring sometimes obscures the fact that clinical monitoring first and foremost requires clinical skills'
(Joachim S. Gravenstein, Curr Rev Clin Anest 23(6): 187-191)

Stellingen behorende bij het proefschrift van J.J.L.C.M van der Aa: 'Intelligent Alarms in Anesthesia. A Real Time Expert System Application'.
Eindhoven, 11 mei 1990.