

Toward the development of an intelligent alarm system in anesthesia

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Toward the Development of an Intelligent Alarm System in Anesthesia

by
R.H.A. Bastings

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INTELLIGENT ALARM SYSTEM IN
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This report was submitted in partial fulfillment of the requirements for the degree of Master of Electrical Engineering at the Eindhoven University of Technology, The Netherlands.

The work was carried out from April 1987 until December 1987 under responsibility of Professor J.E.W. Beneken, Ph.D., Division of Medical Electrical Engineering, Eindhoven University of Technology, at the Department of Anesthesiology, College of Medicine, University of Florida, Gainesville, Florida, under supervision of M.L. Good, M.D., J.S. Gravenstein, M.D., and J.J. van der Aa, M.E.

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Abstract

Abnormal and potentially hazardous fault conditions in the anesthesia breathing system include leaks, obstructions, disconnects and incompetent valves. The capnogram, airway pressure and airway flow waveforms measured close to the patient's mouth were recorded during a number of fault conditions to find all features that describe these cases. Algorithms that can extract these features from the individual waveforms and encode the results were developed. With the features' code it is possible to describe problems in the breathing system. Finally, a method to automatically detect malfunctions in the breathing system is described. The features' code and this method can be used by an expert system to identify clusters of malfunctions in the breathing system.

Samenvatting

Abnormale en potentieel gevaarlijke foutcondities in een anesthesie-systeem bestaan onder meer uit lekken, obstructies, onderbrekingen en niet-werkende kleppen in de slangen van dit systeem. De partiële CO₂ druk, de totale gasdruk en de gasstroom, gemeten dicht bij de mond van de patient, zijn opgenomen tijdens bovenstaande foutcondities om alle kenmerken van deze signalen die deze foutcondities kunnen beschrijven te bepalen. Vervolgens zijn een aantal programma's geschreven die deze kenmerken uit de signalen halen en coderen. Met deze code is het mogelijk om een aantal foutcondities in het beademingssysteem te beschrijven. Tenslotte is een methode beschreven om de foutcondities automatisch te detecteren. De codes en deze methode kunnen worden geïmplementeerd in een expert system om de foutcondities automatisch te detecteren.

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1. Introduction

During surgery the anesthesiologist uses drugs to block the patient's pain, to relax the patient's muscles and to induce a state of unconsciousness, while maintaining essential life functions. For that purpose the patient's state has to be taken through a well defined trajectory of normal and stable states. However, possible complications threaten the above objectives. Therefore it is necessary to monitor several features such as blood pressure, ECG etc., that can indicate possible dangerous complications. These features will be in a normal range most of the time. Deviations from a desired state are often caused by artifacts and thus generate alarms that are not helpful to the anesthesiologist.

At the Department of Anesthesiology of the University of Florida and the Department of Medical Electrical Engineering of the Eindhoven University of Technology research is carried out toward a system that reduces the number of superfluous alarms and generates helpful messages for the anesthesiologist: an Intelligent Alarm system. The proposed system is shown in fig. 1.1. The necessary patient data are collected by a data acquisition system. It transforms the physical signals like pressure and flow to electrical signals. Features of these signals, like the end tidal CO₂ pressure of the CO₂ pressure waveform, are derived by a data processing system. The intelligent alarm system checks a number of possible complications using signal features and complication models, and reports the recognized ones to the display system.

The research in Gainesville is focused on the data processing, intelligent alarms and complication models systems of the real time expert system. This expert system is at the heart of the intelligent alarm system. The medical knowledge obtained from an expert anesthesiologist (J.S. Gravenstein, M.D., Graduate Research Professor in the Department of Anesthesiology at the

University of Florida) will be the basis for the knowledge base. The medical knowledge will be acquired through interview sessions. The results from these sessions will be transferred into a set of rules that can be implemented on the expert system. These rules are checked on completeness and consistency. This may lead to renewed interviews with the expert and re-design of the rules.

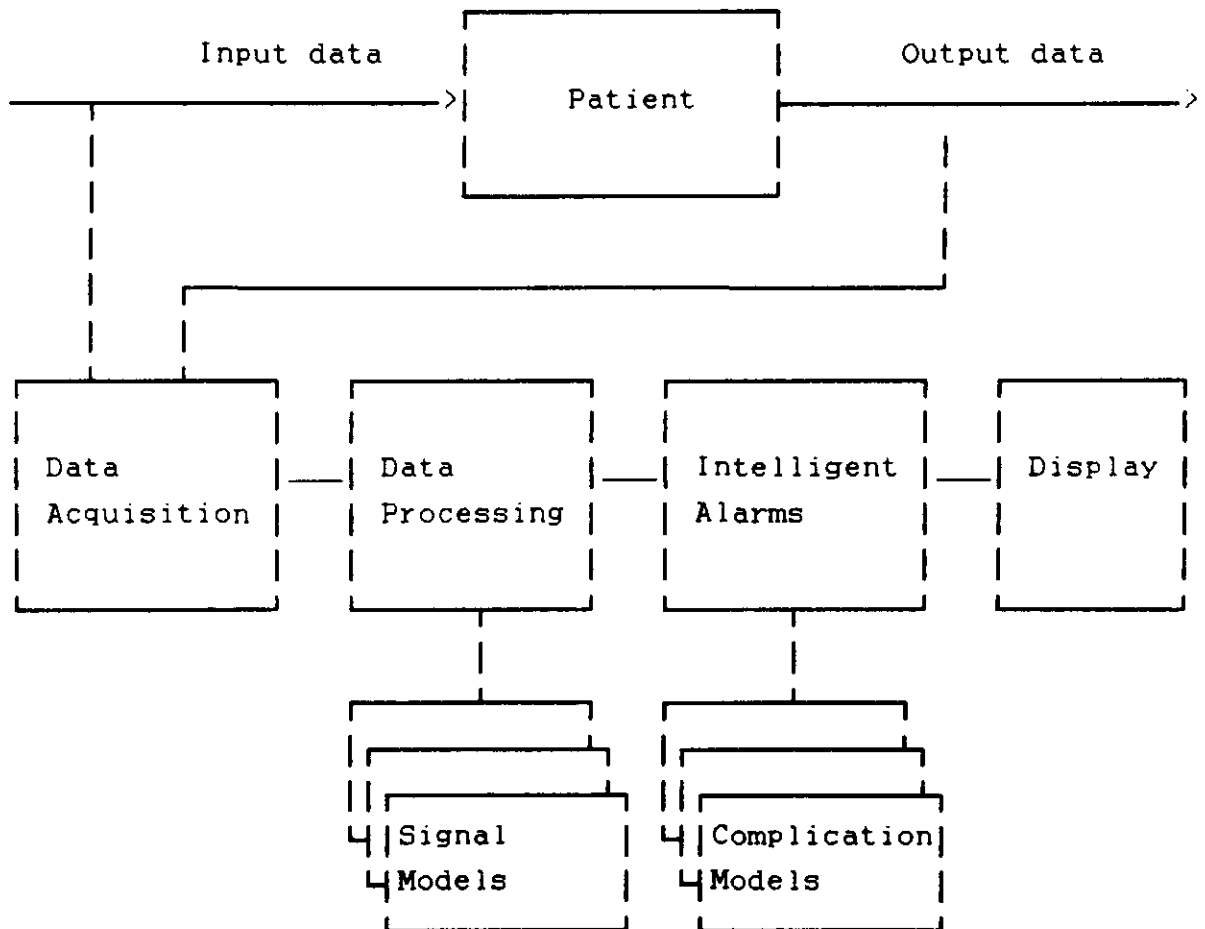


fig. 1.1 The proposed intelligent alarm system

The first prototype of the intelligent alarm system concentrates on a number of major complications that are potentially lethal or can damage the patient. These complications are:

1. Hypoxia.
2. hypoventilation.
3. hyperventilation.
4. hypotension.
5. hypertension.
6. Inadequate level of anesthesia.

In these cases decisions, based on information from a variety of sources, have to be made fast. Helpful messages would enable the anesthesiologist to identify a potential hazardous situation more readily and to evaluate essential data from the monitors more efficiently. They also reduce the possibility of mistakes.

The signals from the patient, anesthesia and monitoring equipment that will be used by the expert system include, but are not limited to the following set:

- ECG (heart rate),
- blood pressure (either invasive, non-invasive or both),
(systolic, diastolic, mean, heart rate),
- Inspired and expired concentrations of oxygen, CO₂, N₂,
N₂O, halothane, enflurane and isoflurane,
- pulse oximetry (SaO₂, heart rate),
- body temperature,
- ventilator settings (like fresh gas flow, respiratory rate,
minute volume, or tidal volume).

The anesthesiologist examines an abnormal situation in a structured way. For example, a continuous increase of the end tidal CO₂ pressure can be the result of inadequate ventilator settings, a malfunction in the breathing system or can be related to a clinical complication. Therefore, he will assess adequacy of ventilation first by inspecting minute volume, subsequently check the integrity of the breathing system and proceed considering clinical complications.

In this report a number of potential breathing system malfunctions will be discussed. The first object of this thesis is an attempt to identify these malfunctions with the signals that monitor the ventilation: the CO₂ partial pressure, airway pressure and airway flow (measured close to the mouth of the patient). The next objective is to develop data processing algorithms that transfer the information necessary for the malfunction identification into a code that can be used by the expert system. The final objective is to describe, how the expert system could process this code.

1.1 Introduction to Expert systems

Ever since the introduction of the computer, people have tried to build a system that would have expert and superhuman performance. As more experience was gained in this area, the severe limitations of the available tools and their inability to solve most complex problems became apparent. Currently, researchers limit themselves to narrowly defined application problems. The branch of computer science that is involved with this research is called Artificial Intelligence (AI).

A computer program is considered Artificial Intelligent if it can solve problems in a way that would be considered intelligent if done by a human. A major breakthrough in the area of Artificial Intelligence was made when the AI scientists began to realize that the problem solving power of a program comes from the knowledge it possesses and not just from the formalisms and inference schemes it employs. To make a program intelligent, it has to be provided with much high-quality, specific knowledge about some problem area (lit.10). The implementation of this statement resulted in the development of expert systems.

Expert systems are programs that solve problems in a certain domain in the same way as human experts in that domain. In its search for a solution, an expert system uses symbolic logic and heuristics that are derived from a human expert. It can therefore also make the same mistakes as this human expert. The advantage of the expert system over the human expert is its knowledge: it is permanently available, easy to transfer, easy to reproduce, easy to document, more consistent in its results, and inexpensive (lit. 5 and 10). However, a human expert will still have to evaluate the results of an expert system because it is limited in its results by its lack of creativity and common-sense knowledge.

A first effort to develop an expert system in medicine resulted in MYCIN. MYCIN was developed at Stanford University in the

mid-1970's to assist physicians in the selection of an appropriate therapy for patients with certain kinds of infections. Knowledge of these infections is related to the patient's history, symptoms, and laboratory test results. The expert system recommends a treatment that is obtained from physicians specializing in infectious disease therapy. An expert system that generates diagnostic and therapeutic messages about patients ventilated in an intensive care unit was developed by L.M. Fagan at Stanford University. This system, called VM (Ventilator Manager), relates its knowledge about ventilation complications with the inputs from the ventilator and monitoring equipment and identifies alarm conditions and suggests possible therapies (lit. 3).

The process of building an expert system is called knowledge engineering. The expert system builder, the knowledge engineer, is a link between the expert system building tools and the domain expert. He has to extract the strategies and heuristics from the expert and implement these in an expert system with the help of the building tools. The knowledge acquisition as proposed in the intelligent alarm project is shown in fig. 1.2. In this case, the interaction with the anesthesiologist will be supported with data from recorded complications. These data not only assist the knowledge engineer in the understanding of the rather complex matter of anesthesia, but also assists the anesthesiologist in the definition of the input signals.

In an expert system the domain knowledge and the problem solving knowledge are separated (shown in fig. 1.2). This makes an expert system very attractive for development purposes like the intelligent alarm project: the domain knowledge can easily be checked on consistency, changed and updated.

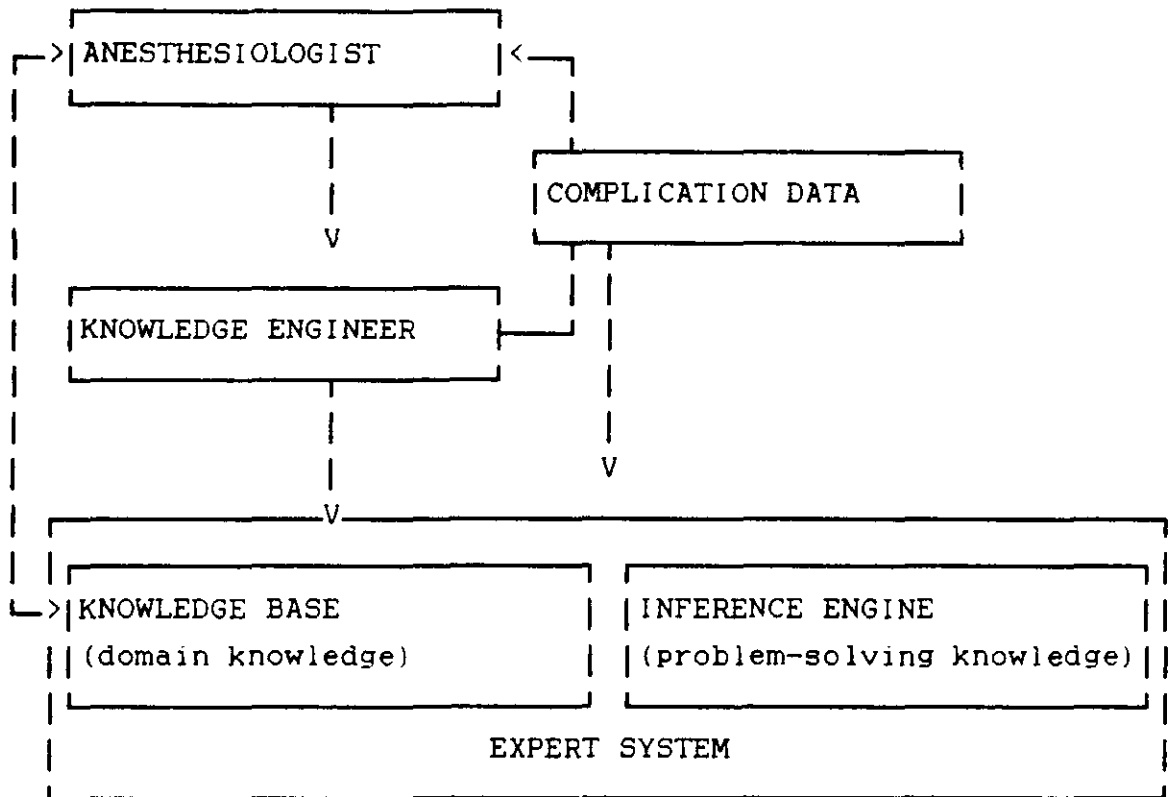


fig. 1.2 knowledge acquisition in the intelligent alarm project

1.2 Introduction to Anesthesia

The first public administration of an anesthetic drug took place in Boston in 1846. Shortly thereafter, chloroform was introduced in England. The introduction of anesthesia was a major breakthrough in medicine. However, the use of anesthetic drugs required great skill. With advances in anesthesia it became necessary to introduce training programs for anesthesiologists. Currently, an anesthesiologist is a highly trained clinician with a broad knowledge of physiology, pharmacology and specific anesthetic requirements. He must also be able to operate and correctly interpret data from a variety of monitor devices.

Nowadays, the responsibilities of an anesthesiologist include the following activities (lit. 7):

- 1) insuring that the patient is in optimal condition for surgery,
- 2) providing a safe and effective anesthetic for the patient during surgery,
- 3) leaving the patient postoperatively in stable condition without anesthetic complication or residual.

Before an anesthesiologist administers an anesthetic to a patient the available records of the patient are examined. These records describe the patient's response to anesthetics. The records also provide the anesthesiologist with information on the patient's current medical problems, possible negative reactions to drugs, and allergies. After the record examination, the patient is interviewed and physically examined. The anesthesiologist evaluates the patient's current condition and decides what anesthetic procedure he is going to use. The results of the history and physical examination plus the proposed anesthetic procedure are recorded in the patient's chart.

Upon arrival in the operating room, the anesthesiologist prepares the patient for the upcoming surgical procedure. He applies a

number of monitoring devices that provide him with physiological information on which to base medical intervention and with which to titrate drugs to a desired end point. In addition to these monitors, the anesthesiologist inserts a small catheter into one of the patient's veins. This enables the anesthesiologist to administer intravenous drugs, blood and fluids to the patient.

Since most anesthetic drugs depress the patient's respiration, it is usually necessary for the anesthesiologist to control the patient's ventilation. In addition to the anesthetic drugs, muscle relaxants are administered which makes it impossible for the patient to breathe spontaneously. In order to control the ventilation of the patient, the anesthesiologist inserts an endotracheal tube into the patient's trachea and connects this tube to a breathing system (discussed in chapter 1.3). After induction, the state of anesthesia is maintained throughout the operation.

When the operation comes to an end, the anesthesiologist prepares the patient for recovery from anesthesia. The effects of the muscle relaxants are reversed to re-establish spontaneous ventilation and the patient is awakened. Once the anesthesiologist is convinced that circulation is stable and spontaneous ventilation is adequate, the monitoring devices are removed and the patient is taken to the recovery room. Here the vital signs are recorded to insure that the patient will maintain a stable condition without complication.

1.3 The breathing system

A very important tool that assists the anesthesiologist in ventilating the patient is the breathing system. It supplies the patient with fresh gas that contains oxygen and anesthetics and removes CO₂ containing gas from his lungs. The breathing system most commonly used in the operating room in the United States consists of: an anesthesia machine, an endotracheal tube, a mechanical ventilator, and a breathing circle.

The anesthesia machine prepares the gas mixture that is delivered to the patient. The two gases commonly used in anesthesia are nitrous oxide (N₂O) and oxygen (O₂). In most hospitals, these gases are piped into the operating room from central bulk storage. Because this central supply of gases may fail, auxiliary cylinders of oxygen and nitrous oxygen are mounted on the anesthesia machine and can be used in case of an emergency. The gas flow of each gas can be regulated and monitored. After leaving their flow meters, the gases are combined and piped to the vaporizer. This is a piece of equipment, in which gas comes into intimate contact with the liquid anesthetic. The gas that leaves the vaporizer is nearly saturated with the anesthetic and is piped to the output port of the anesthesia machine.

When the anesthesiologist has applied the monitors and intravenous access, he lets the patient breathe through a mask that is connected to the breathing system. The fresh gas provided by the anesthesia machine contains an anesthetic gas that puts the patient asleep. As the patient's ability to breathe by himself decreases the anesthesiologist starts to support the ventilation. When the patient is not able to breathe spontaneously anymore, the anesthesiologist inserts an endotracheal tube that seals the airways from the environment. The endotracheal tube is subsequently connected to the breathing circle.

The patient will not be able to breathe spontaneously after the administration of the anesthetic and the muscle relaxants. A mechanical ventilator can be used to ventilate the patient's lungs. During inspiration, the gas is driven into the patient's lungs while during expiration the lungs are allowed to empty. Various types of ventilators are available. They are grouped according to their output pressure/flow waveforms (inspiration) and to their minimum input pressure (expiration). The most common ventilator used in the operating room in the United States is the constant flow ventilator with rising bellows. In the next chapters only this type of ventilator is considered.

The main function of the lungs is to exchange oxygen (O_2) and carbon dioxide (CO_2). The breathing system (shown in fig. 1.3) is responsible for the transportation of oxygen rich gas to the lungs and the removal of gas containing CO_2 from the lungs. The system consists of a fresh gas inlet (connected to the anesthesia machine), a CO_2 absorber, two unidirectional valves and a Y-piece (connected to the endotracheal tube). The unidirectional valves prevent reverse flow in the inspiratory and expiratory limb. The CO_2 absorber removes CO_2 from the inspiratory gases through a chemical reaction with an absorbent in the canister (e.g. soda lime). At the fresh gas inlet the gas mixture from the anesthesia machine enters the system.

At the start of the inspiration, the bellows of the ventilator is forced to contract by a pressure in the housing of the bellows. The gas inside the bellows is forced out the ventilator with a constant flow and is driven through the CO_2 absorber. Note, that the expiratory valve prevents the gas from entering the expiratory hose. After passing through the CO_2 absorber, the gas is mixed with the gas from the anesthesia machine and driven toward the inspiratory valve. The inspiratory valve passes the gas to the inspiratory hose and this hose transports the gas to the Y-piece. At the Y-piece, the gas is driven into the endotracheal tube, which is connected to the patient's trachea.

The gas now enters the patient's lungs. When the ventilator has delivered a desired volume of gas the inspiration is stopped and the expiration begins.

The lungs of the patient can be compared with a large elastic balloon. As its volume increases the pressure goes up. At the beginning of the expiration, a positive pressure with respect to the atmospheric pressure exists in the lungs. This pressure drives the gas into the expiratory hose. The inspiratory valve prevents the gas from entering the inspiratory hose. The expiratory hose transports the gas to the expiratory valve. After passing through the expiratory valve, the gas is mixed with the fresh gas flow through the CO₂ absorber. Finally the mixed gas is driven back into the ventilator. The bellows of the ventilator fills with the returned gas until it hits the top of its housing (rising bellows). At that time, a relief valve is opened allowing the excess gas to escape to the waste gas system (scavenging system).

During inspiration, the constant inspiratory flow delivered by the ventilator and anesthesia machine results in a linear increase of pressure at the Y-piece (compare blowing up a balloon with a constant flow). The resistance of the endotracheal tube result in an addition of a constant pressure to this linear increase (shown in fig. 1.4). During expiration the expiratory flow and pressure decrease at an exponential rate (compare emptying a balloon through a pipe).

The CO₂ pressure at the Y-piece will be zero during inspiration. At the beginning of the expiration it will gradually increase and reach a maximum when the CO₂ pressure becomes the same as the CO₂ pressure in the lungs (shown in fig. 1.4).

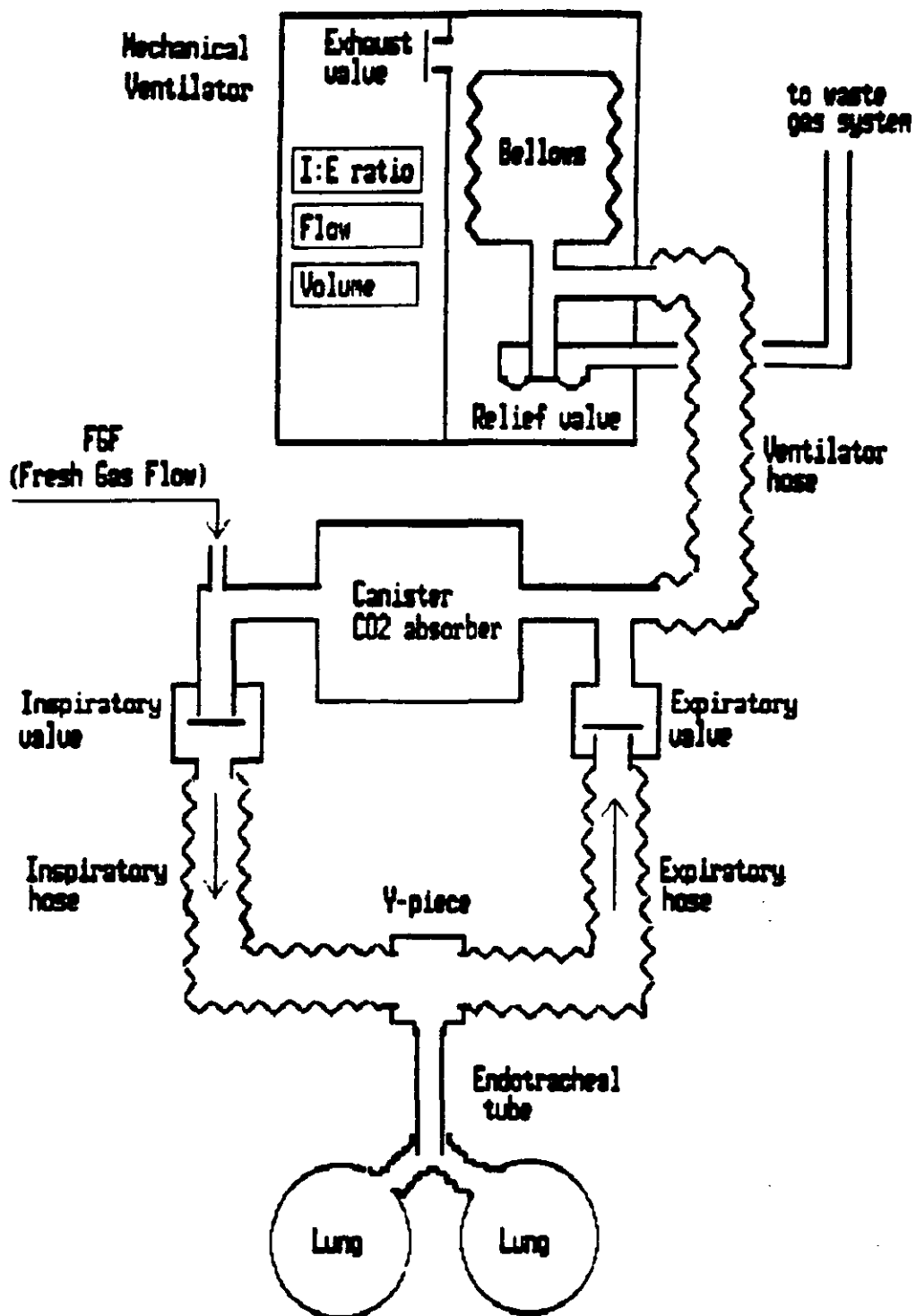


fig. 1.3 the circle system

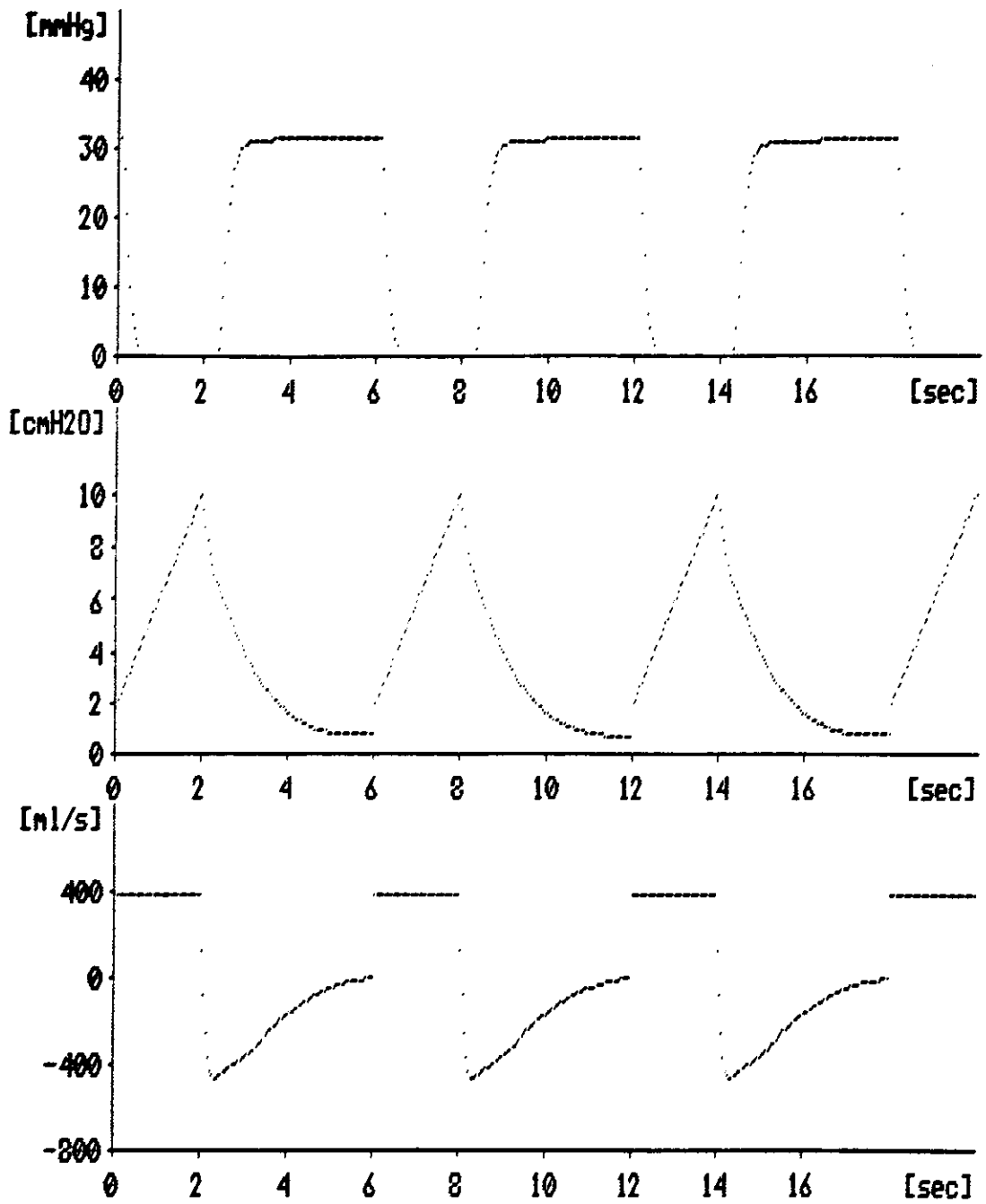


fig. 1.4 The CO₂ pressure, total gas pressure and flow waveform at the Y-piece

2. Extraction and coding of signal features

One type of complication that can occur during anesthesia are problems associated with mechanical ventilation. For example, a ventilation problem develops if the patient is not provided with enough fresh gas, either as a result of inadequate ventilator settings (e.g. tidal volume not large enough) or failure with the breathing system. Possible malfunctions of the breathing circuit include disconnects, leaks, obstructions, incompetent valves, and an exhausted CO₂ absorber. An anesthesiologist examines these deficiencies by inspecting the capnogram, peak airway pressure, inspired and expired volume (if available), ventilator settings, bellows movement and circle system components. The examination of the CO₂ pressure, airway pressure, volume and ventilator settings can be automated because they are available as electrical signals. Unfortunately, no electrical signals are yet available for the movement of the bellows and the quality of the connections and components in the circle system.

When the anesthesiologist looks at the capnogram, he examines the inspired and expired CO₂ pressures and the slopes of the up- and downstroke. If an airway pressure or volume signal is available, peak inspired pressure, inspired volume and expired volume values are examined. These features could be extracted automatically from the CO₂ partial pressure, total gas pressure and volume waveforms and used as an input to the expert system for diagnosis.

In addition to these features the expert system (discussed in chapter 1) requires a status report about the validity of the feature values. The validation will influence the selection of the alarms from the expert system. For example, in case of an artifact the gathered features will be invalid. The expert system requires this information to reduce the number of false alarms. If no features are available for a certain period of time, the

expert system has to know if a signal is flat. It indicates a disconnect in the circle system.

Finally, valid and accurate information about the complication must be available quickly because the expert system must report the complication as soon as possible. This means that the algorithms that extract the features of the signals have to adapt themselves rapidly to all kinds of new situations. For example, in case of a disconnect in the circle system the algorithms have to report as soon as possible that the signals are flat.

The number of diagnoses with the electrical signals that the anesthesiologist has available (capnogram, peak airway pressure and tidal volume) will be limited. Our approach is to record the CO₂ pressure, airway pressure and flow signals during the failures mentioned above and try to find additional features that can identify these breathing system malfunctions. These recordings were made with a normal anesthesia setup. The anesthesia machine and constant flow ventilator (rising bellows) were connected to an artificial lung with a breathing circle (explained in chapter 1.3). A sample point was created between the endotracheal tube and the Y-piece. This sample point consisted of an infrared CO₂ sensor, a pneumotachograph and a pressure gauge. These sensors were connected to a strip chart recorder and a digital computer. The constant flow ventilator was set to deliver 6 l/min with a respiratory rate of 10 breaths/min and an I:E ratio of 1:2. The fresh gas flow was set to 5 l/min. These settings are often used in the operating room for a 75 kg healthy patient. The computer was programmed to sample the three signals at 20 Hz. This is high enough to reproduce the three waveforms. The simulated malfunctions of the circle system are:

- 1) pop-off valve open,
- 2) leak at the cuff of the endotracheal tube (cuff not sufficiently inflated),
- 3) obstruction in the endotracheal tube (kinked tube),

- 4) disconnected endotracheal tube.
- 5) leak in the CO2 absorber (soda lime between the absorber segments),
- 6) exhausted CO2 absorber,
- 7) leak in the inspiratory hose near the Y-piece (hose not properly connected),
- 8) leak in the inspiratory hose near the valve,
- 9) obstruction in the inspiratory hose,
- 10) incompetent inspiratory valve (simulated with a 25 gauge needle between disk and tube),
- 11) leak in the expiratory hose near the Y-piece,
- 12) leak in the expiratory hose near the valve,
- 13) obstruction in the expiratory hose,
- 14) incompetent expiratory valve (simulated with a 25 gauge needle between disk and tube),
- 15) disconnected fresh gas flow.

A segment of the normal waveforms is shown in fig. 2.1. They look very much like the ideal waveforms (as described in chapter 1.3) except for the expiration curves of the airway pressure and flow waveform. This is caused by the ventilator bellows and the scavenging system. Because the bellows was very flexible and light, the resistance in the expiratory path was very low during the beginning of the expiration. When the bellows hits the top of its case the relief valve is opened (shown in fig. 1.3). The resistance of the tube to the waste gas system (in this case to the laboratory) had a higher resistance than the bellows. This results in a step in the airway pressure and flow expiration curve and an increase of the time constant of these curves.

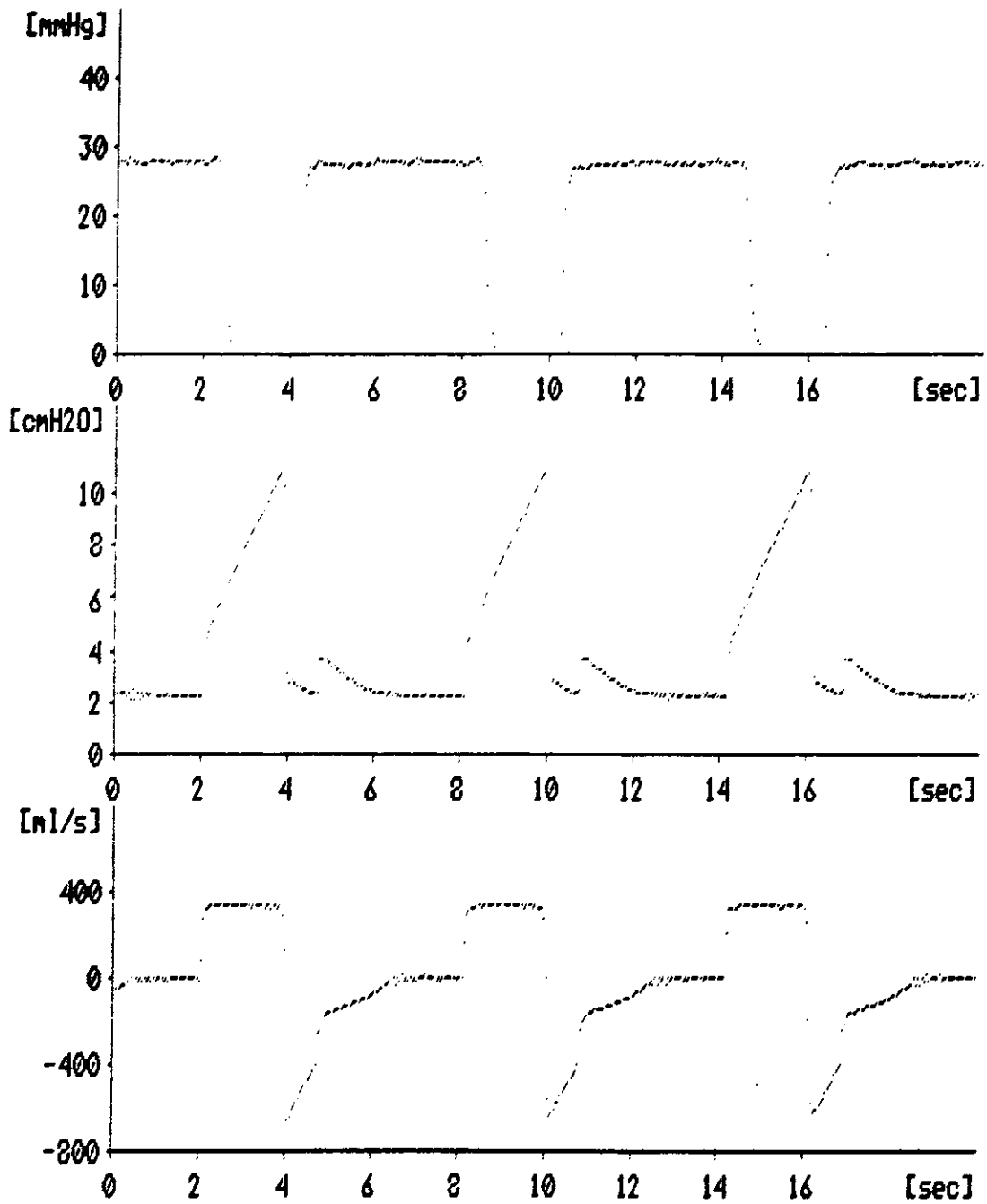


fig. 2.1 the recorded CO2 pressure, airway pressure and flow signals

2.1 CO2 pressure feature extraction

The capnograph is a very important monitor in the operating room; it contains much information about the adequacy of ventilation. It also holds information about the performance of the breathing system. For example, in the case of insufficient minute volume the end-tidal CO2 pressure will go up. If the insufficient ventilation is caused by a leak in the inspiratory hose the transition time from the expiratory to inspiratory level will increase in addition to the end-tidal CO2 pressure.

The capnogram basically consists of an inspired and expired CO2 pressure level and transitions between these two levels: the up- and downstroke. A set of features that describes the capnogram in great detail consists of:

- 1) an inspired CO2 pressure level,
- 2) an inspiration time,
- 3) a slope of transition from inspired to expired level (upstroke),
- 4) an expired CO2 pressure level,
- 5) an expiration time,
- 6) a slope of transition from expired to inspired level (downstroke).

The algorithm that extracts these features from the capnogram samples the waveform with a frequency of 20 Hz. These samples are filtered with a digital low pass filter to obtain a mean value. A positive and negative amplitude can be obtained by filtering the samples above and below the mean value. The low and high threshold are defined as the sum of the mean value and 50% of the positive and negative amplitude respectively (shown in fig. 2.2). The algorithm will start looking for a high level if the CO2 pressure signal exceeds the high threshold and it will look for a low level if the CO2 pressure signal comes below the

low threshold. This method decreases the number of false level detections caused by noise and small artifacts.

An estimation of the derivative is used to determine if a high or low level is reached: if the derivative exceeds 10 mmHg/sec and the signal is still below the high threshold a transition to the high level is expected. If the derivative stays above 10 mmHg/sec until the high threshold is reached and comes below a 10.0 mm Hg/s limit when the signal is above the high threshold, a high level is reached. If it comes below a limit of -10 mm Hg/s and the signal is still above the low threshold, a transition to the low level is expected. If the derivative stays below -10 mmHg/sec until the low threshold is reached and exceeds a 10.0 mm Hg/s limit when the signal is below the low threshold, a low level is reached. The transitions between the high and low levels define the up- and downstroke.

Inspired CO₂ pressure and inspiration time are defined as the minimum pressure and duration of the low level. Similarly, the expired CO₂ pressure and expiration time are defined as the maximum pressure and duration of the high level. The up- and downstroke represent the slope of a straight line between these levels.

Whenever the algorithm locates a low threshold (an indicator of the breath end) it computes the features mentioned above. The time between the last detection of the low threshold and the current one must be within 5% of the breath time; if this is not the case it reports all features invalid. For example, in case of a large artifact the differential time will be smaller than the breath time and the features will be invalid. If the signal reaches a high or low threshold without expecting it (the derivative did not exceed its threshold before the high or low threshold was crossed; e.g. a step changeover) that particular up- or downstroke will be reported invalid.

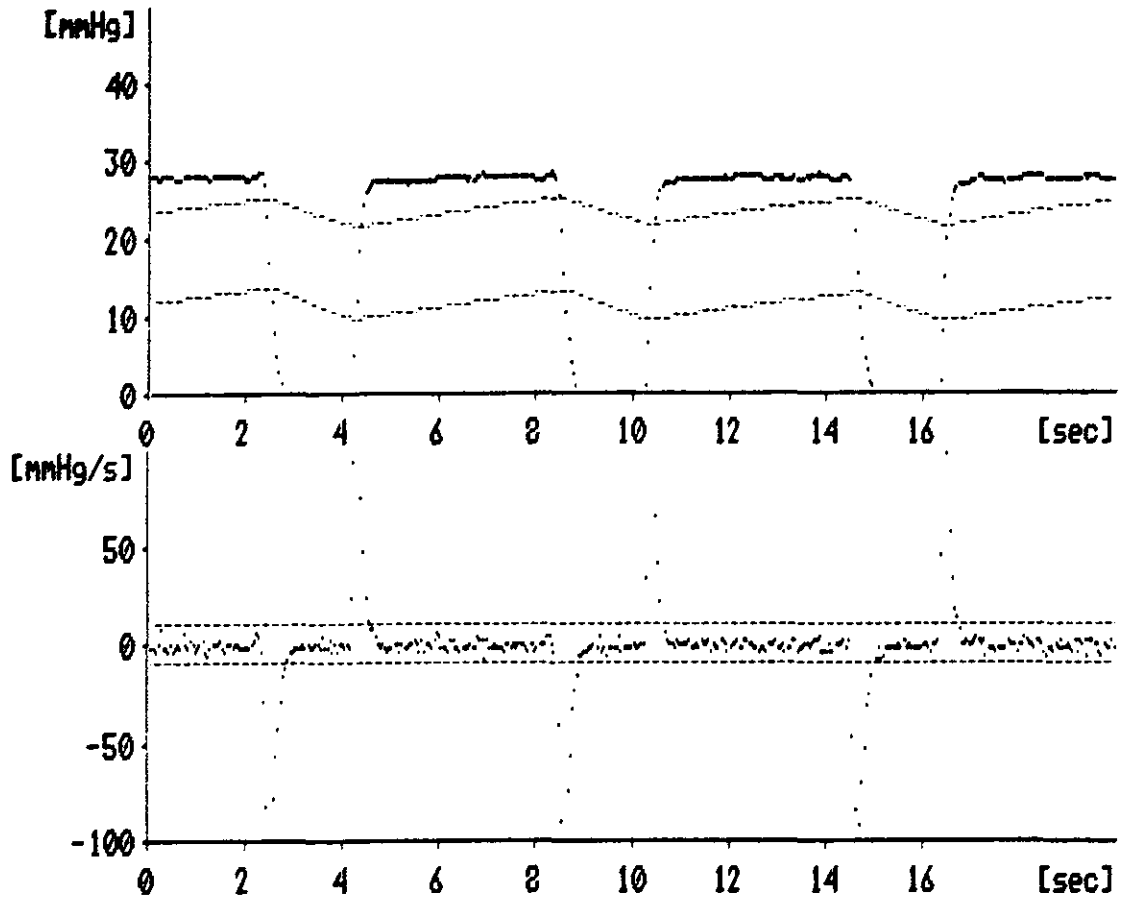


fig. 2.2 Signal and derivative thresholds used to process the CO₂ pressure signal

In the definition of the low and high threshold the speed of the adaptation and the sensitivity for the artifacts have to be considered. For example, define the thresholds as the sum of the mean value and 80% of the amplitudes. A small decrease in expired CO₂ pressure will result in a situation where the high threshold is larger than the end tidal CO₂ pressure. The thresholds have to adapt to the new situation. An artifact however, must be at least as large as the high threshold to trigger a new breath. If, for example, the thresholds are defined as the sum of the mean value

and 20% of the amplitudes, the sensitivity for an artifact is much larger while a variation in the signal is detected immediately.

The threshold for the derivative (10 mmHg/sec) and breath time (5%) are dictated by the noise on the signal. This depends highly on the quality of the ventilator, capnograph and A/D conversion used. The values mentioned above are determined with the recorded cases of malfunctions. The noise on the derivative and the deviations for the breath time were equal to 5 mmHg/sec and 2% respectively. It is very important that these thresholds are close to the noise limits because several malfunctions introduce changes near these limits.

For example, a leak in the inspiratory limb introduces CO₂ in this limb which will be rebreathed during inspiration. This rebreathing results in a decrease of the downstroke. The prolonging in transition time can only be seen at the end of the transition (when the CO₂ pressure level is already very close to the inspired level) because the CO₂ introduced in the inspiratory limb mixes with the inspired gas.

The algorithm was tested with the recorded cases of the already mentioned disconnects, leaks, obstructions, incompetent valves and exhausted CO₂ absorber. In almost all cases the algorithm came up with the correct changes immediately. In extreme cases, like a large leak in the CO₂ absorber, the algorithm adapted immediately to the new situation (shown in fig. 2.3); in the case of a disconnect it took 18 sec (3 X breath cycle) until the flag 'CO₂ signal flat' was set.

The inspired and expired CO₂ pressures that were returned by the algorithm represented the actual pressures very well. The noise introduced by sampling and filtering was less than 1 mm Hg. The slopes of the transitions returned by the algorithm contained some sampling noise because the transitions between the levels

consisted of only a few samples. In the case of a normal CO₂ pressure waveform with an inspired CO₂ pressure of 0 mm Hg and an expired CO₂ pressure of 35 mm Hg that is sampled with 20 Hz the slopes were ca. 50 mm Hg/sec with an additional noise of 5 mm Hg/sec.

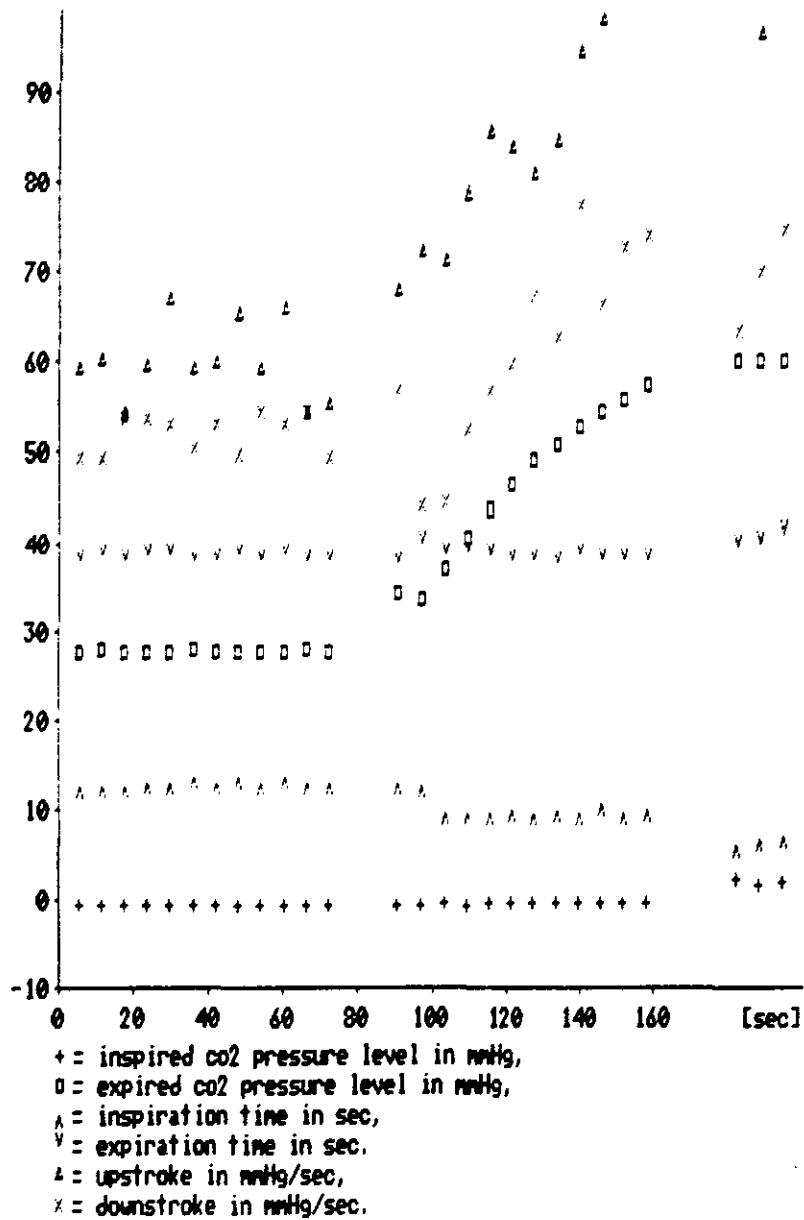


fig. 2.3 CO2 pressure feature values in case of a leak in the CO2 absorber: the leak is created at 80 sec;

2.2 Airway pressure feature extraction

The total gas pressure in the circle system is often measured with a manometer on the CO₂ canister. Currently, a trend to measure airway pressure at the Y-piece exists. This pressure is a better indicator for pulmonary ventilation because it is measured close to the trachea and lungs. It is also a good indicator for breathing circuit malfunctions. For example, an occlusion in the expiratory hose would result in an increase of pressure in the patient's lungs.

The recordings of the pressure waveform, made with a constant flow ventilator, indicated that the pressure waveform consists of a step followed by a linear increase and an exponential decrease. The signal can be described by the following features:

- 1) the step at the beginning of the inspiration (indicator for airway resistance),
- 2) the slope of the linear increase (indicator for lung compliance),
- 3) the peak pressure value,
- 4) the inspiration time,
- 5) the time constant of the exponential decrease (also an indicator for the lung compliance if the airway resistance is known),
- 6) the minimum pressure,
- 7) the expiration time.

The step at the beginning of the inspiration is caused by the resistance of the breathing path. At the end of the inspiration a similar step in the opposite direction occurs. However, it will not be added to the list of features because it is difficult to separate from the exponentially decreasing pressure.

The algorithm that extracts these features from the pressure waveform is basically the same as the CO₂ algorithm. The

waveform is sampled with 20 Hz and the mean value is obtained by filtering these values. The parts above and below the mean value are separated in order to obtain a positive and negative mean amplitude. The high threshold is defined as the sum of the mean value and the positive mean amplitude; the low threshold is the sum of the mean value and 50% of the negative amplitude (shown in fig. 2.4). The algorithm switches to a high level state if the signal exceeds the high threshold and to a low level state if the pressure comes below the low threshold.

The derivative is used to determine the transitions from the step to the linear increase. The mean value of the derivative during inspiration time is calculated and a high derivative threshold is defined as twice this mean value (shown in fig. 2.4). The beginning of a step is detected when the derivative exceeds 5 cm H₂O/s (= fixed low threshold) and the beginning of the slope is found when the derivative comes below the high derivative threshold. The slope is calculated as a linear regression between the beginning of the slope and the peak pressure value. The inspiration time is the time between the beginning of the step and the maximum value. The time constant is calculated by a fitting of an exponential function through the samples between the maximum value and the next step (preliminary version, a validation will be carried out to decide whether it is justified to do this in the final version). The expiration time is the time between the maximum value and the beginning of the next step.

When the pressure signal exceeds the high threshold the algorithm will calculate all the features in the list above. It is also tested if the time between the last calculation of the features and the current time is within 5% of the breath time. If this is not the case all features are reported invalid. If the algorithm did not find the beginning or end of a step before the signal exceeds the high threshold the step is reported to be invalid. The slope is calculated as the slope of a line between the intersection of the signal and the high threshold and the maximum

value. In case the algorithm did not find the beginning of a step, the inspiration and expiration time will also be set to invalid. This validation is a safeguard against invalid interpretation of the features in case very abnormal waveforms are processed.

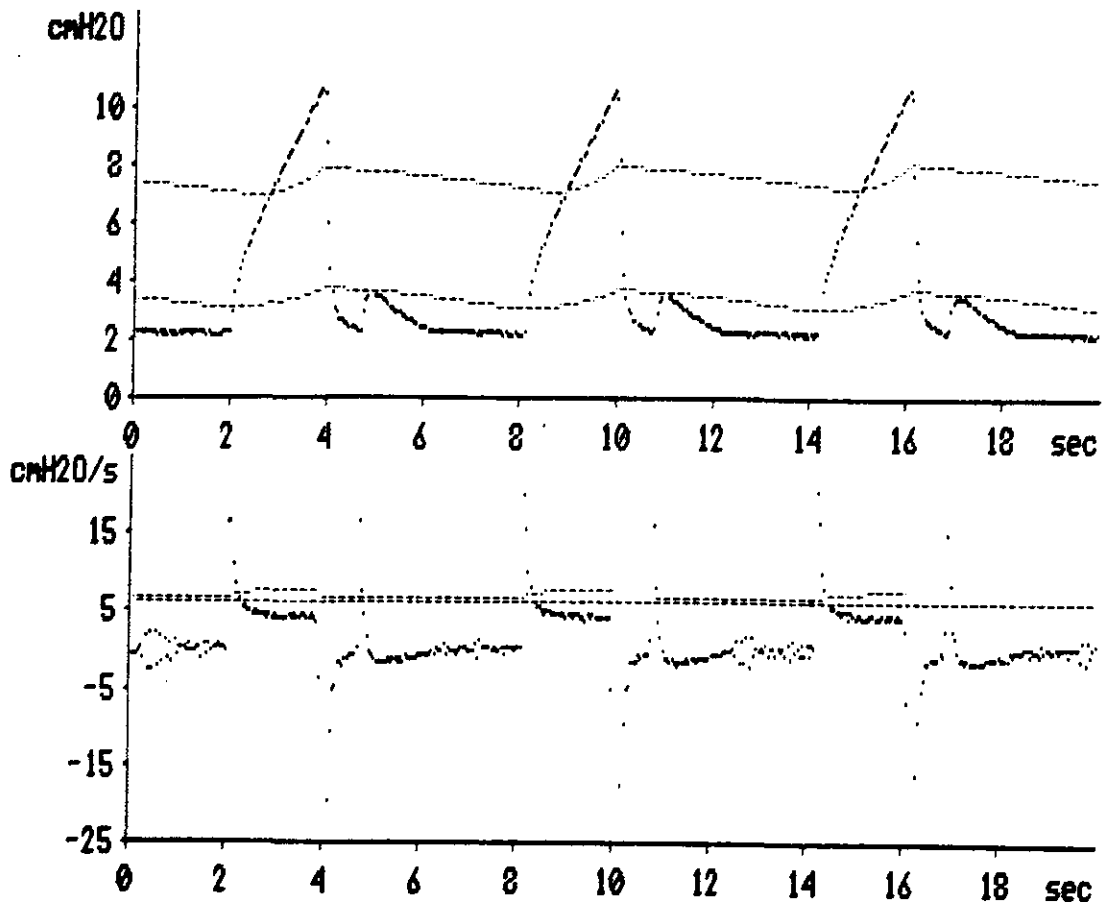


fig. 2.4 signal and derivative thresholds used to process the total gas pressure waveform

The definition of the low and high thresholds is based upon the same arguments as the CO₂ partial pressure threshold: it is a compromise between the speed of the adaptation and the sensitivity for artifacts (explained in chapter 2.1). Similarly, the threshold for the derivative (5 cm H₂O/sec) and breath time (5%) are determined by the noise on the signal which again depends on the ventilator, pressure gauge and A/D conversion used: the noise on the derivative and the deviations on the

breath time were equal to 2 cm H₂O/sec and 2% respectively. The accuracy with which the step at the beginning of the inspiration is returned depends upon the derivative threshold. This threshold must be as small as possible (limited by the noise on the signal) to obtain the highest accuracy.

This algorithm was tested with the recorded cases of disconnects, leaks, obstructions, incompetent valves and exhausted CO₂ absorber. In most bench test cases the algorithm immediately adapted to the changes and reported the new values of all features. For example, in case of an obstruction in the endotracheal tube, where the upstroke and peak pressure increased to two times the original value, the algorithm reported these values immediately (shown in fig. 2.5). In extreme cases, like a very large leak at the endotracheal tube (almost a disconnect) it lasted almost 20 sec before the new features were reported. The signal however, was very unstable and looked more like a square wave. In the case of a complete disconnect it took 20 sec until the flag 'pressure signal flat' was set.

The minimum and maximum values of the pressure signal are very stable features. The variation of these features of a normal signal were within 0.5 cm H₂O. The detection of an upstroke and slope works for a wide range of cases: slopes up to 10 cm H₂O/sec can be distinguished from the upstroke. The deviation is within 0.5 cm H₂O (upstroke) and 1 cm H₂O/sec (slope). The accuracy of the time constant depends on how well the expiration pressure signal can be described by an exponential function. In the test cases the expiration curve actually consisted of two exponential curves with different time constants; one curve describes the beginning of the expiration with the relief valve closed, and the other one describes the expiration phase with the relief valve open. The difference between these curves varies with the ventilator settings and types. In the ideal case just one time constant exists. The algorithm calculates a mean value of the time constants of both curves.

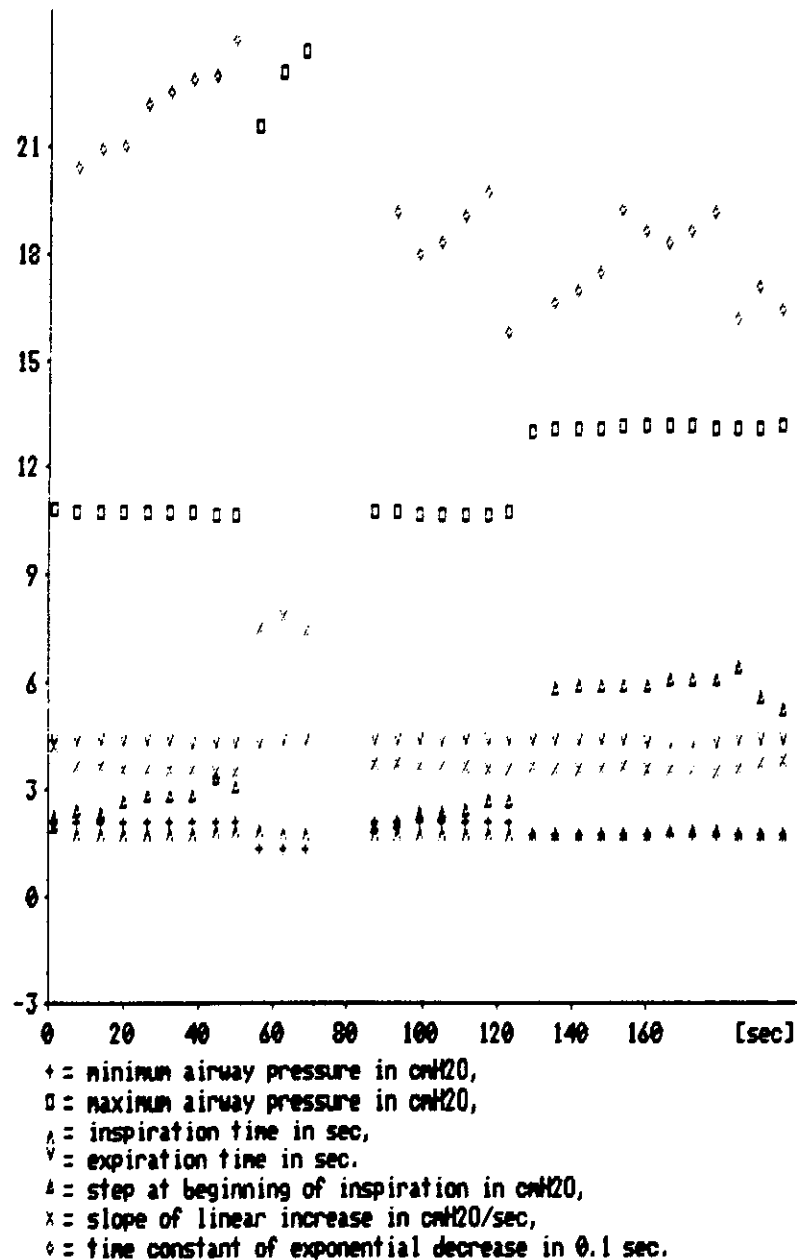


fig. 2.5 total gas pressure feature values in case of an obstruction in the endotracheal tube; a large obstruction is created between 50 sec and 70 sec; a reduction to a smaller one is created from 130 sec and lasts until the end; in the first obstruction the step is validated after 12 sec.

2.3 Airway flow feature extraction

Most ventilators measure an expiratory tidal volume signal at the expiratory valve. In the case of a well working ventilator this signal contains all the information about the ventilation. However, if a leak exists, the inspired volume or flow also contains information about this leak. For example, a leak in the circle system results in a decrease in the amount of gas delivered to the patient. It also changes the shape of the inspired flow waveform: the flow delivered to the patient is not constant anymore but decreases as time goes on. An algorithm that is used to process the flow signal measured at the Y-piece is designed to determine what the significance of the flow signal is in the detection of ventilator malfunctions.

With the ventilator used, the flow signal exists of a constant inspired flow followed by an exponentially decreasing expired flow. If a leak exists the inspired flow will decrease linearly and the inspired and expired volume will be reduced. This waveform can be described by the following features:

- 1) the maximum inspired flow,
- 2) the slope of the inspired flow curve,
- 3) the inspiration time,
- 4) the inspired volume,
- 5) the maximum expired flow,
- 6) the time constant of the expired flow curve (indicator for lung compliance if the resistance is known),
- 7) the expiration time,
- 8) the expired volume (together with inspired volume an indicator for the respiratory quotient).

The algorithm that gathers these features from the flow waveform is based on the method similar to the one that is used to extract the CO₂ pressure and airway pressure features. The signal is sampled with a frequency of 20 Hz. The positive (inspiration)

and negative (expiration) parts are separated in order to obtain an average inspired and expired flow. The high and low inspiration thresholds are defined as 75% and 25% of the mean inspired flow; the expiration threshold is defined as the mean expired flow (as shown in fig. 2.6). The derivative of the flow signal is used to detect the beginning of the inspiration and the transitions to and from the constant flow level.

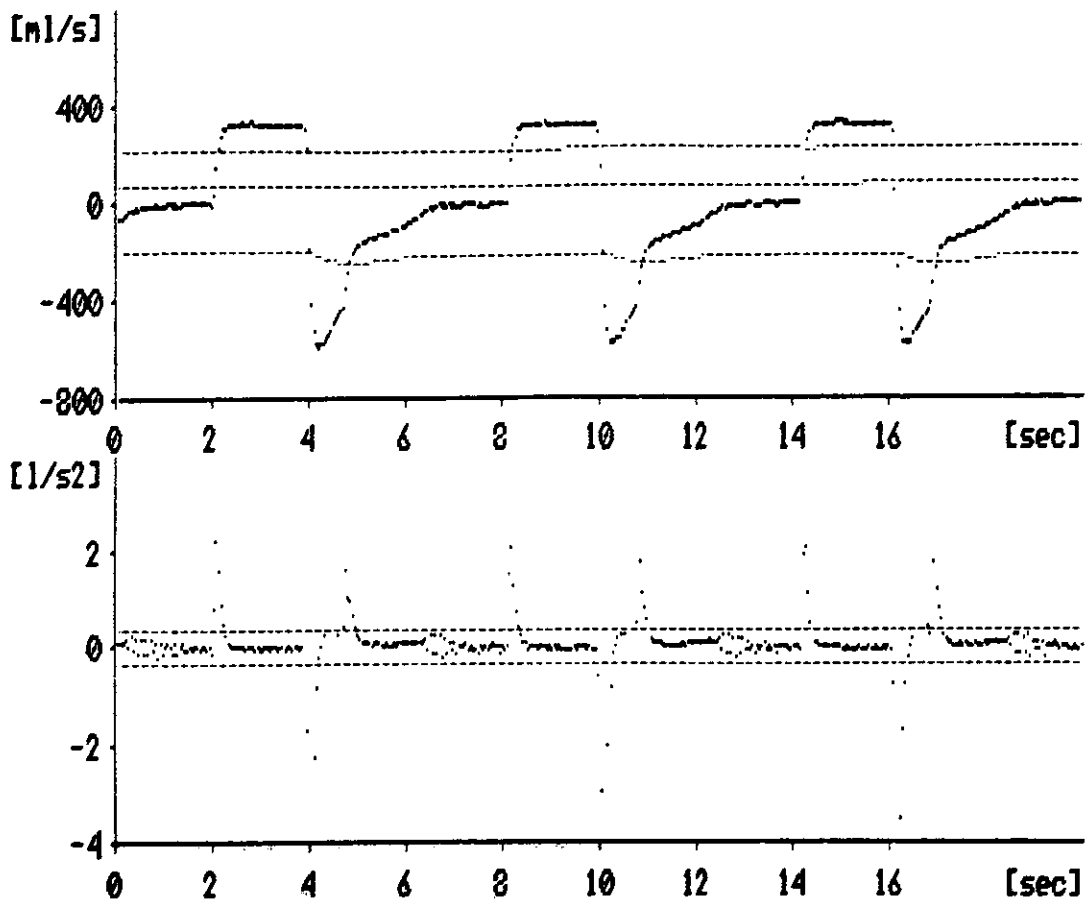


fig. 2.6 Signal and derivative thresholds used to determine the flow features

The beginning of an inspiration is detected when the derivative exceeds 350 ml/s^2 . The inspired flow level is reached when the signal exceeds the high inspiration flow threshold and the derivative comes below 350 ml/s^2 . The slope of the inspiratory flow is calculated using a fitting of a curve through the samples

in the inspired flow level. The inspiration ends when the flow comes below the low inspiration threshold. The expiration is detected when the flow exceeds the expiration threshold. The time constant is calculated by fitting an exponential function through the samples between the maximum expired flow and the beginning of the next inspiration (preliminary version, a validation will be carried out to decide whether it is justified to do this in the final version).

When the algorithm detects a new inspiration it returns all of the above features and a status report. If the time between the last detection of a new inspiration and the current is not within 5% of the breath time, all features are reported invalid. The status report also contains information about the detection of an expiration before the new inspiration and the accessibility of the signal (e.g., no signal available).

The definition of the low and high threshold is based upon the same ground as the CO₂ partial pressure and the total gas pressure thresholds: the speed of the adaptation and the sensitivity for artifacts (explained in chapter 2.1). However, three thresholds are defined to detect whether an expiration phase is present. For example, in case of a disconnect in the expiratory limb of the circle system that is connected to a ventilator with hanging bellows, the inspiratory part of the signal is still present while the expiratory part of the signal equals zero.

Similarly, the threshold for the derivative (350 ml/s²) and breath time (5%) are determined by the noise on the signal which again depends on the ventilator, pressure gauge and A/D conversion used: the noise on the derivative and the deviations on the breath time were equal to 250 ml/s² and 2% respectively.

Tests of the algorithm with the recorded cases showed that the response time of this algorithm equals the response time of the

CO2 and pressure algorithm. For example, in case of a large leak in the endotracheal tube (this case has a very unstable waveform) the algorithm reported the rapidly varying features immediately (shown in fig. 2.7). In the case of a disconnect it lasted 12 sec until the flag 'flow signal flat' was set.

Without any external interference (e.g., pressure on chest of patient) or internal interference (e.g., cough by patient) the signals are very stable: the noise on the signal is within 5% of their average value. If a large leak is introduced into the circle system the deviations around the mean value of the expiration features increased significantly: in case of a leak at the endotracheal tube, the noise increased to almost 25% of the average value. These features were also very sensitive to manipulations of the lungs or the chest (e.g., a surgeon pushing on them). In this case the features are entirely undetermined.

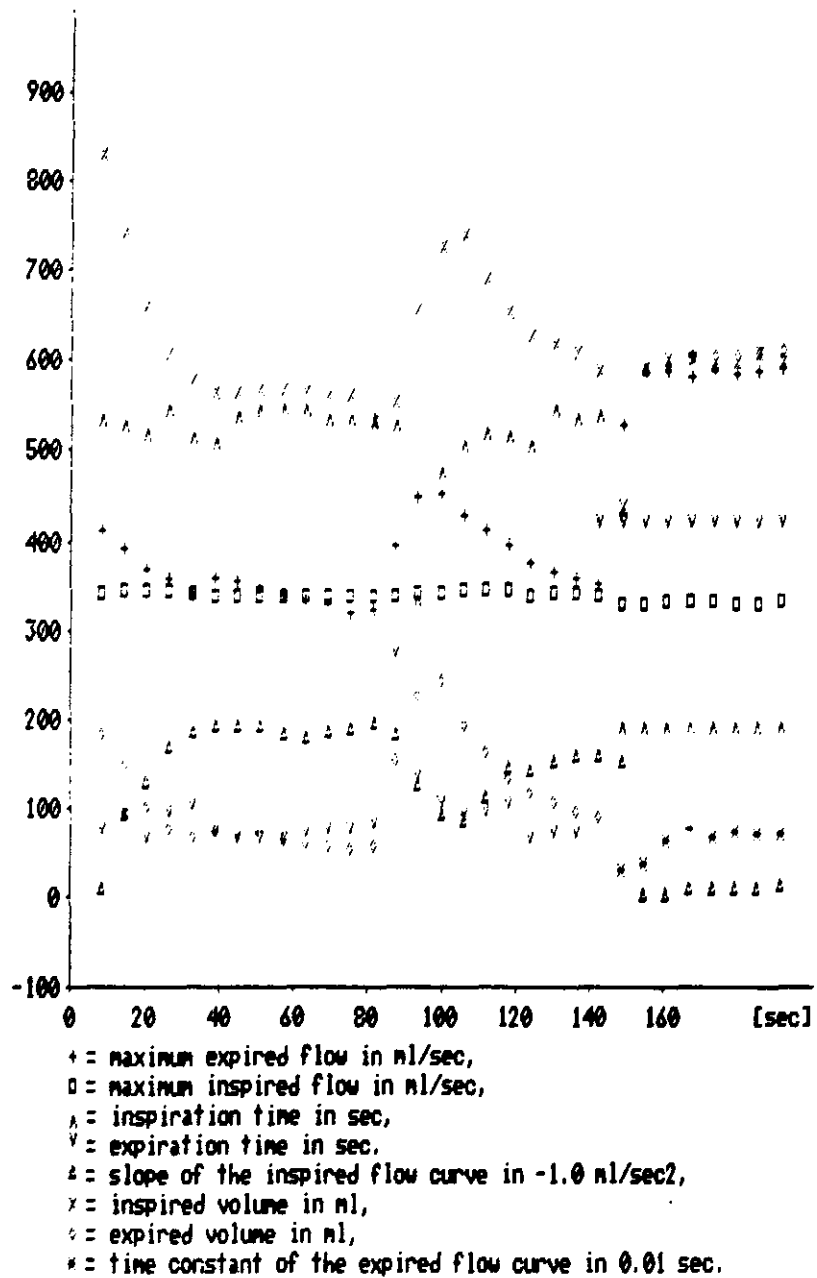


fig. 2.7 flow feature values in case of a leak in the endotracheal tube; the leak is introduced at 0 sec and reduced at 80 sec

2.4 Coding the signal features

In the previous sections sets of features that describe the CO2 pressure, airway pressure and flow waveforms are defined. During anesthesia, the values of these features will be in a normal range most of the time. However, if a complication occurs, some of these features may change.

Interviews with an anesthesiologist pointed out that he likes to know how these values change over time. The current feature values are compared with the average values of the previous ones. Some deviation from this mean value is allowed. The average of the features is taken over the last 5 minutes. This means that very slow trends in the complication identification are allowed. If the absolute values deviate too much from the "ideal" ones the anesthesiologist adjusts the ventilator.

The previous paragraph suggests that the feature values can be coded into normal, high and low feature values. A simple coding algorithm that has been implemented filters the features (to obtain a mean value), determines the normal band and assigns codes to the features (ref. 1):

code 4	-below normal band
code 5	-in normal band
code 6	-above normal band

The normal band is defined as the values within a fixed distance from the mean value. These distances are defined both by the anesthesiologist and the recorded test cases, and are listed in table 2.1. They have not yet been clinically tested. Efforts to make the width of the band vary with the amount of noise on the signal failed because the noise consists of very low frequencies and varies in time.

feature	deviation
inspired CO2 pressure	1 mmHg
expired CO2 pressure	1 mmHg
CO2 inspiration time	0.2 sec
CO2 expiration time	0.2 sec
CO2 upstroke	5.0 mmHg/sec
CO2 downstroke	5.0 mmHg/sec
minimum airway pressure	0.5 cmH2O
maximum airway pressure	0.5 cmH2O
pressure inspiration time	0.2 sec
pressure expiration time	0.2 sec
pressure step at beginning of inspiration	1.0 cmH2O
pressure slope of linear increase	0.2 cmH2O/sec
time constant of linear decrease pressure curve	0.2 sec
maximum expired flow	20 ml/sec
maximum inspired flow	20 ml/sec
flow inspiration time	0.2 sec
flow expiration time	0.2 sec
slope of inspired flow curve	20 ml/sec ²
inspired volume	30 ml
expired volume	30 ml
time constant of expired flow curve	0.2 sec

tab. 2.1 the allowed distance from the mean values of all the features

This coding algorithm has two disadvantages:

- if a value increases to the edge of the band the code will change frequently due to the noise on the signal;
- if a value changes due to a malfunction in the circle system the mean value will adjust to this abnormal value; when the malfunction is neutralized the value falls outside this (false) normal band again but now in the opposite direction.

These shortcomings can be improved upon by adding a counter to the code. This counter is increased if the code equals 6, decreased (into negative numbers if necessary) if the code equals 4 and counts towards zero (it stops counting as zero is reached) if the code equals 5. For example, if a value is just above the band the code will vary a lot but the average counter value will slowly increase as more samples are above the band than in it. A message that indicates the complication can be presented if the counter reaches a certain value and removed if the counter reaches zero again.

If the code is not appropriate, the algorithm can be reset. It will then average only those values that come after the reset and use this value to determine the normal band. This continues until the time constant of 5 minutes is reached. This method is also used when the system is started. It has the disadvantage that it makes the algorithm more insensitive for changes in the beginning because the mean value can vary faster. The algorithm becomes more inflexible as time goes on.

The algorithm is tested with the recorded cases of disconnects, leaks, obstructions, incompetent valves and exhausted CO₂ absorber. The normal band was calculated with the limits in table 2.1. If no malfunction was introduced yet, all the codes except the ones for the pressure time constant (as explained in chapter 2.) were equal to 5. An example of the coding of a leak in the expiratory limb is shown in fig. 2.8. Due to the decrease in minute ventilation the following happens:

- the inspired CO₂ pressure (and with it the up- and downstroke) goes up
- the peak pressure and slope of the inspired pressure curve go down; in case of a large leak, the minimum pressure goes also down
- the maximum in- and expired flow, the in- and expired volume and in case of a large leak the slope of the inspired flow curve and the time constant of the expired flow curve go

down.

The patterns that describes a leak in the expiratory limb are:

5 6 5 5 5 5/6 5/6 4/5 4 5 5 5 5 4 4/5 4/5 4/5 5 5 5 4/5 4 4 4/5

time	CAPNOGRAM:							AIRWAY PRESSURE:							AIRWAY FLOW:																																																																																			
	inspired CO2 pressure level							expired CO2 pressure level							breath time							inspiration time							expiration time							upstroke							downstroke																																																							

fig. 2.8 codes of the signal features in case of a leak in the expiratory hose; leak is introduced at 40 sec and increased at 70 sec

3. The integrity of the breathing circle

The first effort to develop an intelligent alarm is focused on the integrity of the breathing circuit. CO2 pressure, airway pressure, and flow waveforms were recorded for a number of possible breathing circuit malfunctions. These recordings are used to define models that describe the CO2 pressure, airway pressure and flow waveforms in terms of features. In the previous chapter algorithms that extract the model features from the signals and an algorithm to code these features were described.

In the first section of this chapter, the different complications that can be identified with the obtained feature codes are determined. In the second section, the set of features that describes these complications is evaluated and reduced to a smaller set that is required to identify these complications. The knowledge about the identification and the feature codes can be used by an expert system (described in chapter 1.1) to generate the intelligent alarms.

3.1 Complication identification

In this section, the ability of the signal feature codes to recognize the recorded malfunctions is discussed. Only the significantly changing features are used because they identify the malfunction with a high probability. The features that are insensitive for a complication are already eliminated during the encoding of the features. The results of these discussions are combined into groups of malfunctions that can be identified by the CO₂ pressure, airway pressure, and flow signals.

With the CO₂ pressure features, it is possible to identify the following four cases (identification within each case is not possible):

- 1) a leak in either the endotracheal tube or the expiratory hose or the CO₂ absorber or an open pop-off valve,
- 2) either a leak in the inspiratory hose or an incompetent inspiratory valve,
- 3) either an exhausted CO₂ absorber or an incompetent expiratory valve,
- 4) a disconnect in the circle system.

An incomplete obstruction in the circle system cannot be seen readily in the capnogram when the patient's lungs remain sufficiently ventilated.

A leak in the endotracheal tube, expiratory hose or CO₂ absorber and an open pop-off valve result in a decrease in minute ventilation. This causes an increase of the end-tidal CO₂ pressure and in the steepness of both the up- and the downstroke. A leak in the inspiratory hose, or an incompetent inspiratory valve allow some expiratory gas to get into the inspiratory limb. The inspiratory hose now contains some CO₂ and with a new inspiration this can be seen in the capnogram as a decrease in the steepness of the downstroke or an extension of the plateau of the capnogram.

An exhausted CO₂ absorber and an incompetent expiratory valve return unscrubbed gas to the patient because an exhausted CO₂ absorber eliminates not all the CO₂ from the recycled gas while an incompetent expiratory valve allows some of the gas from the bellows to enter through the expiratory hose. Both cases result in an elevation of inspired CO₂ pressure. If minute ventilation, fresh gas flow and CO₂ production stay constant, the end-tidal CO₂ pressure will also go up.

A disconnect in the circle system stops the ventilation of the patient. The CO₂ pressure at the sample point will not change (in line infrared sensor) or go to zero (side stream analyzer).

The pressure features enable a distinction of the following four cases:

- 1) either a leak in the circle system or an open pop-off valve (distinction between these items is not readily possible with this signal),
- 2) a disconnect in the circle system,
- 3) an obstruction in the endotracheal tube,
- 4) an obstruction in the expiratory limb.

An exhausted CO₂ absorber, an incompetent valve or a partial obstruction in the inspiratory hose do not change the pressure waveform.

An occlusion in the inspiratory hose will open the pop off valve because the (constant) flow ventilator increases the pressure until the required inflow is reached.

A leak in the circle system or an open pop-off valve results in a decrease of tidal volume. This causes the slope of the linear increase, the peak pressure and the time constant of the exponential pressure to decrease. A disconnect in the circle

system results in a complete pressure loss in the circle system; the patient is no longer ventilated.

The step at the beginning of the inspiration is to overcome the airway resistance of the inspiratory limb when the ventilator starts the constant inflow. An obstruction in the endotracheal tube increases the airway resistance and this increases the step. As the inflow stays constant, the linear increase will not change and the maximum pressure increases the same amount as the step. An obstruction in the endotracheal tube or an obstruction in the expiratory hose increases the resistance of the expiratory path. This results in a rise in the time constant of the exponential decreasing pressure and, if the obstruction is very large, an increase of the minimum pressure.

The flow features separate the following cases:

- 1) either a leak in the circle system or an open pop-off valve (distinction between these two items is not readily possible with this signal),
- 2) a leak in the endotracheal tube,
- 3) a disconnect in the circle system,
- 4) an obstruction in the endotracheal tube or in the expiratory limb.

An exhausted CO₂ absorber, an incompetent valve or a partial obstruction in the inspiratory hose cannot be readily detected since no change in the flow waveform is detectable (see also pressure features). A leak in the circle system or an open pop-off valve result in a loss of gas. The inspired flow, the maximum expired flow, the time constant of the expired flow waveform and the in and expired volume all go down. The leak flow increases as the pressure goes up. This results in an almost linear decrease of inspiratory flow throughout inspiration (constant flow ventilator); that is, the slope of the inspired flow curve is negative.

A disconnect in the circle system results in a total pressure loss. An obstruction in the endotracheal tube or in expiratory hose increases the resistance of the expiratory path; the peak expiratory flow will go down and the time constant will increase.

If CO₂ pressure, airway pressure and flow features are combined, the following cases can be distinguished (distinction within each case is not possible):

- 1) a leak in either the expiratory hose, the ventilator hose or the CO₂ absorber, or an open pop off valve,
- 2) a leak in the inspiratory hose,
- 3) a leak in the endotracheal tube,
- 4) either an incompetent expiratory valve or an exhausted CO₂ absorber,
- 5) disconnects in the circle system,
- 6) an obstruction in the endotracheal tube,
- 7) an obstruction in the expiratory limb (expiratory hose plus ventilator hose),
- 8) an incompetent inspiratory valve.

A partial obstruction in the inspiratory hose cannot be detected with CO₂ pressure, airway pressure and flow signals measured at the Y-piece. The constant flow ventilator increases the pressure in the inspiratory flow limb until the desired flow is reached. With a large obstruction, this high pressure will open the pop off valve.

The distinction of the location of the leak is limited to the endotracheal tube, inspiratory limb and expiratory limb. The resistances of the inspiratory and expiratory limb are too small to exactly locate a leak within these limbs. The distinction between an exhausted CO₂ absorber and an incompetent expiratory valve is impossible.

3.2 Signal feature analysis

In the previous section a number of breathing circuit malfunctions have been identified. In the identification, a set of features was used that could describe the CO₂ pressure, airway pressure and flow signals as completely as possible. As suspected, a lot of redundancy exists in this set of features. In this section, a smaller set of features, still able to identify the different groups of malfunctions, is derived. This assumes that one of the signals might not be available due to a malfunction or loose transducer. The reduced feature set will be discussed for each malfunction.

Disconnect.

The indicators for this malfunction are:

- 1) CO₂ pressure signal flat,
- 2) pressure signal flat,
- 3) flow signal flat (if the ventilator has rising bellows).

Each signal has its own indicator for a disconnect. A combination of these flat signals can give a very dependable alarm 'disconnect' while one flat signal tends more to a message that the probe might be loose. However, during interviews with the anesthesiologist it became clear that information on the CO₂ pressure signal is always important. If the CO₂ pressure signal is flat and the conclusion 'disconnect' is not reached the anesthesiologist still would like to have a warning 'CO₂ pressure signal flat' because it draws attention to the source of the CO₂, namely the patient.

Leak.

A leak changes at least 16 of the 21 defined features. Most of them however, changed because the features are interrelated. For example, the maximum airway pressure decreases, because the slope

of the pressure-increase and the minimum airway pressure decreases and the step remains constant. The smaller set of features that is directly affected by and very sensitive for this malfunction includes:

- 1) expired volume,
- 2) inspired volume,
- 3) slope of the inspired pressure curve,
- 4) expired CO2 pressure,
- 5) CO2 downstroke,
- 6) time inspired CO2 pressure level,
- 7) slope of the inspired flow curve (in case the leak exists when the system is started).

A leak results in a decrease of expired volume. However, this will also be the case with a change in ventilator settings (e.g. tidal volume decreased). The expired volume can therefore only be used to back up a leak diagnosis.

The slopes of the inspired pressure and flow curves are heavily related. In a circle system with no leaks, they are both approximately linear. In the presence of a leak, these slopes transform to exponential curves (leak flow increases as the pressure in the circle system goes up). However, the time constants of these curves (depends upon the size of the leak) are in the order of several minutes, so each curve can still be approached by a linear model. A leak in the circle system reduces the slopes of the inspired pressure and flow curve. However, a decrease in tidal volume caused by a change in ventilator settings also results in a decrease of pressure slope. The decrease of the pressure slope can therefore only be used as a backup for the leak diagnosis. Because the used ventilator is a constant flow ventilator, the slope of the normal inspired flow waveform is known to be zero. This can also be used to detect a leak when the normal waveforms are unknown.

The expired CO2 pressure is related to the minute ventilation. Both a leak in the circle system and a change of tidal volume by ventilator settings (the gas mixture stays the same) decrease minute ventilation increase expired CO2 pressure. The expired CO2 pressure elevation can therefore only be used to back up a leak diagnosis.

The leak in the endotracheal tube distinguishes itself from a leak anywhere else in the circuit because inspired volume is unequal to expired volume. A leak in the inspiratory limb can be discriminated from a leak in general by the increase in CO2 downstroke time and a decrease in inspiration time. Negative results of the tests that separate these leaks from anywhere else in the system do not necessarily mean leaks do not exist. For example, a small leak in the inspiratory limb only changes the codes of the volumes, slope of the inspired pressure curve and the expired CO2 pressure, while the code of the CO2 downstroke feature does not change in this case.

incompetent inspiratory valve.

This malfunction can be identified by the following indicators:

- 1) expired CO2 pressure,
- 2) CO2 downstroke,
- 3) time inspired CO2 pressure level,
- 4) leak.

The most important signal to indicate an incompetent inspiratory valve is the capnogram. However, both an incompetent valve and a leak in the inspiratory limb allow expiration through the inspiratory limb. Only the leak signs in the pressure or flow signal separate the incompetent valve from the leak.

exhausted CO2 absorber or incompetent expiratory valve.

It is already shown in chapter 3.1 that these two malfunctions cannot be distinguished with the CO2 pressure, airway pressure and flow signals measured at the Y-piece. The only feature that is needed for the diagnosis is the inspired CO2 pressure. This pressure will be elevated if one of the complications occurs. The diagnosis can be confirmed with the expired CO2 pressure. This pressure is also elevated assuming the CO2 production in the patient stays the same.

obstruction in the endotracheal tube.

This malfunction can only be identified with an increase in the pressure step at the beginning of an expiration. The identification can be confirmed by an increase in peak pressure which is a result of the increase of the pressure step but is more sensitive and accurate to determine than the pressure step.

An obstruction in the endotracheal tube cannot be distinguished from the patient complication bronchospasm. A diagnosis for an increase in pressure step would be "obstruction distal to the endotracheal tube".

obstruction in the expiratory limb.

The features that can describe this complication are:

- 1) minimum airway pressure,
- 2) time constant of the exponential pressure decrease,
- 3) maximum expired flow.

A small obstruction will result in an increased time constant of the exponential pressure decrease and a decreased maximum expired flow. A larger obstruction will also elevate the minimum airway pressure (PEEP). The patient will respond to the increase in

minimum airway pressure with an increase in the Functional Residual Capacity (FRC). The FRC increase reduces the compliance of the lungs. A reduction in the lung compliance results in an increase of peak airway pressure and time constant of the exponential pressure decrease. The peak airway pressure can again confirm the diagnosis.

3.3 Alarm generation

The knowledge of the complication identification (section 3.1) and the most important features (section 3.2) are used to design the expert system rules. In this chapter an example of a rule base for the expert system using the described algorithms is discussed. The operation of the designed algorithms in this sample rule base is discussed with the help of a leak in the inspiratory limb.

The rule base for the expert system (described in a meta language of the expert system) can be structured as follows:

breathing_system_malfunction:

disconnect OR leak OR valve/absorber_malfunction OR
obstruction

disconnect:

CO2_flat AND (pressure_flat OR flow_flat)

leak:

(expired_volume_down AND expired_CO2_up) OR
(expired_volume_down AND slope_linear_increase_pressure_down)
OR (expired_CO2_up AND slope_linear_increase_pressure_down)
OR negative_slope_inspired_flow_curve
HYPOTHESIS: leak_endotracheal_tube, leak_inspiratory_limb

leak_endotracheal_tube:

inspired_volume NOT EQUAL expired volume

leak_inspiratory_limb:

CO2_downstroke_longer OR CO2_inspiratory_time_down

valve/absorber_malfunction:

incompetent_inspiratory_valve OR
incompetent_expiratory_valve/exhausted_CO2_absorber

incompetent_inspiratory_valve:
expired_CO2_up AND (CO2_downstroke_down OR
inspiratory_time_down) AND NOT leak
incompetent_expiratory_valve/exhausted_CO2_absorber:
inspired_CO2_up AND expired_CO2_up

obstruction:
obstruction_endotracheal_tube OR obstruction_expiratory_limb

obstruction_endotracheal_tube:
peak_pressure_up AND pressure_step_up

obstruction_expiratory_limb:
(peak_pressure_up AND minimum_pressure_up) OR
(time_constant_exp_pressure_decrease_up AND
maximum_expired_flow_down)

The above rule base can be used to detect malfunctions during anesthesia. However, this rule base can not be used to detect a number of malfunctions that already exist when the system is switched on because the normal values of the features have to be known to decide whether a feature is up or down.

An expert system using this rule base will be able to detect a disconnect, a leak in the circle system (general) and leak in the endotracheal tube (specific) after startup because these conclusions are reached with absolute values for the features (signal flat, negative slope, in/expired volume).

If the ventilator settings are known, an open pop off valve can be identified with a leak and a discrepancy between the inspiratory time delivered by the ventilator and measured at the mouth of the patient.

A leak can be detected more reliably with the ventilator settings because the exact amount of gas that is driven into the ventilator can be calculated:

volume = (ventilator flow + fresh gas flow) * inspiration time.
If the respiratory quotient can be neglected, the amount of expired gas in a circle system with no leaks should be the same as the volume driven into the system.

With the ventilator settings available, the urge to measure the flow at the Y-piece decreases. Flow measurement in the expiratory limb would still enable a leak to be detected when the system is switched on (see previous paragraph) and, in addition, would make it possible to distinguish between an exhausted CO₂ absorber and an incompetent expiratory valve (flow in expiratory limb during inspiration). However, the identification of a leak at the endotracheal tube will not be possible anymore.

The application of the algorithms can be demonstrated with a leak in the inspiratory limb of the circle system. The sampled CO₂ pressure, airway pressure and flow signals (shown in fig. 3.1) are the inputs for the feature algorithms. These algorithms return the values and status of the features as defined in section 2.1 through 2.3 (shown in fig. 3.2-4). The values and status are used to encode the features as described in chapter 2.4 (shown in fig. 3.5). These codes are used in the expert system to identify the complication.

As discussed in chapter 3.1 and 3.2, a leak in the inspiratory limb decreases the tidal volume delivered to the patient. This results in a decrease of expired volume and slope of the inspired pressure and flow curve and an increase of expired CO₂ pressure. In the recorded case (shown in fig. 3.1-5) the leak was introduced at 45 sec after recording. The codes of the features show:

time = 52.35 decreased expired volume (code = 4)

```
time = 53.20    decreased slope inspired pressure
                curve (code = 4)
```

time = 59.35 elevated expired CO2 pressure (code = 6)

The expert system will identify a "leak" at 53.2 sec because the expired volume and the slope of the inspired pressure curve are decreased. The code of the slope of the inspired flow curve does not change (see fig. 3.4) because the slope's decrease is not large enough. This means that it is not possible to detect this leak at system startup.

After the expert system comes to the conclusion "leak", it will try to deduce if it is a leak in the inspiratory limb or the endotracheal tube. A leak in the inspiratory limb will allow some expiration through this limb. The limb contains CO₂ that is inspired in the next breath. The rebreathing of the CO₂ results in a decrease in both the slope of the CO₂ downstroke and the time of the inspired CO₂ pressure level. The codes of the features show:

```
time = 47.10    decreased slope downstroke (code = 4)
time = 71.55    decreased time inspiration (code = 4)
```

The expert system concludes "leak inspiratory limb" immediately after the diagnosis "leak" because the slope of the downstroke was already down when the leak is detected. However, with increasing expired CO2 pressure levels, the slope of the downstroke will also increase and eventually return into the normal band. The time of the inspired CO2 pressure level does not change enough to reach the low threshold of the normal band, but it comes close to the edge of this band and noise on the signal the code code at 71.55 sec.

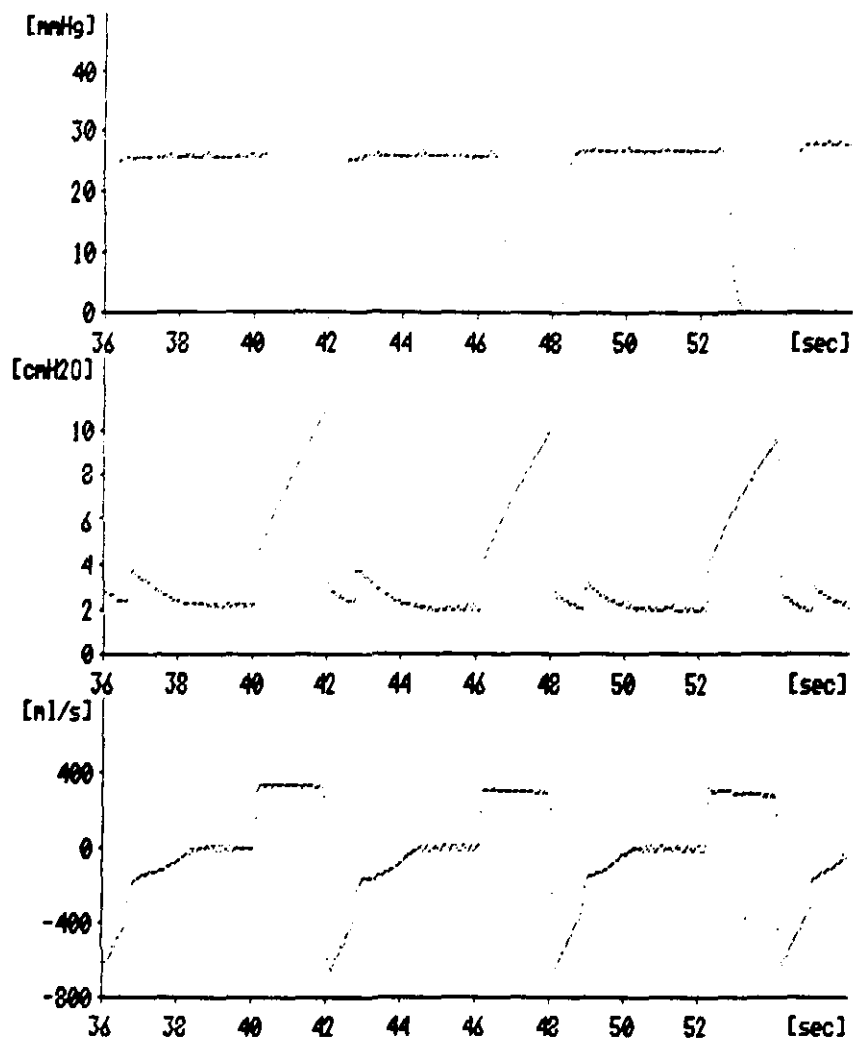


fig. 3.1 signal waveforms in case of a leak in the inspiratory limb; the leak is introduced at 45 sec.

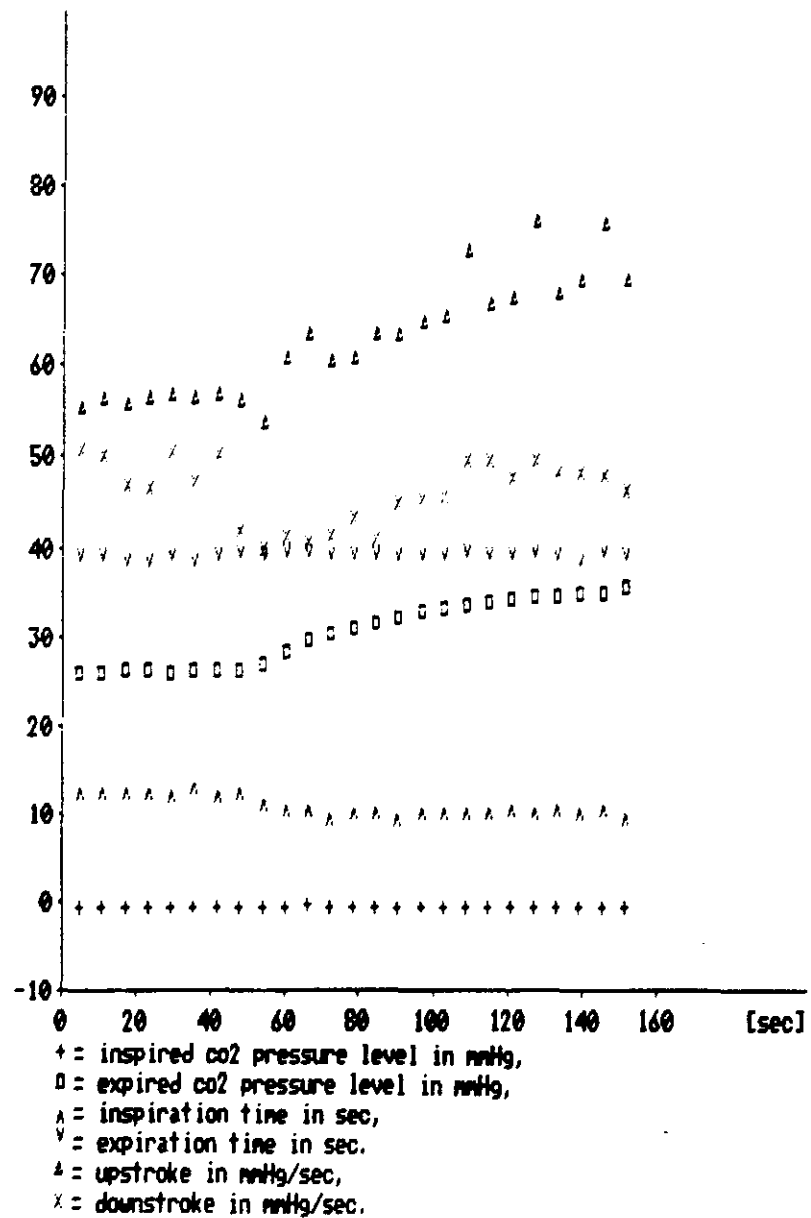


fig. 3.2 capnogram feature values in case of a leak in the inspiratory limb: the leak is introduced at 45 sec.

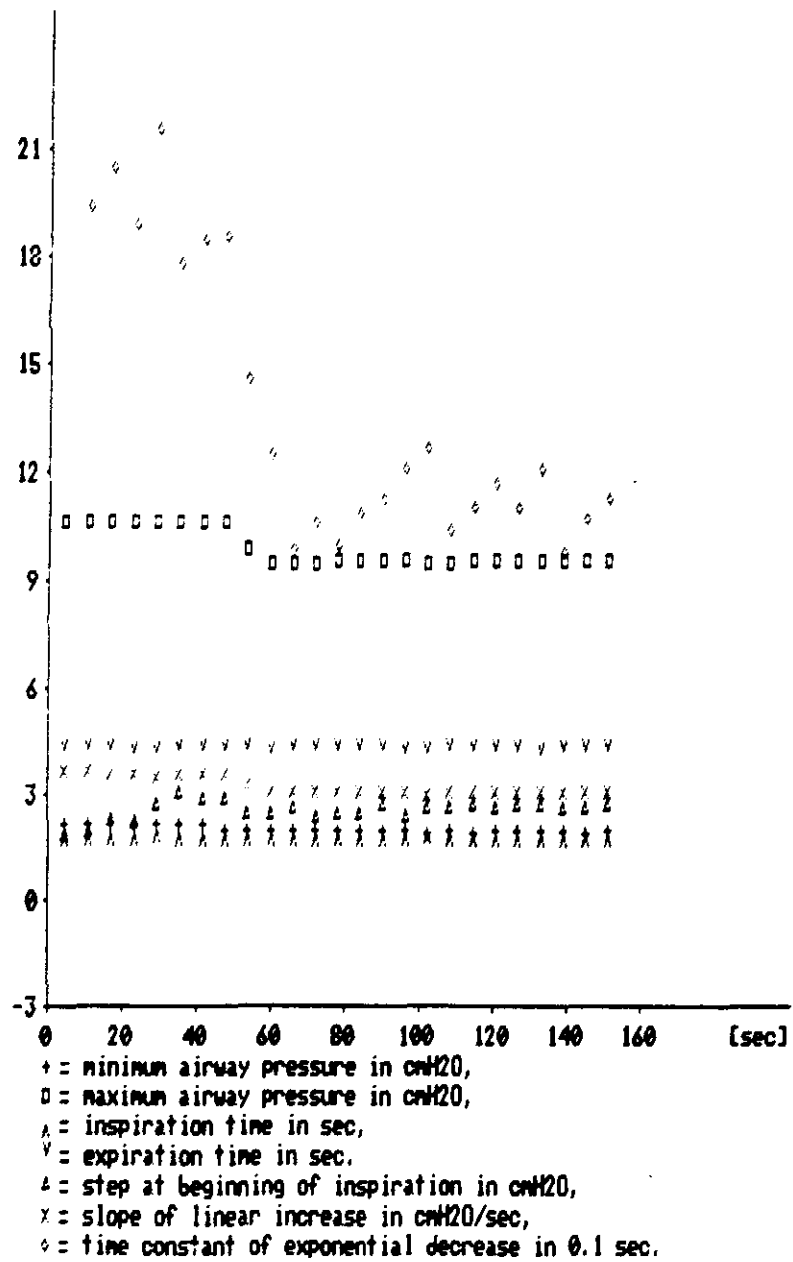


fig. 3.3 pressure feature values in case of a leak in the inspiratory limb; the leak is introduced at 45 sec.

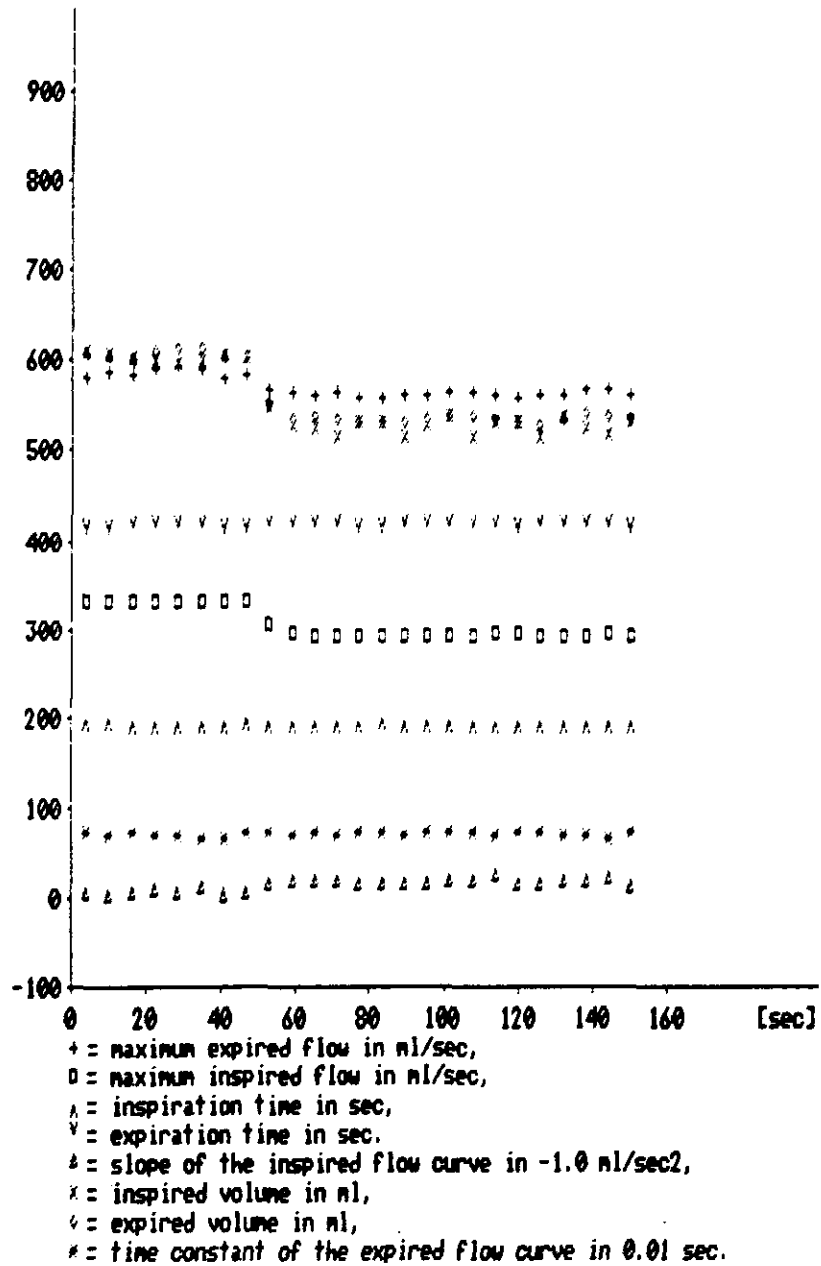


fig. 3.4 flow feature values in case of a leak in the inspiratory limb; the leak is introduced at 45 sec.

time	CAPNOGRAM:																AIRWAY PRESSURE:										AIRWAY FLOW:																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																									
	inspired CO2 pressure level		expired CO2 pressure level		breath time		inspiration time		expiration time		upstroke		downstroke		minimum airway pressure		maximum airway pressure		breath time		inspiration time		expiration time		step at beginning of inspiration		slope of linear increase		time constant of exp. decrease		maximum expired flow		maximum inspired flow		breath time		inspiration time		expiration time		slope of inspired curve		inspired volume		expired volume		time const. exp. curve																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																					
V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V	V

fig. 3.5 feature codes in case of a leak in the inspiratory limb; the leak is introduced at 45 sec.

4. Conclusions

The capnogram, airway pressure, and flow waveforms measured at the endotracheal tube can be used to detect a number of disconnects, leaks, obstructions, incompetent valves and an exhausted CO₂ absorber in the breathing circle. However, distinction between all complications and detection of some complications is not possible. The sensitivity of the detection depends, among others, on the selected ventilator settings and fresh gas flow. For example, a small leak in a circle system with a large fresh gas flow cannot be detected.

The number of identifiable breathing circle malfunctions can be increased if the ventilator settings are known. For example, an open pop off valve can be detected only if the inspiratory time from the ventilator is available while a leak that exists before the breathing system was used to ventilate a patient can be detected more reliably if the fresh gas flow and minute ventilation are known.

The features of the capnogram, airway pressure and flow at the endotracheal tube can be derived with algorithms that adapt to variations in the signal. Processing the signals with these algorithms reduces the sensitivity to noise and artifacts. The normal range of a signal feature can be defined as a band with a fixed width and a central value that is equal to the average value of this feature over the last 5 minutes. A varying bandwidth is not feasible because the variations of the signal are undetermined (colored noise).

The robustness and performance of the algorithms in the operating room must still be evaluated. Compared to computer models and laboratory bench testing, the operating room is a relatively hostile environment that degrades the quality of the the input signals a lot.

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APPENDIX

Appendix: function descriptions

This section is intended as a user manual for the developed algorithms. It discusses briefly the structure and interface of the functions. The definition of methods and constants are discussed in chapter 2 of this thesis.

The CO₂ pressure, airway pressure, and flow algorithms are based upon the same principle. They consist of segments that represent parts of the processed wave forms (knowledge about the signal shape). A status variable remembers the segment the signal is currently processed with. When a new sample comes available, the tests in the segment indicated by the status variable are executed. The tests include checks on a possible transition to the next segment. A general segment containing the criteria for the transitions between segments is always executed.

For example, a square wave form can be described by two segments: a HIGH and LOW status. A criterion for the transitions between these states could be the mean value. The general segment will then consist of the calculation of the mean value. In the high state segment it is tested whether the new sample is below the mean value and in the low state segment it is tested whether the new sample is above the mean value.

The definition of the segments for the CO₂, pressure and flow algorithms and the criteria for the transitions between these segments are derived from the algorithm descriptions of chapter 2.1-2.3 and are discussed in the next passages. The implementation of the feature encoder as described in chapter 2.4 into an algorithm is straightforward and is discussed in the last section of this appendix.

CO2 algorithm

User interface:

analyze_co2(flag, features, sample, breath_time)

short *flag : returns all validation flags, a timeout flag,
a co2 flat flag and a breath complete flag
float features[7] : returns all feature values.
float sample : passes the new co2 sample value.
float breath_time : passes the breath time.

breath complete																	
timeout																	
signal flat																	
downstroke																	
upstroke																	
expiration time																	
inspiration time																	
breath time																	
expired CO2 pressure level																	
inspired CO2 pressure level																	
16	15	14	13	12	11	10	9	8	7	6	5	4	3	2	1	0	-> flag bits (1 = invalid)

feature index -> 0 : inspired CO2 pressure level
1 : expired CO2 pressure level
2 : breath time
3 : inspiration time
4 : expiration time
5 : upstroke
6 : downstroke

Description:

the function calculates the features of the CO₂ pressure signal defined in chapter 2.1) and must be called whenever a new sample of the signal is available. This sample is used to update the thresholds (defined in chapter 2.1) and to determine what the status of the signal is (shown in fig. A.1). If a complete breath is detected, all features with their validation flags are calculated and returned to the main program. The flag "breath complete" is set (the flag is automatically reset after the next call). If no complete breath time is detected after "breath_time" seconds the "timeout" flag is set and the method of threshold adaptation is changed (shown in fig. A.2). If the amplitude of the signal becomes smaller than 2 mmHg the "signal flat" flag is set. The structure of the function is shown in fig. A.2.

In order to use the function the file "analco2.obj" must be linked with and the file "co2def.h" must be included in the main program. The include file contains a number of global variables (e.g. the "status" of the signal). They can also be declared as static variables in the function. This has the disadvantage that they will not be available to the user for debugging.

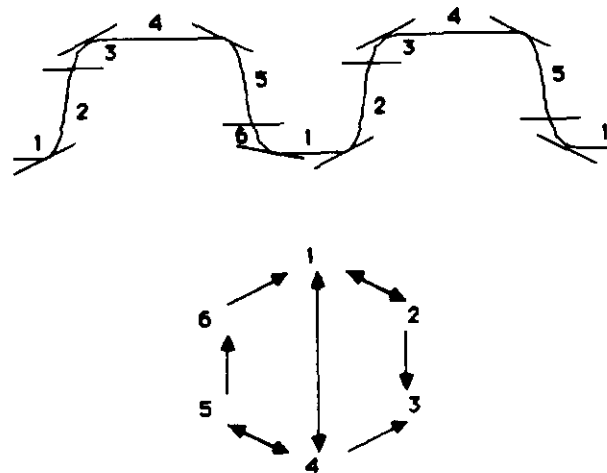


fig. A.1 definition of statuses and possible transitions between statuses of the CO₂ algorithm

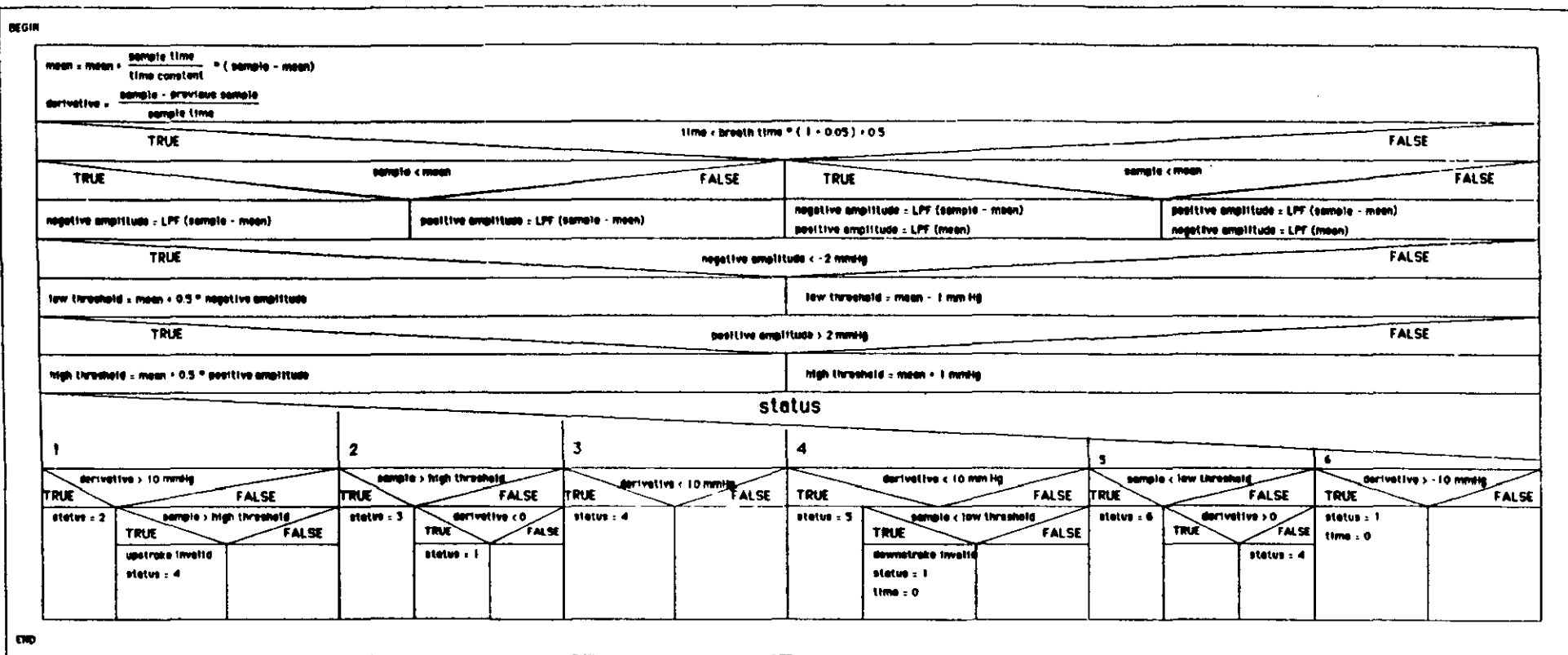


fig. A.2 the structure of the CO2 algorithm

Pressure algorithm

User interface:

analyze_press(flag, features, sample, breath_time)

short *flag : returns all validation flags, a timeout flag, a pressure flat flag and a breath complete flag.

float features[8] : returns all feature values.

float sample : passes the new pressure sample value.

float breath_time : passes the breath time.

breath complete

| timeout

| | signal flat

| | | time constant of exponential decrease

| | | slope of linear increase

| | | step at beginning of inspiration

| | | expiration time

| | | inspiration time

| | | breath time

| | | maximum airway pressure

| | | minimum airway pressure

| | |

16 15 14 13 12 11 10 9 8 7 6 5 4 3 2 1 0-> flag bits (1 = invalid)

feature index -> 0 : minimum airway pressure

1 : maximum airway pressure

2 : breath time

3 : inspiration time

4 : expiration time

5 : step at beginning of inspiration

6 : slope of linear increase

7 : time constant of exponential decrease

Description:

the function calculates the features of the pressure signal (defined in chapter 2.2) and must be called whenever a new sample of the signal is available. This sample is used to update the thresholds (defined in chapter 2.2) and to determine what the status of the signal is (shown in fig. A.3). If a complete breath is detected, all features with their validation flags are calculated and returned to the main program and the flag "breath complete" is set. If no complete breath time is detected after "breath_time" seconds the "timeout" flag is set and the method of threshold adaptation is changed (shown in fig. A.4). If the amplitude of the signal becomes smaller than 0.6 cmH₂O the "signal flat" flag is set. The structure of the function is shown in fig. A.4.

In order to use the function the file "analpa.obj" must be linked with and the file "padev.h" has to be included in the main program.

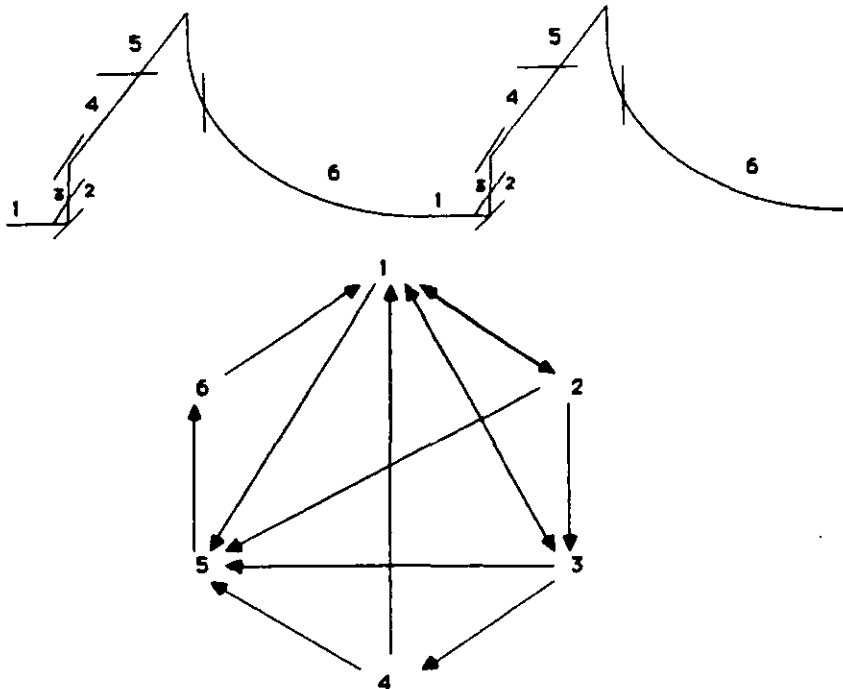


fig. A.3 definition of statuses and possible transitions between statuses of the pressure algorithm

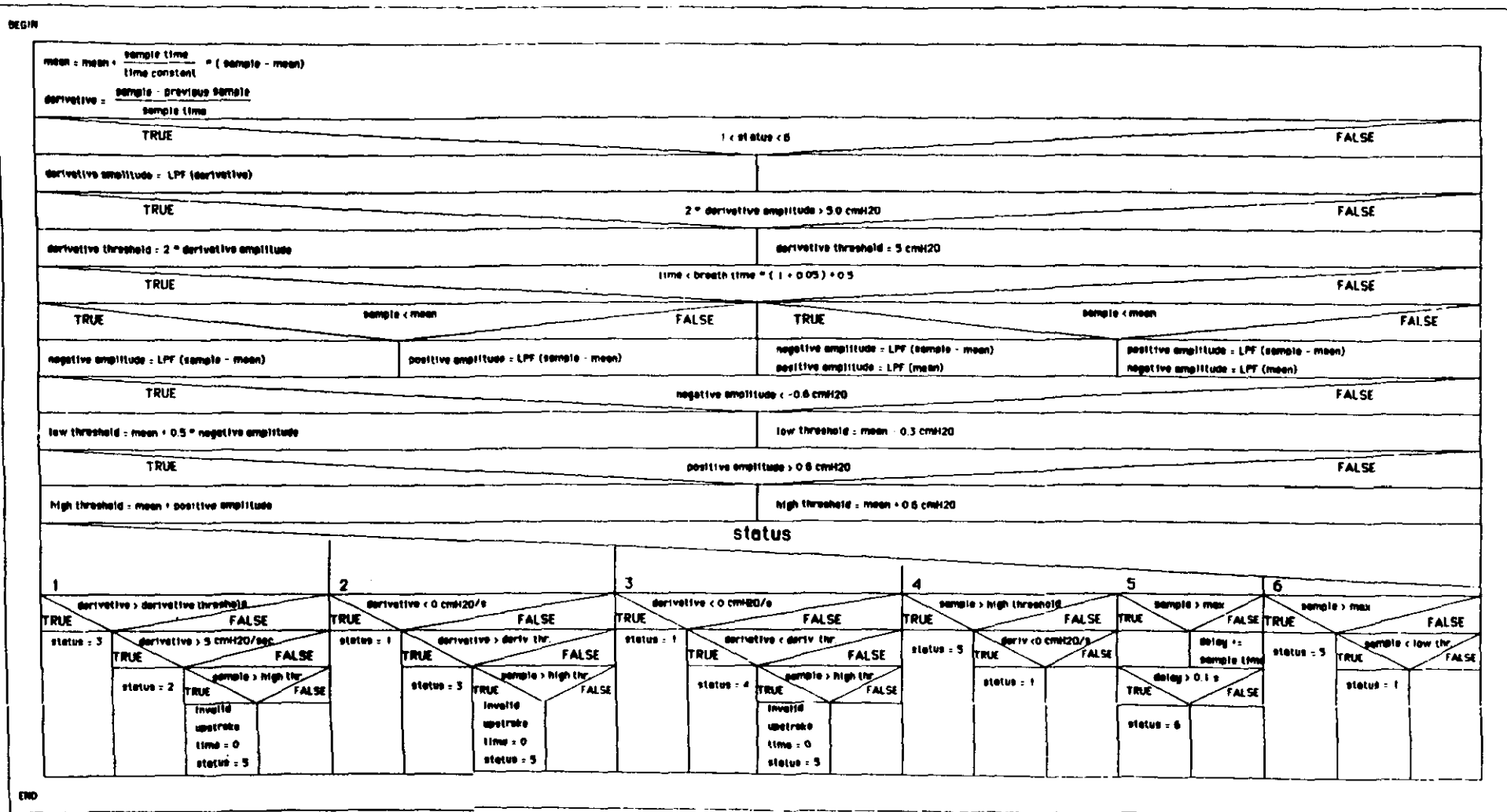


fig. A.4 the structure of the pressure algorithm

Flow algorithm

User interface:

analyze_flow(flag, features, sample, breath_time)

short *flag : returns all validation flags, a timeout flag,
a flow flat flag and a breath complete flag
float features[9] : returns all feature values.
float sample : passes the new flow sample value.
float breath_time : passes the breath time.

breath complete

```
| timeout
| | positive signal flat
| | | negative signal flat
| | | | time constant expiration curve
| | | | | expired volume
| | | | | | inspired volume
| | | | | | | slope of inspiration curve
| | | | | | | | expiration time
| | | | | | | | | inspiration time
| | | | | | | | | | breath time
| | | | | | | | | | | maximum inspired flow
| | | | | | | | | | | maximum expired flow
| | | | | | | | | | | |
```

16 15 14 13 12 11 10 9 8 7 6 5 4 3 2 1 0-> flag bits (1 = invalid)

feature index -> 0 : maximum expired flow
1 : maximum inspired flow
2 : breath time
3 : inspiration time
4 : expiration time
5 : slope of inspired curve
6 : inspired volume
7 : expired volume
8 : time const. exp. curve

Description:

the function calculates the features of the flow signal (defined in chapter 2.3) and must be called whenever a new sample of the signal is available. This sample is used to update the thresholds (defined in chapter 2.3) and to determine what the status of the signal is (shown in fig. A.5). If a complete breath is detected, all features with their validation flag are calculated and returned to the main program and the flag "breath complete" is set (will automatically be reset after the next call). If no complete breath time is detected after "breath_time" seconds the "timeout" flag is set and the method of threshold adaptation is changed (shown in fig. A.6). If the amplitude of the inspiratory or expiratory signal becomes smaller than 40 ml/sec the "positive signal flat" respectively "negative signal flat" flag is set. The structure of the function is shown in fig. A.6.

The trigger for a complete breath is the inspiratory flow. If no expiratory flow is detected but the inspiratory flow still exists, the features of the inspiratory wave form are still reported, the features of the expiratory part are set invalid and the "negative signal flat" flag will eventually be set. If no inspiratory flow is detected, a timeout will be generated because there is no trigger for a complete breath.

In order to use the function, the file "analfw.obj" must be linked with and the file "flwdef.h" must be included in the main program.

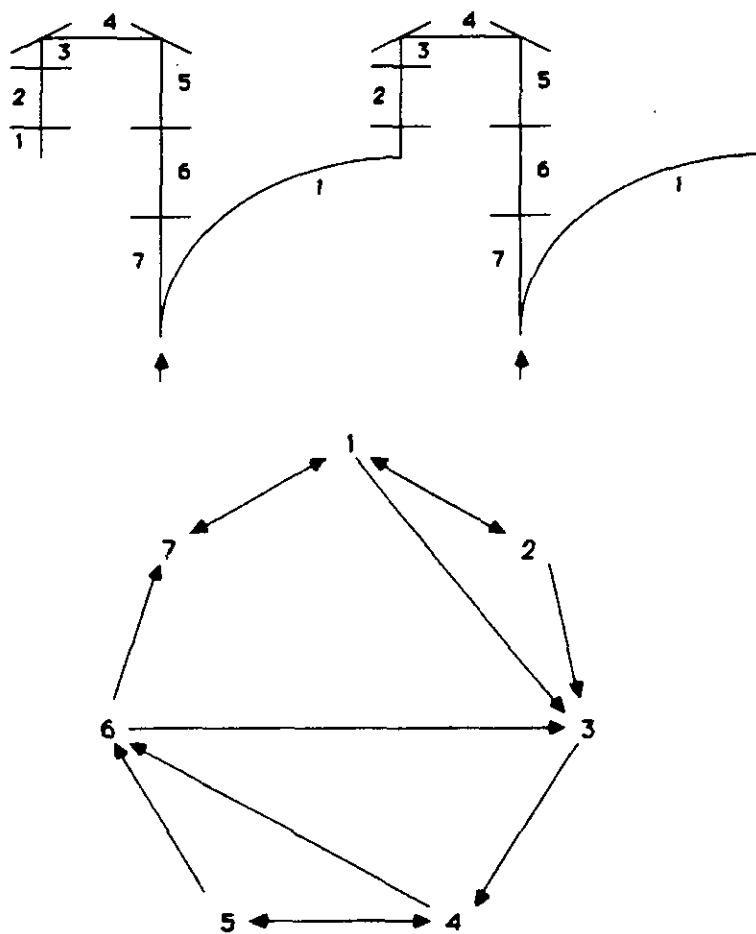
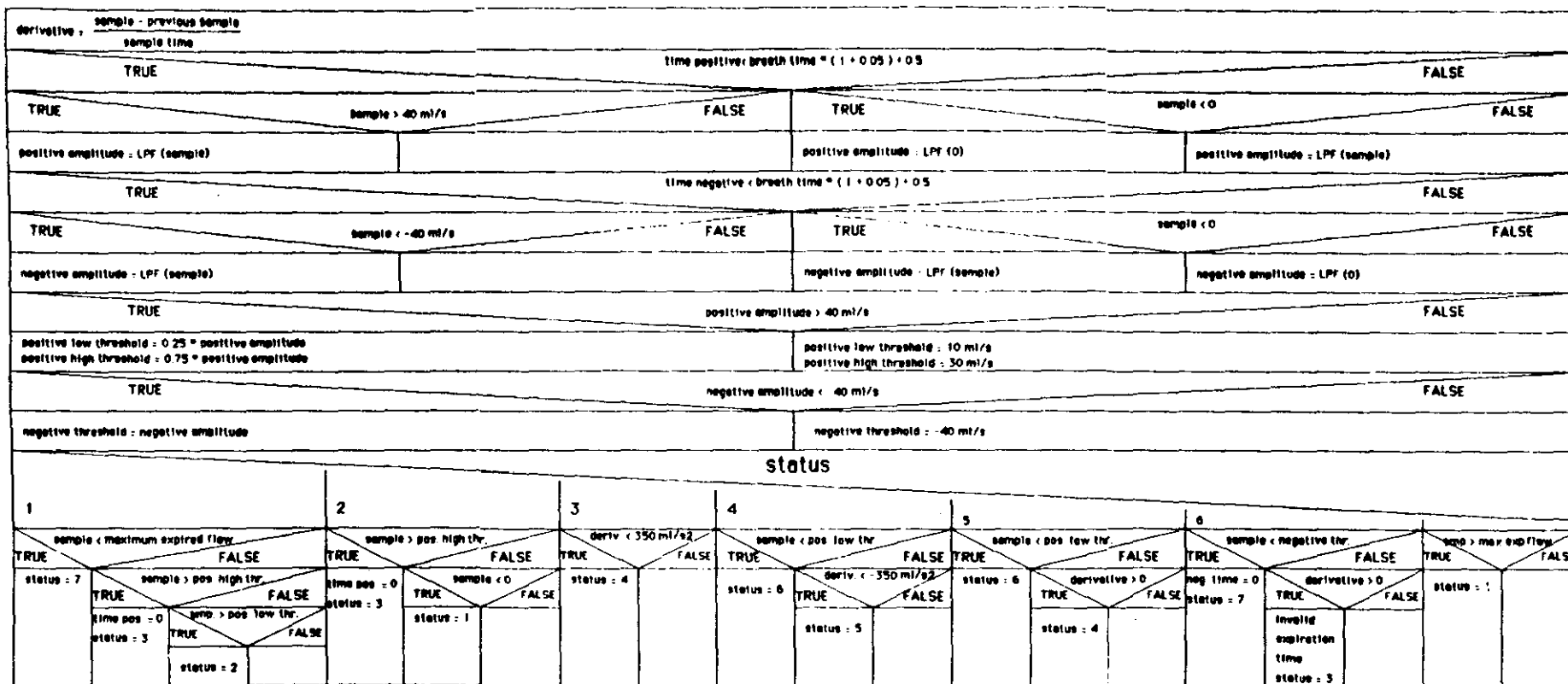


fig. A.5 definition of statuses and possible transitions between statuses of the flow algorithm

BEG'N



END

fig. A.6 the structure of the flow algorithm

Feature encoder

User interface:

struct code

```
{
    short value[9] : returns the codes of the feature,
    long time[9] : returns the history of the features as
                   defined in chapter 2.4 (should not be
                   changed by user).
}
```

```
struct feature
```

```
{
short flag      : passes the feature validation flag,
short init      : passes the features that have to be
                  initialized (should only be changed by
                  user if feature has to be initialized),
float value[9]  : passes the values of the features,
float mean[9]   : remembers the feature's mean value
                  (should not be changed by user),
float limit[9]  : passes the allowed deviation from the
                  mean value,
int    count[9] : remembers the numbers of features
                  starting from initialization (should
                  not be changed by user).
}
```

```
encode_features(codes, features, length)
```

```
struct code    *codes    : returns the codes and history of the
                          passed features,
```

```
struct feature *features : passes the feature information,
```

```
int      length      : passes the number of features in the
                      feature structure (maximum = 9).
```

Description:

The function updates the "mean" values of the valid features and calculates the normal band of these features (described in chapter 2.4). If the "init" parameter is set to zero the mean value is set to the current feature value. Next, the codes and history of the passed features are calculated as described in chapter 2.4.

The "init" parameter has the same format as the feature "flag". The least significant bits in the flag are used for the validation while the ones in the "init" parameter are used for initialization. If a bit in the "init" parameter is set to zero the algorithm checks if the corresponding feature is valid. If this is the case, the mean value is set to the current feature value, the time constant of the mean value filter is set to the breath time (count = 1) and the "init" flag is reset to "1". If the value is invalid, the "init" flag stays "0" and the validation of the feature is checked again at the next function call. The time constant is increased up to 5 minutes whenever a valid feature is passed. An example of a normal band after a reset is shown in fig. A.7. It clearly shows the increase of time constant: the normal band is adapted quickly in the beginning but is harder to change as time goes on.

In order to be able to use the function the file "encfeat.obj" has to be linked with and the file "codedef.h" has to be included in the main program.

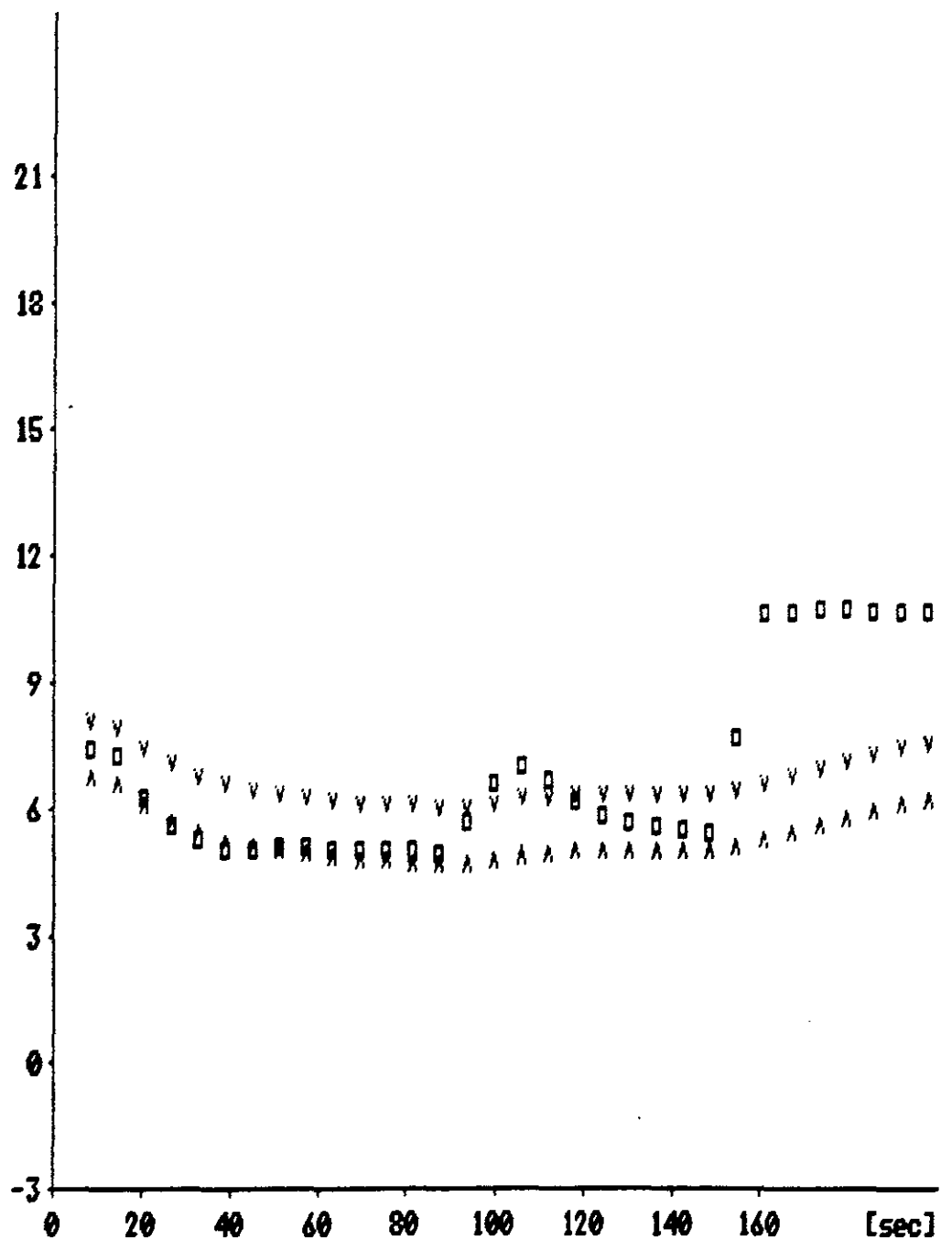


fig. A.7 the normal band of the peak pressure in case of a leak in the endotracheal tube; the encoder is reset at 0 sec.

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