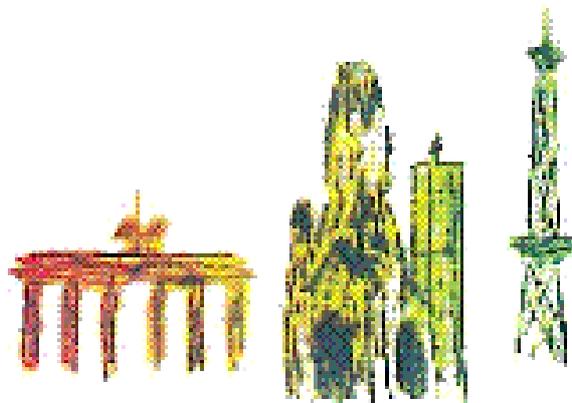


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## **Standards of Anaesthesia**

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We have a continuing duty to improve the quality of the service we provide wherever possible. We have been working in three areas to do this.

### **Audit**

This is the subject of much muddled thinking in the UK – with confusion between audit, data collection and research. Audit may be defined as ‘An enquiry to establish whether quality is being achieved.’ This presupposes that quality in the area being investigated is understood. For some topics that is true – we all know what constitutes hypothermia – but measuring the quality of outcome of resuscitation is much more difficult.

The key issue in audit is to find a valid ‘indicator’. This is a measurement which is in proportion to quality, and the characteristics and requirements of indicators will be discussed.

### **Information for Patients**

Patients in the UK often have very little knowledge of anaesthesia. We have therefore carried out a project over the last two years to establish the best way to communicate with patients before their anaesthesia.

The key point that came through was the need to involve patients in the writing – doctors often do not know how to express issues in the clearest way possible. The way that patients may be selected will be discussed.

It was discovered that we needed a full booklet covering general anaesthesia and a series of complementary booklets covering specific topics.

### **Anaesthetic Records**

Anaesthetic record keeping has hardly changed in the last hundred years – the record of drugs given and patient parameters measured. Automated systems have simply attempted to reproduce this.

A fresh approach may be helpful. This could involve carefully defining the normal course of an anaesthetic, and then noting the abnormalities. In that way the abnormalities become available for later analysis, and form part of the long term record.



## Point of Care Information Systems

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The decisions that are made by anesthesiologists and intensivists at the bedside are based on a multiplicity of variables. These include the patient, the disease, clinical examination, an enormous amount of monitored parameters, results of auxiliary tests, etc. All this information is found at the point-of-care, namely the 'bedside'. However, in order to support informed, real-time decisions, anesthesiologists and intensivists have to know a tremendous, as well as an ever-growing amount of knowledge. Lack of sufficient knowledge about underlying medical conditions, drug dosages (a well-documented source of medical error), specific considerations in various procedures, etc., may be an important and relatively underestimated source of error. Other factors that may contribute to this potential source of error include: a. Lapsing medical skills, shyness of active learning, and absence of reliable monitoring of physicians' knowledge. b. Growth of practice outside major hospitals. c. Cost and production pressures that may lead to the provision of care by personnel with inadequate knowledge and without adequate supervision. Interestingly, though many studies have identified "human error" as a significant reason for perioperative adverse events, there are nearly no studies that have attempted to examine the specific role of insufficient knowledge as a possible source of such error. One study did find "inadequate knowledge" and "lack of alternative plan" to be among the major reasons for anesthesiologists' errors in the operating room. In addition to lack of knowledge by itself, stress, fatigue, anxiety and time-pressure may cause disregard of available data and failure to seek appropriate data, all known factors that contribute to human error. Such lack of information may have severe detrimental effects especially in complex environments where small things may have enormous impact downstream.

An important part of the mass of knowledge that anesthesiologists and intensivists have and are supposed to know, is an ever-growing numbers of standard and emergency operating procedures which define a strict scheme for routine or critical situations. These standards, checklists and standard operating procedures form part of basic organizational structure that can help to reduce the occurrence of human errors. Indeed the provision of protocols and algorithms has been found to have a potential impact on many critical incidents. However, some algorithms may become too complex for practicality and memory, and numerous studies have shown, for example, knowledge deficits concerning CPR and poor adherence to standard guidelines. Thus lack of timely adequate information at the bedside may represent a real 'system failure' that may be responsible for an underestimated number of medical errors. This system failure may be overcome by the introduction of point-of-care information systems that are based on the unprecedented number of information and communication technologies that we have been witnessing over the past decade, including the internet, personal digital assistants (PDA) and specific systems that are incorporated into hospital LANs, electronic patient records and monitors equipped with extensible markup language (XML). Such information systems may provide the clinician with medical knowledge, alerts, reminders and clinical decision support.

The most prevalent point-of-care information systems can be found on PDAs, which offer a tremendous variety of software and are being incrementally used by physicians. However, like with the information that can be found on the Internet, the ultimate acceptance of medical resources by clinicians depends upon the creation of accurate, timely, secure, well-referenced resources with clearly identified authors and publishers. The PDAs are still used mainly by 'technophiles', do not have any standardization, do not offer (as a rule) local information and



guidelines, do not 'interact' with the patient data, to name just a few shortcomings of these devices. However their fantastic spread among physicians reflects the need for point-of-care information, and is due to the fact that electronic patient data management systems are slow to penetrate and have not placed point-of-care information systems high on their priority list.

An example of a novel point-of-care information system for the anesthesiologist in the operating room is the On-Line Electronic Help (OLEH) that has been developed by the European Society of Anaesthesiologists (ESA) and is currently available on Philips IntelliVue monitoring system. By being available on the screen of the patient's monitor (or automated recorder), and by offering quick access to authoritative and up-to-date information as well as various emergency protocols, such system may contribute significantly to patient safety in the operating room. In order to examine anesthesiologists' views on the need for such point-of-care information system, we have circulated a questionnaire during the 2001 annual meeting of the ESA in Gothenburg, Sweden. The questionnaire was answered by 329 anesthesiologists, mostly qualified specialists from Western Europe. Of the responders, 46% admitted that they experience lack of knowledge about drugs, medical conditions and/or specific anesthetic considerations at least once a week. In response to another question, 39% admitted that in the past they have committed medical errors during anesthesia due to lack of medical information that can be found in a handbook. Of all responders 88% think that having a point-of-care information system in the OR is either important or very important. We believe that these results support our notion that there is a relatively high incidence of cases in which anesthesiologists lack sufficient knowledge that might be vital for error prevention. This indeed is a "system failure" rather than an individual one.

The idea to produce the OLEH was presented to the Board of the ESA and approved in 1999. Members of the department of anesthesiology and intensive care, Sheba Medical Center, Tel Aviv University, Israel, prepared the contents of the OLEH. Information from a variety of sources was included in the OLEH, with the major criterion being **the potential real-time usefulness of the information to the anesthesiologist in the operating room**. The OLEH draft was then submitted to the scientific sub-committees of the ESA for a review process in order to ensure the overall quality of the information and its suitability for anesthesiologists from many different backgrounds. Updates of the OLEH will be produced periodically.

The OLEH contains sections on drugs, preoperative considerations, surgical sub-specialties, fluids and electrolytes, transfusion medicine, intraoperative complications, regional anesthesia, postoperative pain management, emergency algorithms (CPR, malignant hyperthermia, difficult intubation, etc.) and fast-access buttons for other emergency situations. The OLEH was prepared in a browser format and was designed to fit a window format on the screen of the patient monitor in the OR. Any item of information can be accessed in no more than 4 steps, and is facilitated by more than 3000 internal hyperlinks, as well as separate alphabetical table of contents for drugs and general subjects.

The ability of such point-of-care information system to improve patient safety during anesthesia has still to be determined. In the meantime we have found that the OLEH system significantly decreased the number of errors made by anesthesiologists during the simulated management of a variety of clinical scenarios and hence seems to be able to contribute to better decision-making (Yusim et al, ESA 2003; Berkenstadt et al, ASA 2003). More information on the potential and practical value of the OLEH needs to be gained by a more realistic simulation and use in the clinical environment itself.

Although the ICU environment is very different then the operating room in many aspects, a variety of point-of-care information may help the intensivist in acquiring information at the bedside, follow protocols and make complicated decisions. For example, the many clinical decisions that are taken in the care of critically ill patient involve a large number of monitored



parameters, the diagnosis and associated morbidities, as well as a variety of auxiliary tests. Each type of information is usually received at a different point in time, and the lack of instantaneous in-depth consideration of new pieces of information can lead to significant medical errors due to delayed diagnosis, delayed clinical action, or omission of appropriate therapy. In our ICU we have developed a variety of rules that are searched for by the Event Manager, which is a module of our patient data management system (Metavision, iMDsoft). These rules are used to describe events that, once identified, trigger one of a number of actions (e.g., opening a window that alerts the clinical staff, suggesting a protocol of therapy, etc.). This is just an example of a truly 'interactive' point-of-care information system, which automatically combines 'knowledge' with patient data.

Point-of-care information systems seem to be an important part of what can be done in the future to further reduce preventable patient harm. These systems will become an integral part of our workstations, just as in modern aircrafts and other complex systems, which have come to the conclusion that the only way to prevent errors is to have information at the 'point-of-care'. This might be another step towards a strong culture of safety, and the development of systems that guard against the fallibility of humans working with complex processes.



## Networks - Protocols - Standards: State of the Art

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### Motivation

While domains like intensive care and anaesthesia are traditionally using advanced computing and real-time communication equipment, similar functionality is now tending to be used not only throughout all hospital departments and wards, but also in home-care and mobile environments. State-of-the-art medical technology applications require, and to some extent already use, interoperation among multiple point-of-care medical devices and with related information systems. Underlying communication architectures, interfaces, transmission protocols and codes, however, still differ dramatically between devices and systems from various manufacturers, resulting in unnecessary barriers, efforts and costs when setting up multi-vendor installations or just exchanging components.

Moreover, incompatible communication standards are already established in specific health-care or clinical domains, e.g. HL7 for enterprise level / Hospital Information Systems (HIS) or DICOM for Picture Archiving and Radiology Information Systems (PACS/RIS). These standards are generally based on incompatible concepts reflecting not only the requirements of their specific application domain, but also their development history and conceptual paradigms.

Nevertheless, standard-based interoperability among medical devices and information systems from different manufacturers is now getting into reach, having been on the agenda of international standardisation for more than one decade.

### Concepts and Standards

Open system architectures encompassing standardised communication protocols and coding schemes are crucial for advanced interoperability concepts.

In the domain of real-time plug-and-play medical device interoperability, CEN standards ENV 13734/35 – commonly known under the acronym “VITAL” - and the related IEEE 1073 documents, which started development more than one decade ago under the title "Medical Information Bus", have undergone a process of alignment and extension in the ISO 11073 standards family.

"Real-time" here means that data from multiple devices can be retrieved, time correlated, and displayed or processed in fractions of a second.

"Plug-and-play" means that all the clinician has to do is 'make the connection' – the systems automatically detect, configure and communicate without any other human interaction.

Another member of the developing ISO 11073 family is POCT1-A – a ANSI NCCLS communication standard for point-of-care analytical devices which was initiated and developed by a joint diagnostic industry consortium. It is already in use by a number of major manufacturers. Its architecture combines elements of both HL7 V.2.5 and IEEE 1073.



## Simulation & Training

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Simulation has traditionally been a method for training and education in medicine. It is defined as a partial emulation of reality for the training of behaviour. Known examples for this are the training of intubation skills at phantom heads and the training of surgical knots at a chair.

During the 1980s several working groups at university anaesthesia departments developed systems which led to a new definition of the concept of simulation. According to this definition a simulator is a computer controlled device which uses mathematical models to recreate human physiology and display it on a manikin. This manikin allows the application of common diagnostic and therapeutic procedures, resulting in physiological reactions. A distinctive feature of these devices is their ability to be connected to regular medical equipment which can be used as usual. The system allows almost unlimited interventions into the physiology of the model physiology, thus enabling the 'construction' of patients. The placement in a real work environment (e.g. an operating room) creates a situation which is so real that the trainees quickly forget that they only treat an artificial patient. As a result their actions and reactions are realistic.

These devices lifted simulation in anaesthesia up to a level of quality which allows direct comparison to aircraft and cockpit simulation. The label 'full scale simulation' has been attached to these new devices, which allow the creation of a patient and clinical situations which are as complete and realistic as possible. Compared with these devices traditional training units with a lower degree of completeness should be called 'task trainers'.

Full scale simulators provide an opportunity for large benefits: They provide a method to gain what distinguishes a seasoned physician from the beginner: Experience. The difference to conventional learning is that the simulator provides an optimised learning situation and experiences can be made without endangering patients. In addition the simulator allows the training of techniques which play only a little role in conventional education concepts in medicine although they are important: The management of critical and other situations which can be created repeatedly.

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## Clinical Evaluation of NICO, Non-Invasive Measurement of Cardiac Output

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### Introduction

The partial CO<sub>2</sub> rebreathing technique uses a differential form of the Fick equation to calculate cardiac output (CO). The ratio of the change in end-tidal CO<sub>2</sub> and the change in CO<sub>2</sub> excretion, in response to a brief period of rebreathing, gives a non-invasive estimate of the CO.

In patients undergoing noncardiac surgery we tested a NICO system that included improved signal processing algorithms, a noninvasive estimation of intrapulmonary shunt, and a disposable dead space adapter.

### Methods

After IRB approval and patient consent the system was tested in one hundred sixty patients (80 Male, 80 Female, Age 20-80 Years) undergoing noncardiac elective surgery. End-tidal CO<sub>2</sub> was measured using a mainstream CO<sub>2</sub> analyzer and a disposable pneumotachograph (NICO, Novamatrix Medical Systems, Wallingford, CT).

CO<sub>2</sub> production was calculated for each breath as the integral of the flow and CO<sub>2</sub> concentration. Actuation of a pneumatic valve under computer control resulted in breathing circuit changes, which increased airway dead space by 120 ml, thereby causing partial rebreathing of exhaled gas. The valve was actuated for 50 seconds once every 3 minutes. Changes in CO<sub>2</sub> excretion and etCO<sub>2</sub> were used to calculate the partial CO<sub>2</sub> rebreathing CO using the differential Fick equation.

Noninvasive estimates of shunt from SpO<sub>2</sub> and FiO<sub>2</sub> measurements were used to correct for intrapulmonary shunts. Measurements made during surgery and anaesthesia.

### Results

A total of 1520 comparisons were made with CO ranging from 1.95 to 9.80 L/min. Bland-Altman analysis resulted in a bias of 0.5 L/min with a precision (1SD) of 0.9 L/min.

### Discussion

Results indicate that the improvements in signal processing algorithms and the use of a non-invasive estimation of shunt help improve the agreement between partial CO<sub>2</sub> rebreathing CO measurements and Respiratory profiles measurements. NICO system is completely automatic and can provide frequent, continuous measurements of CO. NICO technique is a clinically acceptable method for measurement of CO in surgery, anaesthesia and ICU setting.

### Conclusions

Advances in technology have enabled us to implement an automatic partial CO<sub>2</sub> rebreathing technique for near continuous noninvasive measurement of cardiac output (CO) in mechanically ventilated patients.

Results from clinical evaluation of NICO system, non-invasive measurement of cardiac output in patients undergoing elective noncardiac surgery indicates a good method's of CO measurement.



## Estimation of Intra-Blood Substance Concentrations using Photo-technology

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Usage of photo-technology has been limited in anaesthesia and intensive care field. Although an intravenous fibre-optic catheter is available for clinical use, it has not been utilised, except for estimation of the oxy-haemoglobin fraction. The purpose of the work described here is to expand use of the fibre-optic catheter in combination with advanced photo-technology. As initial steps towards this goal, we have performed the following two studies.

### 1. Development of an optical instrument

An optical instrument that is able to supply and receive any wavelength of light was designed for use with Abbott fibre-optic catheters. The light source, a Xenon short arc lamp (Hamamatsu Photonics KK, Japan), provides stable broadband light from 220 to 2000 nm. The light band is focused on one of eight band pass filters that are mounted on a circular disc. A stepping motor driven by a microcomputer is used to rotate the disc, and this allows a maximum of eight different wavelengths of lights to be provided in a time-sharing manner. The filtered light is channelled to a coupler that is specially designed for the optic module of the Abbott catheter. The coupler also receives light reflected by blood and passed through the catheter. Another circular disc mounted with eight filters is positioned just after the coupler to select a specific wavelength from the received light. This disc is also driven by a microcomputer. The intensity of the filtered light is measured by a photodiode (S-6024, Hamamatsu Photonics KK, Japan) and an amplifier (C-5460, Hamamatsu Photonics KK, Japan). Hence, this multiple wavelength optical instrument enables measurement of light absorption and fluorescence of substances in the blood.

### 2. Examination of blood substances

Using the optical instrument described above, we have investigated several intravenous agents and native substances *in vitro* as candidates for study in this project.

**Light absorbent molecules:** We studied indocyanine green (ICG), indigo carmine, sulpho-nate carbachrom, and glucose as light absorbents. Among these molecules, ICG was the most suitable for the absorption measurement. The intensity ratio of the 632 and 800 nm signals correlated well with the blood concentration of ICG (Fig. 1) and did not depend on the haemoglobin concentration. Glucose is one of the most attractive substances to monitor. Although glucose did not absorb light in the visible wavelength region, its near infrared absorption spectrum was only slightly different from that of water.

**Fluorescent molecules:** We studied riboflavin and propofol as fluorescents. Riboflavin emitted fluorescence at 530 nm after excitation at 450 nm, and the fluorescence intensity was correlated with the riboflavin concentration (Fig. 2). Free propofol emits strong fluorescence at 301 nm after excitation at 280 nm. However, we found that propofol in plasma did not fluoresce because of protein binding.

### Conclusions

We concluded that the blood concentrations of ICG, glucose and riboflavin could be measured *in vivo* using fibre-optic catheters.

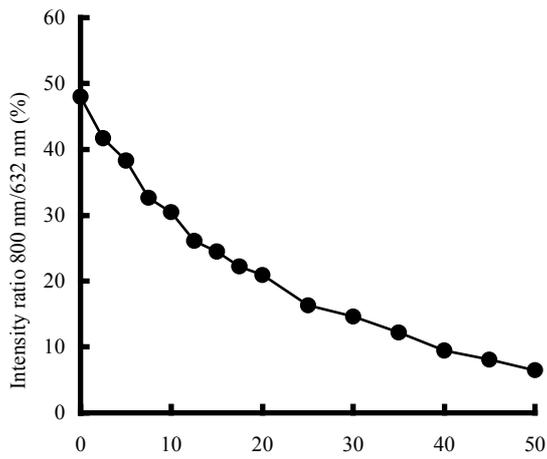


Fig. 1 ICG concentration (µg/ml)

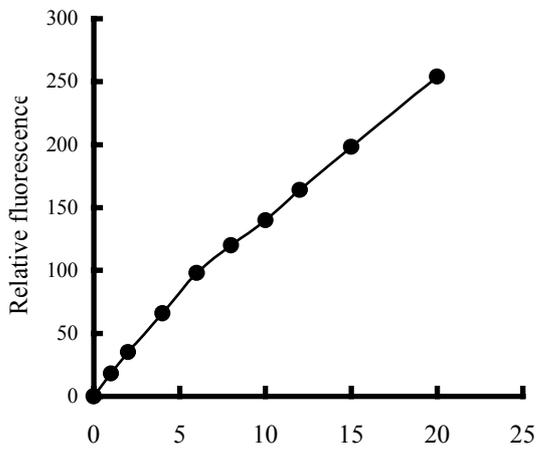


Fig. 2 Riboflavin concentration (µg/ml)



## Low-Flow Drug Administration Strongly Depends on Viscosity Variations

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### Introduction

With regard to home care environments temperature variations occur more frequently and, additionally, cover a much wider range when compared to inpatient settings. With that the dosing accuracy of fluids and drugs being administered continuously is reduced due to viscosity variations especially at low flow rates. Flow rates of continuously applied drugs can be calculated by applying the following equation which assumes a laminar flow within the infusion system:

$$Q = \frac{1}{C_R} \frac{A^2}{\eta L} \Delta p$$

$Q$ : delivery rate;  $\Delta p$ : pressure difference;  $C_R$  geometrical cross section coefficient;  $A$ : cross section area;  $L$ : length;  $\eta$ : dynamic viscosity

Since referential data were not available, we investigated the temperature-dependant viscosity of drugs frequently used in anesthesia and with pain therapy.

### Methods and Material

Considering a temperature range of 15°C to 50°C a high-precision viscometer (AVS, Schott, Germany) was used along with certified measuring glass capillaries (class 532 03/0c). The fluid under test is forced through a thermostatically controlled capillary ( $\Delta T < 0.01^\circ\text{C}$ ) by a pneumatic pump. With each fluid, the specific interval a constant volume consumes in order to pass the capillary, was determined, and subsequently the corresponding viscosity can be calculated according to the Hagen-Poiseulle equation. Initial flow disturbances are considered by computing the Hagenbach correction later in the analysis. As for the accuracy of the measuring configuration, the viscosity of desalted water was determined at different temperatures and compared to referential data. The kinematic viscosity is then calculated as follows:

$v = K (t - \tau)$  ( $v$ : kinematic viscosity;  $t$ : measurement time;  $K$ : capillary constant;  $\tau$ : Hagenbach correction). Finally, the dynamic viscosity is required to correctly determine the flow rate:  $\eta = \rho(T) \cdot v$   $\eta$ : dynamic viscosity;  $v$ : kinematic viscosity;  $\rho(T)$ : density. Viscosity measurements were carried out for Fentanyl®, Sufentanil®, Dipidolor®, Morphin®, Lidocain2%®, Ketanest®, Solu-Decortin H®, and Bronchoparat® from 15 to 50°C.

### Results

The dynamic viscosity of desalted water differs from referential data by 0.1% at 20°C, the disagreement at 30°C and at 40°C is below 0.1%. Not surprisingly, changes in temperature result in inversely proportional (yet not exactly linear) changes in viscosity with all drugs. The dynamic viscosity of Fentanyl®, Sufentanil®, Dipidolor®, Morphin®, Lidocain2%®, Ketanest®, Solu-Decortin H®, and Bronchoparat® significantly exceeds that of water by approximately 10% at temperatures between 15 and 50 °C. Additionally, the characteristic lines of all drugs are positioned nearly in parallel to that of water.



### **Discussion/ Conclusion**

The excellent agreement of the viscosity data of desalted water with referential data verifies reliability and accuracy of the experimental setup. As expected, the kinematic viscosity of the drugs we investigated is inversely proportional to the temperature. However, drug viscosity differs from water viscosity by 3,4% to 51%, and with that, all drugs significantly differ from each other. With regard to eventually significant dosing errors due to temperature-induced variations of the drug viscosity, smart infusion devices are mandatory. To achieve this the flow rate should be monitored quantitatively, and, more desirably, infusion devices should rapidly compensate for deviations of the flow rate.

*The study was granted by the Bavarian Research Foundation.*



## Bispectral Index Monitoring and Depth of Anesthesia

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### Introduction

The bispectral index (BIS) has previously been shown to be a quantifiable measure of the sedative/hypnotic effects of anesthetics drugs and a significant predictor of depth of anaesthesia.

The titration of anaesthetics was guided by knowledge of dose response curves for anaesthetics and by autonomic reactivity to noxious stimuli.

This study was designed to assess the effects of BIS monitoring on the depth of anesthesia and recovery profiles after elective surgery.

### Materials and Methods

Induction of anesthesia were provided with TCI propofol (6 – 8 µg/ml), TIVA remifentanyl (1 µg/kg/min for induction and 0.05 – 0.1 µg/kg/min for maintenance) and cisatracurium (0.15 mg.kg<sup>-1</sup>).

Anesthesia was maintained with O<sub>2</sub> (2 L.min<sup>-1</sup>) + N<sub>2</sub>O (2 L.min<sup>-1</sup>) + sevofluran (0.5-2 %) and TCI (3 – 5 µg/ml)/TIVA remifentanyl (0.05 – 0.1 µg/kg/min).

After induction of anesthesia, one hundred two patients who underwent elective laparoscopic abdominal surgery were allocated to two equal groups (Group I and Group II).

Sevofluran was titrated to maintain the BIS value 40 +/- 5.5 – 45 +/- 5.9 in the group I. In the group II sevofluran was administered according to standard clinical practice, and anesthesiologist was blinded to the BIS value.

Heart rate (HR), mean arterial pressure (MAP), BIS, end-tidal CO<sub>2</sub> (ETCO<sub>2</sub>), end-tidal volatile anesthetic concentration of sevofluran (ETVAC) were recorded.

### Results

The bispectral index values were significantly lower in the Group II compared with the group I. Reaction to surgical stimulation was significantly less in the BIS group I (0 %) compared to the Group II (22 %).

The ETVAC of sevofluran in the Group I was lower (1.7 %) than those of the group II (2.9 %).

Time to emergence was significantly lower in the group I (4.8 min) compared to the Group II (8.2 min).

Similarly, the times to recovery parameters were shorter in the Group I compared with the group II.

### Conclusion

This study confirms that BIS monitoring provided an adequate anesthesia and contributed to a faster emergence from anesthesia.

BIS guided sevoflurane anaesthesia results in improved anaesthesia management.

It needs less anaesthetic (sevoflurane): reaction to surgical stimulation is lessened and awakening times shorter.

### Key Words

Depth of anesthesia, bispectral index, titration of volatile anesthetic



## Wireless Intensive Care Monitoring

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### Introduction

Patients in the neurosurgical intensive care unit (ICU) are at risk of sustaining further brain damage due to unstable vital parameters. Continuous monitoring of vital parameters, e.g. mean arterial blood pressure (MAP), central venous blood pressure (CVP), intracardial pressure (ICP), electrocardiogram (ECG), respiration rate and pulsoximetry<sup>1,2</sup> is necessary. Measurement instruments are connected via cables to the central monitoring unit, with the negative side effect that numerous connections constrain the medical care. Furthermore, neurointensive care patients often have to be transported for examinations such as computer tomography (CT) or magnetic resonance imaging (MRI), or the patients have to be transferred to the operating theatre. Transport of ICU patients may provoke changes in blood pressure<sup>3</sup>, respiratory parameters and ICP<sup>4</sup>, however.

Monitoring of the vital parameters during these transfers should never be interrupted. Yet, the preparation of a patient for transportation includes the disconnection and reconnection of the cables from the central monitoring unit to a transportable unit and rearrangement of all the cables, taking around 30 minutes and implying the risk associated with interrupting the monitoring.

### Methods

We plan to develop a wireless transport device containing two parts. First, an acquisition unit to acquire the vital parameters and containing a wireless module to transmit the data. Second, a transport monitoring unit which can receive the wireless data and monitor them at the bedside. Additionally, the monitoring unit of the ICU should have access to the wireless data.

### Results

The wireless protocol will be implemented using Bluetooth. The wireless data will thereby be embedded into a patient data monitoring system (PDMS) to guarantee monitoring without interruption.

### Conclusion

The wireless solution reduces the number of cable connections in intensive care and may simplify medical care as well as facilitating preparations for transfer. Further studies have to be performed to guarantee no interference problems or interruptions, especially in the environment of CT or MRI stations.

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## Effect on Thyroid Function of Iodine Exposure Due to the Use of Auto-Disinfectant Connector in the Administration of Intravenous Fluids

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### Introduction

Central venous catheters are essential in caring for critically ill patients. This procedure is associated with bacteremia and infection complications. The use of a new autodisinfected connector containing Iodine solution (Segur-Lock) has been shown to prevent central venous catheter infections, but could be a risk of thyroid dysfunction due to Iodine supply of each manipulation. The aim of this study was to evaluate their safety and impact on thyroid function of the intravenous Iodine overloading that occurs during the use of this disinfectant connector in great number of manipulations per day and their urinary excretion.

### Methods

A total of 54 patients from 4 different care units were included, 36 were randomly assigned to the Segur-Lock group (SLG) and 18 to the control group (CG). Exclusion criteria has been previous thyroid dysfunction. Serum samples of TSH, total-T4 (TT4), total-T3 (TT3), free-T4 (FT4) and thyroid autoantibodies and quantitation of Iodine in 24-h urine samples were performed before insertion of the catheter and each 2 days until it withdrawal.

### Results

Serum TT4 was not significantly different in the CG and SLG at the beginning and during the study, and always in the normal range; significantly low TT4 values were seen in patients who died, but not in relation to Iodine excretion. No significant differences were found in serum TT3 or FT4 between the two groups. Basal serum TSH and TSH levels during the study were not significantly different and in the normal range. Because patients with previous medical history of thyroid disease were not included, very few included were positive for Thyroid Autoantibodies and the frequency of them did not change during the study. The 24-h urine Iodine excretion has shown that it was surprisingly high in both groups, 630,6 mcg/24-h in the CG and 669,9 mcg/24-h in the SLG, and more than 1,000 mcg/24-h in 55% of the CG and 61% of the SLG. In the SLG a significant relationship was shown between 24-h Iodine excretion and the number of pulses of Segur-Lock on day 4 ( $p < 0.05$ ) and 12 ( $p < 0.01$ ) of the study.

### Conclusion

These data indicate that the use of this disinfectant does not influence serum thyroid hormones, TSH or the positivity of thyroid autoantibodies. The iodine supply of the disinfectant is much lower than that produced by iodine containing antiseptics or diagnostic compounds during the time in an intensive care unit and the iodine of the disinfectant hub is excreted by urine and do not supposes a significant augment respect to controls.

## A Change Management Strategy to Improve Personnel Safety and Health in the OR

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### Introduction

Workers in the operating room are exposed to hazardous conditions and situations. But, only few attempts were made to reduce personnel risks in the operation room. This is due to the complex and variable task structure. To overcome this situation, the German Project SiGOS (Safety and workers' health in the operating room; funded by the Berlin Accident Insurance Association) was initiated in active co-operation with three Berlin hospitals aiming to develop individual strategies and applications for different types of problems.

### Concept for a Clinical Change Management strategy

For a sustainable management of occupational safety and health issues in the OR an individual and efficient pathway is required considering the low priority of the issue by clinicians. On the basis of a general problem solving cycle as shown in figure 1 [1] the following attributes were outlined for particular importance in clinical work systems:

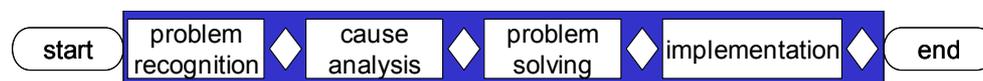


Figure 1: Problem solving Cycle

- Objects to change include a process level, a subject level and an organizational level.
- Each step itself consists of an iterative sequence of actions and assessment, as well as a subsequent decision between the different alternatives to proceed.
- As a base for any decision, possible effects of any alternative have to be anticipated.
- Result may be a changed process or changed organizational rules or structures).
- The problem solving cycle may either be performed in a very elaborated way (making large steps), or it may be performed more quickly (making smaller steps) and accepting possibly iteration loops.

### Application Examples

Following examples result of the problem solving cycle application:

- *Implementation example – needle sticks and sharp instrument injuries:* Existing devices with safety features (technical solution) as well as safe tool transfer procedures (organizational solutions) were implemented to reduce needle sticks and sharp instrument injuries.
- *Problem solving example – spine load:* The Task analysis identified no particular loads, but high total load. As a consequence, the problem solving step concentrates on tasks for which spine load may be reduced by simple means.
- *Cause analysis example – stress:* A task questionnaire acquires different aspects of work stress as well as a self assessment of work strain (e.g. activation, fatigue, emotional state). So, strain relevancy of tasks and conditions for the complex work pattern in the OR can be achieved.

### Consequence

The experience of the project shows, that due to the complex work structures occupational safety and health issues need to be addressed individually. Also expert guidance and participation need to be subtly balanced. The complex systematic approach is hardly to apply but steps (slowly) forward.

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## The medical equipment of the ambulance - A comparing ergonomic study based on an analysis in Germany, Jordan and Palestine

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### Introduction

Before the end of the seventies, there was no rescue cars in Jordan and in the palestinian area only after the end of the eighties [1,2,3,4]. That shows both rescue systems are still in a stage of development and the countries need a help to improve their rescue system. Emergencies can happen everywhere, at any time, in each conceivable constellation and they can concern everybody. Therefore it is extremely important for an appropriate initial care (diagnostics, therapy and monitoring) as well as transport of the patients to the hospital to have all necessary medical equipment with the ambulance. But what is necessary in these countries?

### Objective

Based on the knowledge and experience from the rescue system in Germany an effective, efficient and future-oriented rescue system has to be developed for Jordan and Palestine. In a first step an analysis of the current situation of the rescue system in the respective countries, with the main focus on determining the variables, that influence the ambulance equipment.

### Methods

The relevant data was obtained by questioning and observation. For this purpose a half standardized questionnaire was developed and used in culture-comparative interviews (Jordan, (Amman) N=31, Palestine (Gaza Strip) N=36, Germany (Berlin) N=16). The collected data was then completed by an additional observation of the different rescue chains and a photo documentation as well.

### Results

The ambulance in Palestine (Gaza Strip) has a good, but nevertheless insufficient medical equipment, whereas the ambulance in Jordan has almost no medical equipment – only oxygen cylinders, sphygmomanometer and sometimes suction units; further medical devices are missing. The complex emergency situation in Palestine leads to, that the staff has always to carry bulletproof vest.

This indicates that the medical equipment of the ambulance must be improved in both countries. The staff of the ambulance in Palestine was better qualified than the staff of the ambulance in Jordan and they have the permission to give the patients drugs.

### Conclusion

2. The staff of the ambulance has to be qualified to use the equipment of the ambulance.
3. The equipment of the ambulance must vary in different countries to have an effective and efficient rescue system according to the political situation, geographical location, cultural identity, medical progress and economical situation.
4. It is very important to generate and to evaluate a requirement catalogue for the ambulance in the respective countries.
5. It has to be investigated, if the developed concept can also be transferred as standard for other developing countries.

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## Depth of Anesthesia - Detection of Awareness

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General anesthesia may be defined as a combination of hypnosis and amnesia, analgesia, and suppression of stress response. Today, this is achieved by administration of a combination of more or less specific drugs. The degree to which each of these components (and drugs) contributes to the phenomenon "general anesthesia" is variable. A regimen that heavily relies on opioids may require a reduced amount of hypnotic drugs, whereas the administration of high doses of an hypnotic may require only little additional analgesia. This indicates why it is problematic to define the term "depth of anesthesia". Separate assessment of each of the components analgesia, hypnosis, and suppression of stress response may be a solution, even if the assessment of analgesia is a great challenge that is unsolved. Stress responses can be detected with standard monitors. During the last decades, monitoring of electric activity of the brain has been advanced to a degree that it may serve as a monitor of the hypnotic component.

In order to validate the performance of this possible monitor, the term "hypnotic component" must be specified. The extremum of inadequate hypnosis is reflected by patients who remember events which had occurred during anesthesia. As recent multicenter studies showed, the incidence of this event is relatively low (<0.2%)<sup>1,2</sup>. However, patients who remember being aware are only the top of the iceberg, the term "awareness" describes a related, but different phenomenon. Awareness means a functional short-term or working memory, i.e. a memory function of limited capacity, which spans several seconds and contains everything the person currently thinks. Awareness means complete or partial perception of the surroundings. A patient who is able to follow command is aware. Intraoperative awareness and perception does not necessarily induce postoperative conscious recall. Information can be stored in the implicit ("unconscious") memory. Implicit or non-declarative memory can be seen as an independent form of memory. Its contents are of implicit nature and may not be recalled. Despite of this lack of recall, they may influence feelings and behavior. This can be illustrated by a simple study which was performed by Bennett et al during general anesthesia<sup>3</sup>: During general anesthesia, half of the patients were instructed to touch their ears during the postoperative interview. In the interview, patients who had received the instruction touched their ears significantly more frequently than patients without the instruction. There was no recall of the instruction neither had patients recognized that they had touched their ears. The next level is explicit memory, where events are stored in memory and are directly recalled.

These definitions explain why the quality of an awareness monitor can not be tested with a postoperative interview, which only tests for explicit memory. Several studies have demonstrated that the risk of explicit memory is increased with increased duration of awareness periods<sup>4</sup>. Thus, we recommend that anesthesia monitoring should help to prevent awareness. This may be a conservative measure, but if additional monitoring is intended to increase patient comfort and safety, this may only be reached by such a conservative measure.

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## EEG - Spontaneous Electrocortical Activity

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During the last years, monitoring of anesthetic effects on the main target of anesthesia, the brain, has attained increasing interest. The EEG shows characteristic changes during anesthesia: In general, with increasing drug concentrations EEG amplitudes increase and EEG frequencies decrease. The exact pattern of these changes depends on the anesthetic drugs that were administered. Visual classification of raw EEG waveforms is time-consuming and requires long experience. This limits the clinical application of this method as a monitor of anesthesia. The use of processed EEG variables may allow an easy quantification of EEG properties, reducing the complex pattern to a (single) numerical value. During the last decades, several processing methods have been suggested that are based on basic, statistical, spectral, entropy, nonlinear analysis and pattern recognition. These signal processing methods condense EEG information and may facilitate the analysis of EEG changes.

In general, two approaches must be differentiated. In the first approach, parameters are calculated from the basis signal, EEG. These parameters describe characteristics of the EEG waveform. Similar to systolic or diastolic blood pressure (being the maximum or minimum of the invasive blood pressure curve), these parameters reflect characteristics of a physiologic measure, the EEG. Measures of complexity and entropy of the EEG are examples for this approach. The Datex entropy module is a commercially available monitor that shows signal entropy. Two entropy values are calculated by the monitor, response entropy and state entropy. Whereas state entropy is calculated from the traditionally used EEG spectrum (up to 32 Hz), response entropy uses higher frequencies <sup>1</sup>. During awareness, response entropy shows a faster increase than state entropy. However, it is unclear whether response entropy reflects electrocortical or muscle activity. Thus, even if it is more responsive, it may not directly monitor brain activity but illustrate a surrogate parameter, muscle activity. It remains to be determined, whether this surrogate is reliable during neuromuscular block.

The second approach is the design of an EEG-based index of anesthetic depth. This must be differentiated from the calculated EEG parameters. An depth-of-anesthesia index is constructed on the basis of a patient- or volunteer- database. For this approach, several EEG parameters are selected and combined by statistical means. As a consequence, such indices do not directly reflect characteristics of the physiologic EEG but can only be used to provide information about anesthetic depth, the primary goal during design. In addition, an index can only be as good as the underlying database. The EEG Bispectral Index (BIS) is an example for this approach. In the case of BIS, the quality of the underlying database has already been questioned. The BIS-algorithm was mainly designed on the basis of mono-substance anesthesia. In daily clinical practice, general anesthesia is mainly attained by a combination of drugs (e.g. analgesic and hypnotic drugs). So far, BIS has not been sufficiently validated for these combinations <sup>2</sup>.

Calculated EEG parameters directly reflect EEG-characteristics, i.e. changes of brain activity which are related to the state of consciousness or anesthesia. With increasing experience or after introduction of a new drug, threshold values can be adjusted to the new requirements. In contrast, a specifically designed anesthesia index may not be valid for a new drug or drug combination. As a consequence, a new index must be developed.

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## AEP – Auditory Evoked Potentials

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Auditory evoked potentials (AEPs) were first used clinically by audiologists and neurologists to detect tumours and hearing defects. We have these professionals and the biomedical engineers to thank for the detailed knowledge that we have today.

An AEP is an average, of a number (usually large) of electroencephalogram (EEG) waveforms recorded from scalp electrodes, in response to a repetitive sound stimuli. The 11 or so waves which make it up represent the electrical activity passing along the auditory nerve pathway via the brainstem, midbrain, pons and thalamus to the primary auditory cortex, secondary auditory cortex and association areas. Early reports of the effects of anaesthetics on the AEP showed a reduction in amplitudes of the cortical waves by nitrous oxide (Lader & Norris 1968) and secobarbital (Mendel & Hosick, 1975). The study of the AEP as basis for monitoring anaesthetic depth started in earnest in the early 80's and since that time anaesthesiologists have added their contribution to the body of knowledge.

The AEP has certain advantages over the EEG, i.e. the anatomical origins are known and it shows similar changes with different anaesthetics. In addition there are features within the early cortical section of the AEP which indicate awareness, show appropriate changes with noxious stimulation and the attenuation of such stimuli by opioids. Disadvantages are that the AEP has to be averaged from the background EEG and unlike the EEG it is not instantly obtained. As with the EEG it requires expert interpretation and muscle artefact contaminates the signal. The sound stimulus is delivered to the patient's ears by headphones/earpieces. If the patient is deaf or the earpieces fall out then the AEP will not be generated.

These challenges are being addressed. Techniques which reduce the time to obtain an averaged response are now incorporated into monitoring devices. Attempts are being made to derive indices related to anaesthetic depth in order to simplify interpretation.

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## **Limitations of current Hypnosis Monitors**

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## Computational Intelligence

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For more than 150 years, general anesthesia has been performed with increasing security. Despite detailed knowledge about anesthetic effects and high safety standards, the risk of intra-operative awareness cannot be excluded [1]. A promising monitoring strategy exists in the extension of the standard monitoring by monitoring activity of the brain as primary target organ of anesthesia. Appropriate signals are the spontaneous EEG and evoked potentials. The visual analysis of these complex signals requires excessive experience and can hardly be done during clinical routine.

At present neither standards for the determination of relevant parameters nor sufficient, explicit a-priori-knowledge about the relationship between basis signals and depth of anesthesia exist. Thus, a possible solution is the application of appropriate computational models which automatically learn from examples (e.g. determination of relevant parameters from given data or assignment of given data to appropriate patient states).

The term Computational Intelligence (CI) summarizes computational methods which allow handling of knowledge that is not explicitly given. Here, three main paradigms are considered: Fuzzy Logic (FL), Neural Networks (NN) and Evolutionary Algorithms (EA). Their methods are adapted from nature: While FL is related to the ability of humans to deal with inexact observations and reasoning, NN emulate the principles of the human brain and EA the natural biological evolution.

Specific methods that were derived from these paradigms have been applied successfully to concrete problems [2]. According to the current trend of development and application of hybrids of paradigm our working group combined FL and NN to build a pattern recognition system for neurophysiological depth of anesthesia monitoring. It was developed to analyze auditory evoked potentials (AEP) during repeated propofol sedation by means of wavelet transform [3]. The selection of relevant parameters from the calculated wavelet coefficients was performed by an automatic fuzzy-based procedure. The assessment of the selected parameters was performed by reclassification of patient data based on a NN. The reclassification results and the transparency of the developed system suggest an advanced application of CI methods in the field of neurophysiological depth of anesthesia monitoring.

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## Patient Data Management Systems in clinical use – Centricity® Critical Care

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*(Director: Univ.-Prof. Dr. med. H. Van Aken)*

The use of Patient Data Management Systems (PDMS) in an Intensive Care Unit (ICU) has become more and more important. It's not only the rising amount of data which has to be documented by the ICU staff but also the growing need for statistical evaluation and communication of the collected data for medical and economical purposes.

We report about our experiences of two and a half years with a “paperless” ICU.

In our hospital the department of Anaesthesiology and Intensive Care runs three ICUs equipped with the PDMS “Centricity® Critical Care” former known as “Quantitative Sentinel®” by General Electric Medical Systems. We started routine use in February 2001 and since then 4.000 patients were documented with the system. The University Hospital Muenster is an educational centre for physicians and ICU nurses so there is a reasonable turnover of medical and nursing staff. In the last 30 months there were more than 300 users trained in using the Centricity® Critical Care system.

From the beginning, we had the aim of completely paperless documentation during the ICU-stay of the patient. This includes the charting of vital signs and bedside device settings, the documentation of medications, nursing activities and a daily plan as well as the recording of the results from other departmental systems like radiology, any kind of laboratory and the administrative data. Furthermore there is a semi-automatic computation of scores like APACHE II, daily SAPS II and SOFA. These scores are automatically computed and only need to be validated or corrected by the physician, so the time needed to get the results is minimized.

The medical and nursing ICU-staff as well as the consultant physicians and physiotherapists do their complete patient documentation on the ICU electronically. Only when a patient is transferred to the intermediate care unit a comprehensive report is generated as a paper printout and handed along with the patient. The complete archiving of the ICU data is done electronically.

Beside the medical patient record there are several additional functions realized by the use of data from the PDMS like statistical analysis of the treated patients, computation of treatment costs per patient, usage of drugs, compilation of critical care procedures, etc. For billing purposes, data like diagnoses- and procedure-codes, ventilation- and haemofiltration-durations are automatically transferred to the hospital's invoice department. Other databases like the lot number documentation of blood products and the nosocomial infection database are provided with data from the PDMS for convenient evaluation and look-back purposes.

The electronic documentation opens up the possibility for automated data retrieval from the used devices without user interaction. The staff is freed from routine tasks like hourly vital signs documentation and the frequency of documentation can be raised without additional workload. Modern devices like ventilators provide a wide range of additional parameters, which usually were not documented in former times. In our ICUs all transmitted data are automatically stored at a 15 minutes interval. This seems to be a good compromise between comprehensive data capturing and readability. In case of emergency the automatic documentation interval is switched to one minute so that there is a reliable documentation of these acute situations.

Our experience of two and a half years with the Centricity® Critical Care system suggests that the use of PDMS in ICUs improves the quality of work and the quality of the documented data. The fact that information from all parts of critical care is stored in one database opens up a wide range for further improvements like online decision-support and complex automated calculations.

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## **Implementation of new PDMS - investigation of the consequences on doctors and nursing staff**

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### **Introduction**

The implementation process of electronic data processing in anesthesia and intensive care is often dominated by considerations of efficiency and economy. However, motivation and human resources are not taken into account sufficiently. In extreme cases this lack can lead to total rejection of the system by the users (1). In this prospective study we investigated whether and how work strain and job satisfaction of doctors and nurses change due to the introduction of new PDMS on an ICU (intensive care unit), in order to take the medical users' needs and abilities into consideration.

### **Methods**

To separate the consequences of the new technologies from the reorganisation process itself, a longitudinal study with three points of measurement was conducted. Characteristics of workplace, of individuals and of the new system are recorded before (baseline, t1), during (t2) and after (t3) an implementation of a new system with means of standardised questionnaires, checked for reliability and validity (2).

### **Results**

Doctors and nursing staff of one surgical (n=19) and one medical (n= 25) ICU were investigated during the introduction of two different PDMS. Current results show a neutral to positive attitude towards computerisation in medicine, a high job satisfaction in spite of high workload, accompanied by a strong dissatisfaction with the organisation. Expected problems of acceptance of the questionnaires (anonymity concerns, motivation of participants, different lobby groups) occurred in the difficult setting of an ICU.

### **Conclusions**

For the first time an accompanying longitudinal investigation allows an assessment of the consequences of the introduction of new PDMS on doctors and nursing staff. The comparison of data before, during, and after the introduction indicates whether and in which direction work strain and job satisfaction change because of the reorganisation process itself and/or because of the new documentation system. Sophisticated recommendations for workplace design, for a favourable style of introduction of the new technology, and for the development of a user training adapted to the special needs of medical users can be derived from this study.

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## Improving the quality of documentation with a patient data management system

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### Introduction

The advantage of a patient data management system (PDMS) for the documentation of anaesthesia cases (1) and for charting hemodynamic data (2) has already been shown. A more complete documentation of the administered drugs can be achieved by using plausibility checks in a PDMS.

### Method

Since 1999 we have been using the PDMS (COPRA®) for all our cardiac anaesthesia cases. Up to now, more than 14000 anaesthesia cases are documented with our PDMS. Retrospectively, we have studied the documentation of 3 different drugs in the last 3 years. This was done for 9660 cases. We have checked how often the application of heparin, protamine, cephazoline was not documented. Heparin and protamine are obligatory in operations using Cardiopulmonary Bypass (CPB) and no substitute for them is used at our clinic. Cephazoline is our standard antibiotic prophylaxis. Only in cases of known allergy or a previously started different antibiotic treatment a substitute is used. After the analysis of our data a plausibility check was introduced in September 2002. Until July 2003 we have more than 3600 cases documented with the new plausibility check.

### Results

Our retrospective analysis showed, that in 2 % of all operations with CPB heparin and in 3% protamine has not been documented. Since both drugs are absolutely necessary for CPB and

	patients	heparin	protamine	cephazoline
2000	2318	3,0%	4,3%	14,9%
2001	3935	1,9%	3,7%	10,9%
2002 Jan.-Aug.	3407	1,6%	2,5%	6,5%
2002 Sept.- Dec.	1045	0,0%	0,0%	1,8%
2003 -July	2621	0,0%	0,0%	1,1%

theoretical possible alternatives are not used in our clinic, we can assume the documentation was omitted. The same is true for cephalosporins.

The introduction of the plausibility check has led to a complete documentation of heparin and protamine. In cases of failed documentation

of cephazoline an alternative antibiotic treatment was always found in the charts. Therefore a complete documentation of antibiotic prophylaxis can be assumed.

### Conclusion

The most significant reduction for the omission of drug documentation shows that a computer aided PDMS can improve the quality of documentation remarkably and prevent irregularities and their legal consequences.

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## Using a Patient Data Management System for Automatic Calculation of the Nine Equivalents of Nursing Manpower Use Score (NEMS)

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### Introduction

The most recent approach to estimate nursing resources consumption has led to the generation of the Nine Equivalents of Nursing Manpower use Score (NEMS) (1). The objective of this prospective study was to establish a completely automatically generated calculation of the NEMS using a patient data management system (PDMS) database and to validate this approach by comparing the results with those of the conventional manual method.

### Methods

The NEMS of consecutively admitted patients, between July 24<sup>th</sup>, 2002 and August 22<sup>nd</sup>, 2002, to an operative intensive care unit of a tertiary care university hospital was calculated automatically with a PDMS and manually by two physicians (consultant and resident) in parallel. The results of the three methods (Consultant, Resident, and PDMS) were compared using the method of Bland and Altman (2) and the interclass correlation coefficient (ICC) (3). Furthermore, inter-rater variability for the nine categorical variables of the NEMS was measured computing the percentage of agreement (and disagreement), and the kappa index of concordance,  $\kappa$ .

### Results

On 20 working days the NEMS was calculated in 204 cases. The Bland-Altman analysis did not show significant differences in NEMS scoring between the three methods (consultant, resident, and PDMS). The interclass correlation coefficient revealed high inter-rater agreement: PDMS vs. consultant (95% confidence intervals) 0.87 (0.84-0.90), PDMS vs. resident 0.83 (0.79-0.87), and consultant vs. resident 0.92 (0.90-0.94). The  $\kappa$ -statistic showed good results ( $\kappa > 0.55$ ) for all NEMS items apart from the item "supplementary ventilatory care".

### Conclusion

This study demonstrates that it is possible to construct an automatically calculated NEMS computation exclusively using data collected with a PDMS leading to comparable results to those of the conventional manual approach. This may lead to a decrease in consumption of nursing resources.

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## Automatic Computation of Nursing Activity Using a Patient Data Management System – A Comparison of TISS-28 and NEMS-Calculation –

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### Introduction

The impact of therapeutic activity on resource calculation becomes more and more important in the frame of reimbursement. The aim of this prospective study was to evaluate, whether the TISS-28 (Therapeutic Intervention Scoring System) (1) and the NEMS (Nine Equivalents of Nursing Manpower use Score) (2) can be equally used to represent the nursing expense of an operative intensive care unit (ICU).

### Methods

For this study all patients aged 18 years or older, treated in the year 2002 at least for 24 hours on ICU were included. Complete documentation of the stay on ICU was performed using a patient data management system (PDMS) database. This PDMS supports automatically recording of all vital signs and ventilatory data via RS232 interface. Additionally all laboratory and microbiology results are imported on a routine basis via the hospital information system. All other procedures relevant for documentation are either entered manually by the physicians, nursing staff, physical therapists, or other persons attributing to the care of the patient. For every patient and every day on ICU the TISS-28 and the NEMS score were automatically computed. The concordance between the two score-calculations was tested by Bland-Altman analysis (3).

### Results

687 patients (604 survivors, 83 deceased) with a total of 3,238 days on ICU could be included in the analysis. The average ( $\pm$ standard deviation) TISS-28 was  $27.7 \pm 8.6$  (NEMS:  $27.3 \pm 6.8$ ) on admission and  $18.4 \pm 6.6$  ( $20.3 \pm 5.5$ ) on discharge. The survivors had a TISS-28 of  $23.8 \pm 4.6$  (NEMS:  $22.6 \pm 5.6$ ), the deceased  $28.5 \pm 6.7$  ( $28.3 \pm 7.5$ ). The Bland-Altman analysis could demonstrate, that the TISS-28 scored approximately 1.6 points higher than the NEMS ( $p < 0.05$ ) with  $R^2 = 0.125$  and a linear regression-function of  $y = -0.227x + 7.394$ .

### Conclusion

The NEMS scores comparably to the TISS-28 in representing the nursing activity on an ICU. Furthermore, both scores reflect the severity of illness as one can see both in the differences between admission/discharge and survivors/deceased. To conclude both scoring systems can be used for external quality assurance projects in parallel allowing the comparison of nursing power.

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## Development of a Decision-Support-System for calculated antibiotic therapy in intensive care medicine integrated into a PDMS

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### Introduction:

Patients treated in an intensive care unit (ICU) are at significantly increased risk to acquire infections [1], necessitating antibiotic treatment. This causes high resistance of strains and enormous consequential costs. Furthermore many medication errors associated with antibiotic treatment are well described [2]. The aim of this study was to develop a rule-based expert system for antimicrobiological treatment integrated into an established patient-data-management-system (PDMS) of an ICU to support physicians in prescribing calculated antibiotic therapy.

### Methods and Results:

In a first step, a decision tree for calculated antibiotic treatment was defined according to the guidelines of the Paul-Ehrlich-Institut, considering the local empirical data of strains and resistances. At every node of the tree, comments and information for physicians were added, resulting a decision tree with 1800 nodes and 74 therapeutic procedures. Thus physicians were guided through the decision tree by “questions and answers” to an antibiotic therapy with the mostly probable effect. Secondly, the decision tree was mapped to a data model and implemented into the database of the PDMS (ICUData, IMESO GmbH, Hüttenberg, Germany). Finally, programming of the application was solved with C++ using the development environment Microsoft™ Visual Studio. The recommended antibiotic treatment of the application, called “Treatment-Wizard”, additionally includes a standard of diagnostics and attendant therapy. The application was integrated into the PDMS via the HL7-interface. The data are sent to the PDMS with a non authorized result status, forcing the physician to control and to acknowledge the orders. For further analysing the acceptance of the application and the quality of recommended treatment the path through the decision tree was stored with every item of the therapy into the database of the PDMS.

### Conclusions:

The application “Treatment-Wizard” offers decision support for antibiotic therapy for physicians on ICU based on accepted guidelines. The effect of the calculated antibiotic therapy on patient care and its acceptance by the staff are presently investigated in a prospective study.

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## Automated interconnection of differently structured databases in genomic research

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### Introduction

At the “Giessen Research Center in Infections Diseases” (GRID) project location, DNA micro array data and clinical data from intensive care unit (ICU) patients suffering from sepsis and septic multi-organ failure should be stored in a central study database [1]. Clinical data were recorded using a patient data management system (PDMS). The aim of this project was to develop an automated data transfer from the PDMS database to the central study database, thereby reducing redundant data entry.

### Methods

At all ICUs involved in the GRID project (medical, surgical and paediatric ICUs) the PDMS ICUData (IMESO GmbH, Hüttenberg, Germany) [2] was used for paperless documentation. The PDMS database (Oracle7™) was structured partially as relational and partially according to the principles of the Entity Attribute Value (EAV) data model. Administrative data (ID, name, gender, age) from the patients in the GRID study were entered manually into the study database (Microsoft Access™). On request, a text file was created automatically for each point of time as defined by the study protocol. Subsequently, these files were imported into another database (Oracle7™) running on a gateway computer. Firstly, patients were identified using the clinical patient ID from the PDMS’s admission, discharge, transfer (ADT) database. In case of implausible IDs, the patient’s last name, first name, date of birth, and gender were used to identify the patient. Secondly, clinical data meeting the study protocol and special structured query language (SQL) data definitions were transferred from the PDMS database into the gateway database. Finally, all available data were communicated back to the study database as response messages in text format.

### Results

After development and a two-month testing period, the data transfer started in routine use. Until now, data of 115 patients were automatically transferred on request from the PDMS database into the study database via the gateway. Verification of a sample size of every tenth processed data request showed complete data sets according to the study protocol and the data definitions. The time needed between requesting data and data import in the study database averages around two minutes.

### Conclusion

The described data transfer system helps the user in avoiding duplicate, manual entry of digitally available clinical data and in simplifying the data collection process. We expect an improvement of data quality by avoiding redundant, manual data entry. This data transfer system also acts as an important step for integrating clinical and genetic information [3].

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## Patient Safety in Anaesthesia

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Since the publication of the report “To Err is Human, Building a Safer Health System” (Kohn, Cirragan & Donaldson, 2000), a controversial discussion has arisen with regard to the impact of medical mistreatment. The given survey of the Institute of Medicine (IOM, 1999) estimates that between 44,000 and 98,000 patients die each year in the U.S.A. due to medical mistreatment. The costs resulting to the U.S. American Health Care System were estimated between \$20 and 35 billion each year. The reliability of the results have to be discussed critically, because of its methodological background and its non-transparent evaluation parameters (Sox & Woloshin, 2000). Several studies from different nations have tried to analyse the impact of medical mistreatment. (see also Wilson et al., 1995; Weingart et al., 2000; Vincent, 2001 or Rall et al. 2001). They all have a decisive weakness though. They cannot determine the real number of patients handicapped by medical mistreatment. Moreover, data collection becomes even more complicated by some basic methodological problems. As a matter of fact, not every medical mistreatment necessarily leads to an impairment of health. Moreover, it is not evident how medical mistreatments can be defined or how they can be classified by the dimension of the impairment of health they cause. While there is still a need for clarifications from a scientific point of view, it is also important to analyse where main potential factors can be found that contribute to critical situations in patient’s safety.

Since there is no specific data available on the situation in Germany, it is necessary to rely on sources from abroad. Valuable clues can be found in a database of the anaesthesiological department of the University of Basel (CIRS), for instance. In German press coverage, one can find several individual cases of medical mistreatment. Even the technical press deals with this topic from time to time. A decisive factor in the context of critical incidents in the operating room (OR) seems to be the lack of team performance. A medical journal summarizes the results of the sources mentioned above as follows: “Team spirit in the OR is quite evasive” (Marburger Bund-Ärztliche Nachrichten, 2001).

In this regard, an attempt was made to discover -of cause within the context of a scientific study- the contributing factors leading to the deficiencies of team performance in the OR. It is assessed in which division team performance is considered as “good” and in which division obvious deficiencies can be found. Considering the complex work system, attention has to be paid to the fact that within the development of critical incidents organisational and technical factors can be involved. Their influence on the performance of a team in the OR should also be examined. In order to find out and remove factors which endanger patient’s safety, the use of safety concepts seems to be inevitable. These safety concepts should not only consider the individual himself but also include systems in which several individuals work together as a team in cooperation with technical devices. That means an attempt is made to consider the complex correlations of the socio-technical system.

The expected results should help to develop special treatments for team performance trainings which could be used in appropriate advanced trainings and further education in specific simulators.



## Bug or Feature? On the sensible use of software

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*“Better processes, not greater individual efforts produce the greatest enhancements of quality and productivity” (Bill Bornstein)*

Talking about safety in technical systems and software, one immediately agrees that this is an important issue, especially in sensitive environments. For decades, methods have been developed to improve the quality and safety of devices. Since more and more software is being used, research has led to strategy and tools to yield safe programs such as code verification, watchdogs or voting in avionics.

As has been proven, sound safety in software affects not only the programming itself, but the entire software life cycle. The following example has been taken from the Safeware methodology:

- Project management
- Software Hazard Analysis
- Software Requirements Specification
- Software Design and Analysis
- Design and Analysis of Human-Machine Interaction
- Software Verification
- Feedback from Operational Experience
- Change Control and Analysis (changes to software)

However, most approaches to safety in devices and software are technology centric, being made by engineers for engineers. The societal challenge has often been neglected.

Technology is a tool that should ease every day's life. But in most environments one can not decide on her own, which of these tools, products etc. to take and use. Even worse, often the decision for software is driven by people of not using it and having a different agenda: infrastructure departments and the administration decide on the equipment bought and installed. If not introduced properly, the decisions are enforced on the people, raising anger and unwillingness.

In addition, software seldom fits perfect for all tasks. Once a situation is encountered that the product does not support, people have to develop fallback mechanisms, e.g. using empty space in (electronic) forms for which it was not designed. Not only mean such crooks additional effort, but impose additional risks. Even if the software fits its task, the intention and mental model of the system developers will be transmitted to the users.

In short, safety in technical systems does not only mean putting efforts into the development of each component. But taking into account the full context in which it is being used, starting from the awareness of needs over requirements, development, introduction and daily operation and feedback.



## Patient data management system- how to pass from one millenium to the next one ?

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Monitoring of the hemodynamically unstable patient started almost one century ago, with the first measurements of blood pressure during surgery.

Since then, curiosity, need for precision, patient follow up as well as medico-legal fear brought up to daily routine the practice of monitoring and recording of vital data of the seriously ill patient.

The first efforts to introduce the automatic recording of patient data have been done in the 70s, with the introduction of the first automatic anesthesia chart record. Unfortunately till today the number of operating room which use it as a compulsory tool during anesthesia is still low.

Introduction of the patient management data system in Critical Care was even more difficult. An editorial in Lancet 1983 (2:86-87) failed to mention computerization of data of the critically ill patient as part of the high standards of intensive care.

Soroka Medical Center in Beer Sheva , Israel was among the first hospitals which introduced (in 1988) a computerized system of data storage of critically ill patients, based on manual filling of a special ICU worksheet from which the main data were transferred to a special program , called **TOREN**.

During the last years the system was gradually improved and it is still in use today.

Both manual and computerized TOREN are updated with every single detail regarding :complications, management techniques, antibiotherapy, invasive procedures and vital organs involvement. Beside TOREN is used for admittance notes, daily presentation of the patient, discharge summary, statistics as well as retrieval of former admittances.

TOREN was used in the last 5 years for 3845 patients and often assisted the staff for drawing the right conclusions regarding patient management and prevention of complications.

Needless to say, TOREN has a long list of drawbacks. It implies manual/voluntary activity and does not provide any on-line data on the critically ill patient. The stored data do not include very important parameters, like vital signs, fluid balance or daily laboratory data (except those on discharge).

TOREN does not directly influence the error rate in ICU, it is time consuming and does not include nursing activity or reports.

Recently the introduction of patient information system, based on automation of the ICU flowchart tried to solve the above deficiencies of the existing manual-computerized systems.

A new concept of on line computerization of the critically ill patient was recently introduced in some Israeli ICUs.

The program , **MetaVision Suite**, permits minute-by minute collection of patient data from monitors, ventilator, infusion pumps. Written orders are also recorded as well as diagnosis and complications. The system collects laboratory and radiology data and also automatically performs calculations (fluid balance, oxygen consumption, etc). It records nursing activity and tasks and offers an integrative view of the ICU team work



The automatic database is supposed to save time and money, to facilitate quality assurance, to support bedside decision making process and help clinical research projects.

The MetaVision Suite is designed to be flexible yet intuitive for the users. The hospital project manager can customize all aspects of the patient record, from basic parameters, through tables, graphs and layouts, and all the way to formulae, forms, reports, events, scores, balances, and targets. Various layouts may be configured to meet the need of different units, various types of patients or groups of surgical procedures. No programming skills are required.

MetaVision includes the Query Wizard, a built-in query tool operated by simple "drag and drop" technology that enables non-programmer users to take advantage of it.

The Event Manager is a messaging container based on a structure of parameters and conditions set up by the user to identify certain patient profiles or conditions.

Some recent data based on similar programs proved the efficiency of the system regarding decrease of documentation time and increase in patient care time (Intensive Care Medicine 2003;29:83-90).

Finally two important questions are still to be answered.

The first is about the cost effectiveness of the system. One has to reach the conclusion whether the clinical information systems respond to the well known law of Moore, which specifies that efficient programs eventually double performance and halve the price every 18 months.

The other important question is about the information systems impact on patient outcome. Data on this topic are still scarce, but a recent paper (Crit Care Med 2003;31:120) showed that the use of a computerized information system significantly reduced the rate of complications and adverse events in critically ill patients. Incidentally, the paper presented the negative impact of the temporary return to the paper-based prescriptions (increase in medication errors, ventilation adverse events, etc).

A transitional period from the classical systems of information storage to the new millennium computerized programs seems to be essential for the success of the change. Anecdotal data show that this transition is in most cases smooth and very well accepted by the staff.

Investment is needed to adjust infrastructure and purchase the equipment.

One has to create evidence based data on time consuming aspects of this new system in order to proof its impact on the ICU budget and patient outcome.

But there is no doubt that soon our bedside activity would be tremendously influenced by the new concept of collecting and storage of data as well as of decision –making process in critical care.



## **Error prevention by human factors training in aviation**

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Working in fields where conditions are difficult like in always changing teams, in dynamic situations or at night-shifts require special training to achieve good results. Non-technical skills, that are essential for good teamwork, can and must be trained like technical or procedural knowledge. Abilities in effective communication, time management, structured decision making increase the efficiency of teamwork. Increasing safety by minimizing the risks is a key-issue in many professions. Why do humans make mistakes, what are the reasons for failure and what can be done as a prevention-strategy?. Is a higher degree of atomisation a solution ? Training by simulation can be a effective way to improve teamwork.

What can be simulated and what is essential for training ? Review of the inputs of the participants and their behaviour is very effective but must be done with good knowledge.

Aviation and medical professionals share some of these problems and do have the same questions.

An outside look from an aviation professional.



## A preliminary study of performance obstacles and facilitators of ICU nurses

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Our research aims at examining the work-related factors that contribute to employee and organizational outcomes, such as job satisfaction and job stress, and patient outcomes, including quality and safety of patient care. The conceptual model of our SEIPS project is based on the work system model developed by Smith and Carayon (Smith and Carayon-Sainfort 1989; Carayon and Smith 2000) and Donabedian's (1988) model of quality. In this paper, we examine elements of the work system of ICU nurses that can hinder (performance obstacles) or facilitate (performance facilitators) their capacity to perform their job. These work-related factors are assumed to contribute to workload, which in turn can lead to job dissatisfaction and stress (Kalimo, Lindstrom et al. 1997), and poor quality and safety of care (see, for example, Pronovost et al. (1999)).

We conducted interviews with 15 nurses of an intensive care unit at an academic hospital in the USA. The interview was semi-structured around the following questions:

*"Please think of instances in the past when your workload was high, you felt stressful and your performance was challenged due to problems in the ICU system. Please briefly describe any such instance(s) you experienced by explaining the situation and what you think caused it."*

*"Please think of instances in the past when you had a reasonable workload, you were satisfied with your job and were able to perform the job very well. Please briefly describe any such instance(s) you experienced by explaining the situation and what you think caused it."*

All interviews were audiotaped and then transcribed into text files. The qualitative data analysis software, NVivo©, was used to analyze the content of the interviews. A five-dimension node structure was developed to code the interview data: (1) categories of obstacles and facilitators, (2) people (or units) involved in the obstacle or facilitator (most frequently cited: nurses and physicians), (3) location related to the obstacle or facilitator (most frequently cited: patient rooms), (4) time component of the obstacle or facilitator (most frequently cited: night shift, shift change and day shift), and (5) output of the obstacle or facilitator. The most frequently cited obstacles were patient requirements and inadequate staffing (performance, skills, number), followed by inappropriate tools and equipment, ineffective inter-provider communication, materials and supplies, and 'road trips'. The most frequently cited facilitators were quality and performance of staff, followed by appropriate tools and equipment, availability of materials and supplies, effective inter-provider communication, and training.

The next step of this research project involves the development and administration of a questionnaire to collect and analyze systematic data on performance obstacles and facilitators and their impact on nurses (job satisfaction and stress, and perceived quality and safety of care). In the long-term, this research will lead to the identification, implementation and evaluation of work organization interventions in ICU's.

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## Predictors of Hypotension Following Induction of General Anesthesia

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### Introduction

Hypotension following induction of general anesthesia is a common event. The purpose of the current investigation was to determine the predictors of hypotension following the induction of general anesthesia.

### Methods

Computerized anesthesia records of 5793 patients undergoing general anesthesia were queried for BP, demographic information, preoperative drug history, and anesthetic induction regimen. The median BP was determined pre- and for 10 min post-induction of anesthesia. Hypotension was defined as either: (1) mean arterial pressure (MAP) decrease >40% and MAP <70 mm Hg; or (2) MAP <60 mm Hg.

### Results

*Hypotension was more prevalent in the second half of the 0-10 minute interval after anesthetic induction ( $p < 0.001$ ). In 2406 patients with retrievable outcome data, the proportions of adverse events (prolonged postoperative stay and/or death) in patients with and without hypotension post-induction were 13.3% and 8.6%, respectively ( $p = 0.012$ ). Statistically significant multivariate predictors of hypotension 0-10 minutes after anesthetic induction in ASA 3-5 patients included: baseline MAP <70 mm Hg, age  $\geq 50$  years, and propofol induction. In ASA 1-2 patients, fentanyl dosage was an additional predictor of hypotension.*

### Conclusions

It is prudent to consider alternatives to propofol anesthetic induction (e.g., etomidate or thio-pental) in patients over 50 years of age with ASA physical status  $\geq 3$ .

**Table.** Multivariate Predictors of Hypotension 0-10 Minutes Following Anesthetic Induction

	ASA 1-2	ASA 3-5
Variable	OR [95% C.I.]	P-Value
Baseline MAP <70 mm Hg	6.180 [3.063 – 12.471]	3.154 [1.081 – 9.201]
Age $\geq 50$ yrs	2.415 [1.812 – 3.219]	1.754 [1.075 – 2.861]
Propofol Induction	5.234 [1.914 – 14.310]	3.135 [1.785 – 5.507]
Fentanyl dosage	1.394 [1.132 – 1.717]	--



## Sympathetic nervous system seems to have little effects on the control of the diastolic blood pressure

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### Introduction

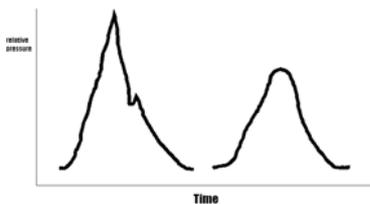
The arterial contractility is related to the sympathetic nervous system. However, we do not know how the sympathetic nervous system controls the smooth muscle contraction in detail [1]. If one sympathetic chain is cut and the other is intact, this period is a good model for the study of sympathetic activity because there is no individual bias. This situation occurs during hyperhidrosis treatment. We had selected this model to investigate how the sympathetic nervous system controls the arterial contraction.

### Methods

Following approval by IRB, 20 healthy hyperhidrosis patients were recruited for the study. After routine anesthesia induction, both radial arteries were cannulated and monitored simultaneously. We had used the SpaceLab monitor and the EZAD A/D converter for the data collection and the Matlab program for the analysis.

### Results

After the sympathectomy, the pressure wave form of the sympathectomized arm were changed suddenly. (Fig. 1) Even though the SBP area was reduced drastically, the DBP area was similarly maintained.



**Fig. 1.** Relative pressure comparison between sympathetic controlled arm pressure wave (left) and sympathectomized arm pressure wave (right). Note that the SBP area was changed a lot and the DBP area was maintained.

### Conclusions

We conclude that only the SBP may be controlled by sympathetic nervous activity. It seems that the sympathetic activity has little effects on the control of the diastolic blood pressure.

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## "QualiTEE" - An Intelligent Guidance and Diagnosis System for the Documentation of Transesophageal Echocardiography Examinations

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### Introduction

The intraoperative monitoring of critical ill patients is a permanent challenge in modern anaesthesia. The use of transesophageal echocardiography (TEE) is a well established method in monitoring these patients. But besides the understanding of the technical aspects, the results of a TEE examination can be improved, if the exam is done in a correct and efficient way.

### Methods

The "QualiTEE" project is a cooperation of the Department of Anaesthesiology of the University of Wuerzburg Hospitals and the Department of Artificial Intelligence and Applied Computer Sciences of the University of Wuerzburg. The major goal of this project is the development of a knowledge system supporting the anaesthesiologist when performing a TEE examination. Major aspects of the "QualiTEE" project are:

*Quality assurance by using a standardized examination protocol:* The system is proposing and guiding the documentation process by presenting the user a standardized documentation giving choice of practical, useful and relevant questions and alternatives. The dialog structure of the documentation process can be led by the system („guided dialog“) or the user („free dialog“). The standardized, guided examination protocol enables even the beginners to take a high-quality examination and documentation.

*Automatic inference of conclusions, e.g. diagnoses:* The diagnostic module of the system will be able to derive abstractions based on the gathered examination results. The system will recommend diagnoses, e.g. valvular defects, heart sufficiency, based on the findings of the examination.

*Automatic generation of medical reports using templates:* The system will be able to publish the results and diagnoses in tabular form or as a medical report by using preformatted text templates. An integration to enterprise software e.g. SAP/R3 is planned in the future to save the gathered data in an electronic patient's file.

*Further use of data:* All gathered results can be collected in a case database. It is possible to evaluate the database systematically and retrospectively by using data-mining methods. Different examinations of the same patient can also be evaluated by setting the results in a time dependent context.

*Tutor system extension:* The knowledge system together with the database can also be utilized for problem based learning. For this purpose the system is performing a step-by-step presentation of a case and the learner will be able to describe the findings using sample material and derive consecutive interpretations, i.e. diagnoses and therapies.

### Conclusion and Outlook

The "QualiTEE"-system will be able to help and support the anaesthesiologist during the TEE examination and learning the examination techniques. In addition to the usage as a documentation system for results in the OR or the ICU, the system will also be able to perform sophisticated methods of data evaluation and will also offer the possibility using the gathered database for problem based learning.

First clinical testings of "QualiTEE" are in design and will deliver first results about the systems validity and the users acceptance.



## Calculation of arterial acid-base status from peripheral venous blood.

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### Introduction

Measurement of the acid-base status of arterial blood is a routine part of intensive care. In many other departments, for example medical and surgical wards, this is not the case. In these departments large numbers of peripheral venous blood samples are taken, but these are seldom used to assess acid-base status.

### Methods

This abstract presents and evaluates a method for calculating values of the acid-base status in arterial blood from blood samples taken in peripheral venous blood, combined with pulse oximetry recordings of arterial oxygen saturation.

For peripheral venous blood sampled at a warm well-perfused arm, the ratio of oxygen removed from and carbon dioxide added to the blood as it passes through the tissues, i.e. the respiratory quotient (RQ), is relatively constant. In this method a mathematical model of acid-base chemistry (e.g., Rees et al, 1996) has been used to simulate arterial blood from peripheral venous blood, i.e. simulating addition of oxygen and removal of carbon dioxide to the peripheral venous sample in a constant ratio RQ. This simulation is performed until the calculated arterial oxygen saturation matches that measured using a pulse oximeter, at which point all calculated arterial values should be equal to those measured.

Arterial and peripheral venous blood samples were taken simultaneously from 82 patients residing in the ICU. Patients were selected so as to have a wide range of acid base status, with median and range values of arterial base excess (BE), pH and PCO<sub>2</sub> equal to SBE = 0.3 mmol/l (-7.3 to 22.6 mmol/l); pH = 7.397 (7.243 to 7.538); and PCO<sub>2</sub> = 5.61 kPa (4.03 to 10.81 kPa). Values measured in the peripheral venous blood were used to calculate arterial values using a constant RQ = 0.80. Calculated arterial values were then compared to those measured. Ethical approval for studying these patients was obtained from the Ethics Committee of North Jutland and Viborg Counties.

### Results

Values of arterial acid-base status calculated from this method compare well with the measured values. The mean and standard deviation of the difference between measured (m) and calculated (c) values of arterial pH, PCO<sub>2</sub> and PO<sub>2</sub> is equal to: pH<sub>m</sub>-pH<sub>c</sub> = 0.009 ± 0.014; PCO<sub>2m</sub>-PCO<sub>2c</sub> = -0.14 ± 0.28 kPa; and for arterial oxygen saturations ≤ 98%, PO<sub>2m</sub>-PO<sub>2c</sub> = -0.18 ± 0.79 kPa;

### Conclusions

The calculation of arterial acid-base status may be possible from peripheral venous blood samples combined with pulse oximetry measurement of arterial oxygen saturation. This method may be particularly useful in situations where arterial blood samples are not routinely taken.

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## Approximate entropy (ApEn) and detrended fluctuation analysis (DFA) of HR Signals of Surgical Patients During their Stay in a Multidisciplinary Intensive Care Unit

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### Introduction

Investigation of heart rate signals may be useful in assessing the nonlinear characteristics of neuroautonomic modulation of heart rate. One such method is detrended fluctuation analysis (DFA) that assesses the degree of long-range correlation in a nonstationary time series. In addition, approximate entropy (ApEn) is a nonnegative statistical measure that distinguishes data sets by their amount of regularity, with larger numbers indicating more randomness. Therefore, we studied different kind of patients (surgical with and without past medical history) who were admitted to our ICU and all these parameters were measured and correlated with the everyday SOFA score of severity of illness.

### Methods

We studied 38 patients who were admitted to the ICU from March 2003 until July 2003. Two cohorts of surgical patients (group 1 and 2,  $n=19$  for each group, 11/8 m/f) with mean age  $69.52 \pm 3.7$  and  $58.21 \pm 3.15$  years respectively were identified on the basis of the absence or presence of past medical history (ASA I, II and III, IV respectively). Patients with previous history of atrial flutter or fibrillation were excluded from the study. The ECG signal was recorded for 512 secs from a standard lead II ECG. Analog ECG signals were obtained with monitors (Marquette 8000, GE, Milwaukee, USA) with a low-pass filter at 100Hz. Data were collected and analyzed using an L8400K Asus 850MHz Pentium III PC. Daily SOFA scores were recorded until patients were discharged from the ICU. Approximate entropy and DFA ( $\alpha_2$  exponent) were estimated according to Kaplan in a Matlab version 5.3 environment [1]. Differences between the groups were evaluated by analysis of variance (ANOVA-test). Tests were performed with SPSS Software Version 8 and values of  $p < 0.05$  were considered to be significant.

### Results

In both group of patients ApEn seems to decrease for the whole period of the study, except for the group 1, where we observe an increase between the 7<sup>th</sup> and 12<sup>th</sup> day and then a final fall of its value.  $\alpha_2$  also increases slowly, especially in group 2 (ASA III,IV) while we observe a decrease in group 1 parallel to the ApEn upward change. ApEn and exponent  $\alpha_2$  values were significantly different between the two groups of patients ( $p < 0.05$ ). The strongest correlations were between  $\alpha_2$  and  $\Delta$ SOFA (SOFA max-SOFA min) of ASA III, IV group ( $r^2 = 0.59$ ,  $p < 0.01$ ). The minimum ApEn was correlated strongly with SOFA maximum ( $r^2 = 0.92$ ), SOFA discharge ( $r^2 = 0.89$ ),  $\Delta$ SOFA ( $r^2 = 0.73$ ) and length of stay ( $r^2 = 0.72$ ) in group 1 patients (ASA I,II,  $p < 0.01$ ).

### Conclusions

Our results suggest that the parallel increase of  $\alpha_2$  with  $\Delta$ SOFA in group 2 indicates persistent phenomena, where positive feedback mechanisms enhance the inflammatory response. ApEn, especially in group 2, is maybe altered in state of chronic pathology and use of medication. Its pre-terminal increase in surgical patients could be correlated with increased sympathetic tone and dynamic equilibrium (low  $\alpha_2$ ) before the onset of septic shock

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## A Novel wavelet-based Quantitative coronary analysis (QCA) Technique

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### Introduction

On-line QCA has been used predominantly for the selection of the optimal size for the interventional devices, and assessment of the effectiveness of the interventional procedure [1]. Severity of coronary diseases, the increasing number of people who are diagnosed with coronary disease, and the multiplicative rate of deaths due to coronary disease offer a motive and a challenge for introducing high quality QCA tools to enable both accurate detection of vessel's parameters and minimum variations among cardiologists. Therefore, several groups of research are working hard to provide an acceptable solution to the problem [2].

### Methods

In this paper, a novel wavelet-based edge detection algorithm for accurately identifying vessel boundaries and enhancing their centerline features is proposed. The algorithm is based on converting the x-ray image into wavelet space using an orthogonal mother wavelet. The image is decomposed into three levels. The low frequency version of the wavelet space (approximation) is processed by a bank of Canny filters that have different resolutions. These filters are convolved with approximation in order to obtain an edge image. Each filter will give maximum response to the segment of vessel having the same spatial resolution as the filter. The resulting responses across filters of different resolutions are combined to create an edge map for edge optimization. Boundaries of vessels are represented by edge-lines and are optimized on filter outputs with dynamic programming. The determined edge-lines are used to create an approximate-vessel centerline. The centerline is used for further improving the edge locations. Higher frequency images are added respectively, and previous procedure is repeated. If new edge-locations are a way from the approximated ones, the new locations are considered spurious and not included. Otherwise, further improvements on the edge map and centerline will be achieved. The final centerline is then used to compute percent-diameter stenosis and coronary lesions. The system has been validated using synthetic images, flexible tube phantoms, and real angiograms. It has also been tested on coronary lesions with independent operators for inter-operator and intra-operator variability and reproducibility.

### Results:

The validation of this approach is conducted through synthetic images, modeled phantoms, and real x-ray angiograms. The results show that the accuracies obtained are 0.070 pixels, 0.0102 mm, and 0.04 mm respectively, and the precisions obtained are 0.1212 pixels, 0.0215 mm, and 0.03 mm respectively.

### Conclusions:

A novel QCA approach is proposed that is found to be accurate, precise, reliable, reproducible, and adaptable when compared with recently published works.

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## A cognitive process model for decision making in anaesthesia

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### Introduction

To support decision making in anaesthesia it is necessary to have a general cognitive process model of the decision making tasks of the anaesthesiologist. Decision making in anaesthesia differs from general decision making in medicine. Anaesthesiologists are confronted with many highly coupled sub-systems, large problem spaces, mediated interaction as the patients' state must be observed via monitoring devices, and a high degree of potential hazard (the life of the patient) under enormous time pressure. We focus on per-operative tasks between intubation and extubation, and distinguish between maintenance and repair tasks in order to identify and support different cognitive processes.

### Methods

In 2001, we introduced our first model of the per-operative task of the Anaesthesiologist [1]. Extending this model with the results of our survey [2] and Klein's theory of the Recognition-Primed Decision model [3], we developed a descriptive cognitive process model for decision making in anaesthesia.

### Results

Most events are expected during maintenance. This induces low cognitive workload and sometimes decreasing vigilance. Repair tasks, however, are triggered by an unexpected change of the patient's variable values which increase the cognitive demands laid upon the anaesthesiologist. Our process model introduces three levels that determine cognitive behaviour during repair tasks: Familiarity, Urgency and Diagnosing.

The level with the lowest cognitive workload for the anaesthesiologist is **Familiarity**. He compares the real time patient data with her/his own mental database to find out whether this special configuration of patient data is familiar to her/him. If it is familiar s/he will opt for the typical treatment for the diagnosis s/he found.

If the setting is not familiar to her/him s/he has to decide how urgent the problem of the patient is, e.g. how life threatening this situation is for the patient. In **Urgency**, when time for proper diagnosing lacks, s/he will apply symptom treatment following e.g. the rule "treat first what kills first". This level requires more active attention and more cognitive resources.

If the situation is not too dangerous for the patient an extensive process of **Diagnosing** starts. This leads to a very high cognitive workload of the Anaesthesiologist. All the real time patient data, the anaesthesiologist's mental database and her/his personal strategy as well as general constraints are used for diagnosing and finding a "diagnosed treatment". After the treatment the patient's variable values have to be observed. If the value (trend) is acceptable, the anaesthesiologist goes back to the maintenance task. Else s/he has to go back to the beginning of the repair task. See Figure 1.

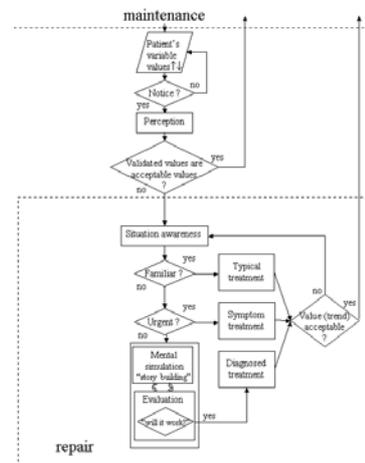


Fig. 1: Descriptive Cognitive Process Model

### Conclusion

A cognitive process model can only sketch the work of anaesthesiologists. However, in order to improve the health, safety and productivity in the OR, we are now able to show where Decision Support can be most useful. Furthermore our model differentiates between behaviours of novice and expert anaesthesiologists, and also according to their mental state e.g. being fatigue and personal strategies. It also shows that a life threatening situation of the patient does not always lead to cognitive stress of the anaesthesiologist.

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## Intravascular Pressure Monitoring System

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### Introduction

Monitoring of blood pressure and pulse rate offers diagnostical and therapeutical opportunities in hypertension disease and arrhythmia. A transponder-based intravascular pressure monitoring system is presented consisting of an implantable silicone capsule, which can be placed in the arterial system via a guiding catheter.

### Methods

The silicone capsule (diameter 2.6 mm) contains a dedicated microchip with pressure sensors and signal conditioning circuits, and an antenna for wireless data and energy transfer using 6,78 MHz transponder technology. Three self-expanding legs at one end of the capsule serve as a locking mechanism at an arterial branching. A silicone flow model of an arterial vessel system, driven by a ventricular assist system, was used for testing and optimization of the implantation equipment, tests of the anchoring mechanism and of pressure detection and transmission to the readout unit.

### Results

Flow model tests revealed a maximum deviation of pressure and heart rate measurement of 5% compared to the reference. Signal transmission was reliable over a distance of 3-4 cm. The sampling rate of 10 ms was sufficient to determine systolic and diastolic pressure.

### Conclusions

The proof of principle of a micro transponder capsule for measuring intravascularly pressure and pulse-rate was carried out. With respect to a future clinical application, further refinements of the transmission technology are necessary to extend the transmission distance between capsule and reader antenna. The technology of the intelligent implant investigated in this study has further implications, as monitoring of other physiological parameters, as well as the design of a control loop, which may be used for therapeutic options.

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## A new type of pulse oxymetry with integrated carbon dioxide sensor for respiration monitoring

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### Introduction

Assessment of arterial carbon dioxide (PaCO<sub>2</sub>) and oxygen saturation (SaO<sub>2</sub>) is essential to monitor critically ill patients. The “gold standard” in monitoring requires repetitive arterial blood gas punctions which are inconvenient and painful for the patient. A simple non-invasive technique for combined blood gas measurements of PaCO<sub>2</sub> and SaO<sub>2</sub> would be desirable. Therefore, the purpose of the study was to evaluate accuracy of a combined heated sensor placed at the ear lobe (Tosca, Linde Medical Sensors) for monitoring PtcCO<sub>2</sub> and SpO<sub>2</sub>.

### Methods

The novel sensor comprises an electrochemical Stow-Severinghaus type carbon dioxide electrode and an optical pulse oxymetry sensor. The sensor is heated to 42 °C to create local arterialisation. In 18 critically ill patients (63±14 years) we compared PtcCO<sub>2</sub> and SpO<sub>2</sub> measured by the novel device to values from blood gas samples (PaCO<sub>2</sub>) and co-oxymetry (SaO<sub>2</sub>). The monitoring extended over 3 to 4 hours in each patient. Since SpO<sub>2</sub> in patients had to be kept above 90% oxymetry of Tosca was further evaluated in 12 patients with sleep apnea syndrome (57±8 years). In these patients SpO<sub>2</sub> sampled by Tosca was compared to values of commercially available pulse oxymeters.

### Results

PaCO<sub>2</sub> in 3-6 arterial blood gas samples per patient ranged from 25-59mmHg. The bias and limits of agreement (LA = ±2SD) of PtcCO<sub>2</sub> compared to direct measurement of PaCO<sub>2</sub> were +3 ±7mmHg (n=80, p<0.05). Changes in PaCO<sub>2</sub> were estimated by Tosca with a bias ± LA of 0± 8mmHg. Comparative measurements to co-oxymetry in critically ill patients revealed a bias ± LA of -1% ±4%. In patients with sleep apnea syndrome the detection of desaturations >4% and the rate of its changes was significantly higher with the Tosca sensor compared to various pulse oxymeters.

### Conclusion

Our data suggest that the novel sensor accurately estimates arterial oxygen saturation, carbon dioxide tension, and its changes. It may be useful for monitoring critically ill patients and patients with sleep disordered breathing.



## Noninvasive Cardiac Output Measurement by Partial CO<sub>2</sub> Rebreathing

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### Introduction

Conventional partial CO<sub>2</sub> rebreathing methods for measuring cardiac output assume that the amount of CO<sub>2</sub> removed from pulmonary blood in the lungs can be measured at the mouth. Because of the effects of the CO<sub>2</sub> stores in the lungs, this assumption only holds if the rebreathing and post-rebreathing recovery periods are sufficiently long to allow establishment of steady-state conditions. We have developed a novel method that allows compensation for the effects of CO<sub>2</sub> stores. Using a mathematical model of the lung, the new method allows estimation of CO<sub>2</sub> excretion at the alveolar level from signal measured at the mouth. Cardiac output can then be estimated using the slope of the linear regression between end-tidal CO<sub>2</sub> concentrations and alveolar CO<sub>2</sub> excretion. The size of the model's lung CO<sub>2</sub> stores is selected to optimize the linear relationship between estimated alveolar CO<sub>2</sub> excretion and end-tidal CO<sub>2</sub> concentrations. We have studied the cardiac output estimation performance in animal experiments and in ICU patients.

### Methods

**Animal Study:** Using a IACUC approved protocol, anesthesia was induced in five mongrel dogs (26-42kg). The dogs were intubated, mechanically ventilated, and anesthetized using halothane or isoflurane. Cardiac output was changed with dobutamine, halothane, or xylazine. Thermodilution (TD) cardiac output was measured every 10 minutes (3 boluses of 10mL iced injectate). **ICU Study:** Following informed consent, the new method was evaluated in ten ICU patients recovering from thoracic surgery. Periodic TD cardiac output measurements were made in triplicate using boluses of 10mL room temperature saline. In both studies a NICO<sub>2</sub> monitor (Respironics-Novametrix, Pittsburgh, PA) was set to provide continuous rebreathing cycles (30sec rebreathing followed by 30sec recovery). Respiratory data were processed using the model-based method described above. Each average TD measurement was compared against the NICO<sub>2</sub> cycle immediately following the injections. Comparisons were evaluated using Bland-Altman statistics.

### Results

**Animal study:** Compared to TD, the new method gave a bias of -0.059 L/min with a standard deviation of the difference of 0.58 L/min and a correlation coefficient of  $r=0.966$  ( $n=96$ ).

**ICU Study:** Results showed a bias of -0.11 L/min and a standard deviation of the difference of 0.72 L/min ( $n=53$ ).

### Conclusions

The cardiac output estimation performance observed in this study is comparable to the performance of conventional partial CO<sub>2</sub> methods that use considerably longer rebreathing cycles. By not requiring steady-state conditions the new method allows shorter and more frequent measurements that are less sensitive to respiratory noise. This may offer the possibility of automated partial CO<sub>2</sub> rebreathing cardiac output in spontaneously breathing subjects.



## Volumetric Capnography – The Next Advance in CO<sub>2</sub> Monitoring

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Current trends in monitoring and patient safety are leading to the adoption of capnography as a standard of care in many clinical environments and the recognition of the importance of volumetric capnography in these same environments. The history of the development of instruments for the measurement of respired carbon dioxide concentration has been closely tied with the development of devices for ventilation monitoring. Investigators have recognized that to properly interpret the carbon dioxide curves it is essential to have available flow/volume waveforms as well. Within the last decade the clinical utility of time based capnography (i.e. end-tidal CO<sub>2</sub> monitoring) and volumetric capnography have found widespread recognition. Medical societies representing anesthesiology, cardiology, critical care, pediatrics, respiratory therapy, emergency medicine and other organizations have either mandated or strongly recommended the use of capnography for patient monitoring during general anesthesia, conscious sedation, resuscitation, intubation, weaning, transport and a variety of other procedures.

Combined monitoring of carbon dioxide and expired volume is increasingly being recognized as an important monitoring and diagnostic tool in a number of areas including airway management (endotracheal tube management, feeding tube placement), ventilator management, intraoperative assessment, patient transport, cardiopulmonary resuscitation and pulmonary embolism management. Since the lung is considered a volume-based organ, volumetric capnography provides a clearer and more comprehensive picture of the patient than a single point measure of the patient such as PetCO<sub>2</sub>. With the availability of integrated gas and flow sensors, well-known physiological measures such as CO<sub>2</sub> elimination, alveolar and physiologic dead space ratios and rates of emptying are finding greater use at the bedside. Together, the measurements derived from flow and CO<sub>2</sub> and flow and airway pressure (respiratory mechanics) allow a comprehensive clinical and physiological assessment of the patient's cardiorespiratory status. The better understanding of respiratory physiology and related disease processes that volumetric capnography can help provide is only now beginning to be realized.

### References

- [1.] *Michael B Jaffe*, Advanced Technology Projects Manager at Respironics Novamatrix LLC, received the B.S. degree from the Cooper Union for the Advancement of Science and Art, New York in 1979, the M.S. degree from Dartmouth College in 1982 and the Ph.D. degree in Biomedical Engineering from the University of Southern California in 1994. He currently is serving as a co-editor of multi-contributor clinically oriented text on time and volumetric capnography (in preparation) that is expected to be published in late 2004 and on international standards committees relating to anesthesia and respiratory equipment.



## Information Desing in Patient Monitoring

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### Introduction

Conventional displays used in patient monitoring up-to-now visualize medical data with numerical and waveform representations. The introduction of more and more parameters, longer periods of monitoring time (e.g. by including pre- and postoperative stages), the need of more timely decision-making induced by e.g. high potency drugs yield a higher complexity of visualized medical data on the monitor. Various studies on human factor errors in anaesthesia indicate that the conventional display format is not able to cope with this complexity in an ergonomic way (see e.g. [1]).

### Methods and results

Modern graphical systems deliver many design options that have not been exploited up-to-now. These include techniques as animation, transparency, colour runs, or blurring. New coding schemes of medical data to visual variables and attributes could be used. Emerging theories and design methodologies (e.g. ecological interface design) allow for a systematic development towards ergonomic displays coping with high complexities.

Studies with patient monitoring displays based on such principles showed that these new displays can improve situation awareness and support a faster detection of evolving critical incidents (see e.g. [2, 3]). But these results only hold for certain situations. In some other test scenarios, no performance differences could be found in comparison to conventional displays. Hence, the tested displays did not improve situation awareness in all circumstances.

### Conclusion

Some constraints and approaches for further research and development can be derived:

- Anaesthesia simulation seems to establish itself as a method to conduct controlled experiments with new display types.
- Effectiveness of the visualization is measured by testing situation awareness and time to detect (simulated) critical events.
- Information architectures and visualizations coping with the complexity of pre-, peri-, and postoperative patient monitoring should follow the basic design principle of overview first, zoom in, and details on demand. This will result in more integrated displays and display hierarchies besides conventional display formats.
- Since coding of medical data to visual variables and attributes has to change slowly in order to be accepted by the intended users, new display types must evolve from conventional monitors by adding new features step by step.

### References

- [1] Walsh T., Beatty P.C.W.: Human factors error and patient monitoring, *Physiol. Meas.* 23 (2002): R111-R132
- [2] Bermudez J. et al.: Data representation architecture: Visualization design methods, theory and technology applied to anaesthesiology, *ADADIA 2000: Eternity, Infinity and Virtuality*: 91-102
- [3] Jungk A., Thull B., Hoefft A., Rau G.: Evaluation of two new ecological interface approaches for the anaesthesia workplace, *J. Clin. Monit.* 2000 (16): 243-258

## Networked Thinking and Analysis of the future context of use –tools for the design of Context Determined Auditory Alarm Systems (CDAAS)

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### Introduction

The detection of critical situations by clinical experts depends on a number of influencing factors such as staff qualification, features of technical devices and, the task itself. The design of context determined auditory alarm systems (CDAAS) requires a proper estimate of future work systems context of use as well as knowledge about precise scenarios of relevant applications.

### Method

As methodological approach for designing CDAAS a combination of methods, such as Networked Thinking, Delphi and scenario- based Design was applied. This presentation focuses on the results of a three round Delphi Study, accomplished in 2002. The Delphi was a postal survey of 312 international experts (chiefs of surgical ICU's, chiefs of nursing services, representatives of Health Technology Industries). In the first round 51 experts provided feedback, in the second round 31 and in the third 24. The questionnaire was developed on the basis of networked thinking results by the Monitor Group (experts of: intensive care medicine, administration, medical technology development/sales).

### Results

The main results of the study might be summarized as follows: There is a trend to anticipate organizational changes in the near future (till 2005), especially changes in staff qualification. Technological changes, such as unification and networking of medical devices are predicted for farther future (till 2010). German and non German participants valued similar. Only four items show different trends (cp. chart1). The analysis of the free answers show, that major effort are required in following fields: standardization of work processes and information flow, new financing concepts and a better co-operation between industry and the health-care system.

		Time of probable realization					
		never	today until 2003	until 2005	until 2010	until 2015	> 2015
Standardized workplaces with a standardized alarm concept are common in every surgical ICU.	G	0%	0,75 1 1,25	1,75 2 2,25	2,75 3 3,25	3,75 4 4,25	4,75 5
	NG	4,3%		1,75 2 2,25	2,75 3 3,25	3,75 4 4,25	4,75 5
Physicians and nurses are working together as a team with shared tasks, but without any hierarchy.	G	30%	0,75 1 1,25	1,75 2 2,25	2,75 3 3,25	3,75 4 4,25	4,75 5
	NG	15%		1,75 2 2,25	2,75 3 3,25	3,75 4 4,25	4,75 5
The integration of every medical device is possible without any restriction of manufacturers.	G	4,3%	0,75 1 1,25	1,75 2 2,25	2,75 3 3,25	3,75 4 4,25	4,75 5
	NG	4,3%		1,75 2 2,25	2,75 3 3,25	3,75 4 4,25	4,75 5
"Plug and Play" of medical devices is a standard.	G	0%	0,75 1 1,25	1,75 2 2,25	2,75 3 3,25	3,75 4 4,25	4,75 5
	NG	0%		1,75 2 2,25	2,75 3 3,25	3,75 4 4,25	4,75 5

**chart1:** significant national distinctions in expected time of realization, 1.- 3. Quartil, Median; G-german, NG- non german participants

### Conclusion

The results of Delphi help to estimate changes in future context of use and provide the frame work for the scenario- based design approach proposed. Parts of the new draft standard – Medical electrical equipment- [1], will be incorporated.

### References

- [1.] (Draft standard) DIN EN 60601-1-8, Publication date:2003-02 Medical electrical equipment - Part 1-8: General requirements for safety; Collateral Standard: Alarm systems; Requirements, tests and guidelines; General requirements and guidelines for alarm systems in medical electrical equipment and in medical electrical systems (IEC 62A/397/CDV:2002); German version prEN 60601-1-8:2002



## **A Comprehensive Display concept for an Integrated Anesthesia Workplace**

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## An Object Oriented Graphic Display of Physiologic Data alters Decision Making Following an ICU Alarm

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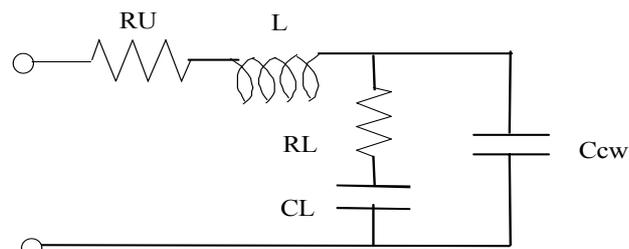
The development of an object oriented display of pulmonary physiology began with user questionnaires that identified seven primary respiratory variables used to assess a patient's pulmonary state. We used the linear, lumped, electrical model shown in Figure 1 to transform the patient variables generally monitored into the primary variables needed for clinical diagnosis. The model's parameters are identified in real time by adapting the parameter values to find the best fit between the model-predicted and measured pressure and flow waveforms in the frequency domain.

We developed the pulmonary display design shown in Figure 2 as a means of presenting the seven primary respiratory variables to the clinician. Five design iterations were needed to develop an intuitive display. The display has emergent features that highlight abnormal pulmonary physiology and reference frames that surround each feature defining normal pulmonary physiology.

Nineteen anesthesiologists participated in a simulator-based evaluation. The average time to begin treatment of an obstructed upper airway was 1.6 minutes shorter for the subjects that used the pulmonary display ( $p < 0.02$ ). Subjects who used the display reported a decrease in temporal demand, effort, and frustration level. Post-simulation interviews revealed that clinicians felt the display helped them to perform their anesthesia tasks.

We studied 20 ventilator dependent patients for 12 hours each in the Medical Intensive Care Unit (MICU). The display was placed at the bedside next to the ventilator for half the patients. We used the sounding of an alarm to trigger a data collection event. A study investigator continuously observed and recorded actions taken by the ICU nurse when an alarm sounded. If the nurse was outside the patient's room, action was taken in response to only 4% of the alarms. When the nurse was in the patient's room, action was taken 48% of the time. The presence of the display resulted in a more appropriate response to alarms, as measured by a reduction in upper airway resistance with airway suctioning.

Hospital patients are at risk when life-threatening events are not corrected quickly. Graphic displays have been shown to reduce event detection time, increase the accuracy of diagnosis, and to improve the efficacy of treatment.



$R_U$ : air flow resistance of the upper generation airways + air flow resistance of the endotracheal tube.

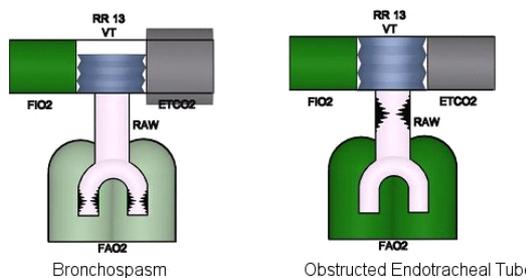
$R_L$ : air flow resistance of the lower generation airways + lung tissue resistance

$C_L$ : compliance of the airways of lower generations + compressibility of the gas

$C_{cw}$ : compliance of the chest wall

**Figure 1:** A linear lumped electrical model describing the mechanics of the pulmonary system.

1.6 minutes shorter for the subjects that



**Figure 2:** The emergent feature pulmonary display. **Left:** the triangular shaped set of black lines in the lower airway, decreased tidal volume, and increased end-tidal CO2 indicate bronchospasm. **Right:** the triangular shaped set of black lines in the upper airway indicate an obstruction in the patient's endotracheal tube.



## **Technical Applications Aspects of Head Mounted Displays in Surgery**

*O. Hellwich*

*Photogrammetrie & Kartographie at the Technical University of Berlin*

The presentation describes various augmented reality technologies for the use in surgery. The idea behind an augmented reality system is that real pictures are completed by additional information which is inaccessible to the human eye. Augmented Reality therefore represents the connection between real and virtual, invisible world. The calibration of the technical instruments (like camera, head mounted display) and the transfer of all involved coordinate systems are necessary for this purpose. The mathematical model, the software used and the utilised hardware including different kinds of head-mounted displays are introduced. First test results will be presented and judged regarding their accuracy.



## Combining static and hand-held information systems for multi-centre neurosurgical intensive care audit and research

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In order to improve the management of head injury patients in neurosurgical intensive care units, it is essential that such units have the capability to capture and share detailed clinical information about the treatment of these patients. However, there is very wide variation in the information processing systems and practices in European neurosurgical ITUs. Many units use essentially paper-based records. Even those with computerised information systems (commercial or academic) find it difficult to share clinical information. **BrainIT** is a 3-year, €2million EU-funded project which started in early 2003. (<http://www.brainit.org/>).[1] The chief goals of the project are:

1. capture very detailed clinical information about the management of a large set of head injury patients in neurosurgical intensive care units (ITUs) across Europe, using a standard dataset
2. pool this information in a central database
3. provide controlled web access to the central database for international neurosurgical critical care research

Thirty neurosurgical ITUs are participating in the project, from the following EU countries: Belgium, Czech Republic, Denmark, England, France, Germany, Italy, Lithuania, Netherlands, Romania, Scotland, Spain, Sweden, Switzerland. Essentially the project will focus on two types of information, using a combination of two different information system types. Time series parameter data (such as heart rate, blood pressure, intra-cranial pressure) will be collected directly from monitors to static repositories. All other data, including history details, and information about investigations, clinical observations, treatments and outcome, will be collected using a specially designed advanced hand-held mobile workstation, fully translated into 8 different languages. The workstation can send data represented in XML to a local server, using either wired or wireless communications. At the local server the records can be viewed, then automatically anonymised, translated and exported to a central database in Glasgow.

We believe this approach combining the use of static and hand-held systems provides a solution which satisfies the needs of the project in supporting detailed clinical data capture in a wide variety of neurosurgical ITUs, whilst being affordable, easy to install, and easy to use for busy nurses and medical staff. The use of hand-held systems in anaesthesia and intensive care generally is still in its infancy. However hand-held technologies (hardware, software and communications) are advancing rapidly, and these platforms have enormous potential in healthcare. The presentation will include a demonstration of some components of the BrainIT information system.

### References

- [1.] Piper I, Citerio C, Chambers I et al. The BrainIT Group: Concept and Core Dataset Definition. *Acta Neurochirurgica* (IN PRESS) 2003.



## High Resolution Trends and Clinical Events Analysis Going beyond Basic Bedside Patient Monitoring

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### Introduction

The **High Resolution Trends** are a display representation of measurements shown as synchronized high resolution waves on a monitor display. The **Event Analysis** allows the clinician to define event criteria to capture clinically relevant events, to review, annotate and document them.

### Method

The classic oxyCRG is a dedicated display representation showing up btbHR, SpO<sub>2</sub> and compressed Respiration wave as a 6min trace on a patient monitor display. It is useful in neonatal monitoring as it correlates HR, SpO<sub>2</sub> and Respiration allowing to visualize Bradycardia, Desaturation, Apnea conditions and combinations of them. The **High Resolution Trends** are a generalization of the oxyCRG allowing the user to choose from a list the measurements to be displayed as High Resolution Trends. Correlating e.g. HR/Pulse, Arterial Pressure, SpO<sub>2</sub>, CO<sub>2</sub> or BIS in a continuous High Resolution Trend Display gives the clinician better indication about fast changes in the patient's status.

The **Event Analysis** allows the clinician to define event parameters and event conditions/trigger rules on which he wants to store the episode around the event. (e.g. HR, SpO<sub>2</sub>, Resp and CO<sub>2</sub> as event parameters and Apnea alarm as event trigger for Respiration and CO<sub>2</sub>). An episode is captured for each event (e.g. 4min of High Resolution Trends or 20min Average Trends or 15sec Real-time wave snippets around the event). The episode gives the clinician information on the development of the event, the sequence of event conditions and the recovery of the event.



### Results

The Event analysis of neonatal events was introduced several years ago in our patient monitors. The new generation of patient monitors extends the event analysis to cover also other application areas (like adult ICU, CCU and Neuro ICUs). The Event Analysis assists the clinician to capture those situations, where critical events may develop and to review the event episodes for decision support on further therapy or medication.

## Data Display Technology as a Partner in Clinical Decision Making

*D. Westenskow & N. Syroid & F. Sakaguchi & J. Agutter & T. Egan & F. Drews*

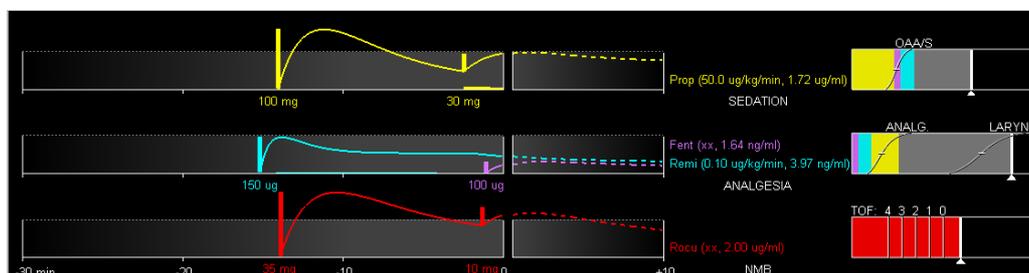
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### Introduction

Clinicians titrate drugs to achieve desired clinical effects: unconsciousness, stable hemodynamics and adequate analgesia. Because clinicians are unable to measure directly the concentrations of drugs in tissues, they must use indirect measures of clinical effect, such as blood pressure and heart rate. Control theory holds that the absence of direct feedback makes a control task difficult and increases the likelihood of human error. Pharmacologic models give reasonably accurate predictions of drug concentrations and drug effects and can help control drug delivery.

### Methods

We developed a display to visualize the pharmacology of the drugs given to a patient. The display uses pharmacokinetic ( $P_K$ ) and pharmacodynamic ( $P_D$ ) algorithms to predict drug effects. Drug doses are translated into drug concentrations and linked to drug effects. We used the models with 24 patients undergoing abdominal laparoscopic surgery under total intravenous anesthesia with propofol and remifentanyl. Drug infusion rates, blood pressure, heart rate, and EEG bispectral index were digitally acquired. A clinical observer assessed the inadequacy of anesthesia by patient movement or a 20% increase in heart rate during painful phases of surgery (e.g., tracheal intubation, skin incision). The model accurately predicted loss of consciousness, return of consciousness and response to painful procedures.



**Real-time Graphical Presentation of Drug Kinetics and Dynamics**

A study was conducted in a high-fidelity anesthesia simulator with 24 anesthesiologists. One-half of the subjects used the drug display. Subjects induced anesthesia, intubated the patient's trachea, cared for the simulated patient throughout a simulated shoulder surgery, and then awoke and extubated the patient following skin closure.

### Results

Subjects who used the display managed drug delivery more effectively by keeping heart rate and blood pressure closer to normal: reducing the rise in heart rate and blood pressure associated with painful surgical manipulations and the fall in heart rate and blood pressure associated with drug overdose. The simulated patients woke-up faster ( $4.5 \pm 3.3$  versus  $7.5 \pm 2.1$  minutes) without hemodynamic complications. Participants who used the display reported a decrease in mental demand, effort, and frustration with an increase in perceived performance.

### Conclusions

Pharmacologic modeling has been successfully incorporated into a display to support drug management in the operating room. Clinical studies indicate that the  $P_K P_D$  models adequately predict the physiologic effects of intravenous anesthetics. Simulations studies show that the drug display is an aid to clinical decision making.

## Workshop: Agent Based Information Logistics (AGIL<sup>2</sup>)

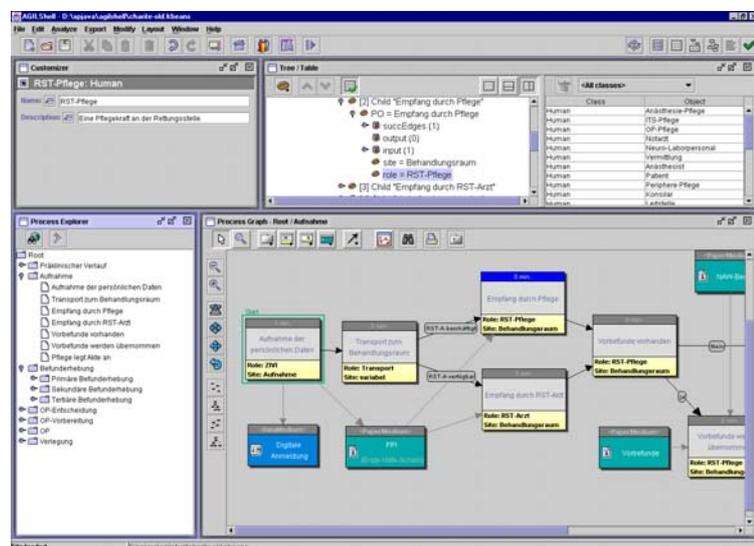
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Clinical care is characterised by the distribution of data among personnel, locations, and various types of media. Clinical information systems (CIS) should provide help in collecting, preparing and presenting data. The dispersal of information surfaces as a problem in clinical information systems in particular when decisions have to be made with emergency patients.

The primary goal of AGIL is to develop a multi-agent system that supports the clinical information flow. The secondary goal is to explore and generalize an agile development methodology for such multi-agent systems. We acquired a semi-formal model of the existing clinical processes and potential agent application scenarios resulting in an “agentified” process.

Agents have a huge potential to support clinical decision making by their ability to provide intelligent and proactive services within a distributed environment. In the clinical information space, autonomous agents can proactively collect, integrate and analyze the relevant patient data, and condense and communicate the most relevant information to the responsible decision makers. Compared to conventional (client – server) architectures, agents represent a more natural mapping of the clinical distribution.



In AGIL<sup>2</sup>, we acquired a semi-formal model of the existing clinical processes. This model could be used to identify information bottlenecks and potential agent application scenarios. Based on the existing process, we designed in collaboration between engineers and clinical experts an “agentified” process, in which agents fulfil tasks like operating theatre management, notification services, and patient tracking. Using the AGILShell editor (screenshot), the framework of the final information system will be automatically generated.

The modularity of agents allows one to customise a clinical information infrastructure to a hospital’s individual requirements and prerequisites. Existing agents like those for real-time monitoring, for patient scheduling, and context-aware, proactive clinical user interfaces can be reused. Furthermore, the designs of typical agent application scenarios can be reused, since recurring patterns can be identified among different hospitals. Multi-agent systems are inherently distributed and decoupled, so that the overall system remains functional even if single agents fail. The co-ordination mechanisms found in multi-agent systems offer high flexibility, e.g. when unexpected emergency patients need to be treated.



## Workshop: Telemedicine

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Telemetric surveillance of vital functions and other physiologic parameters increasingly enables a variety of caregivers to improve medical support for the patient and, simultaneously, to reduce costs. Consequently, the duration of hospital stay of patients at risk can be reduced by means of mobile extra-clinical monitoring, furthermore, pathologic patterns that appear irregularly and/or are very rare are detected immediately. This also includes numerous advantages for chronically ill patients. First, it does support temporal optimization and diagnostic-therapeutic process optimization. Pro-active integration of the patient increases his motivation and compliance complementarily. Mainly therefore, we expect that telemonitoring (and teletherapy) will become much more important during the next years.

The Personal Health Monitoring (PHMon) research project aims at improving patient care and at the same time at reducing costs by combining micro-technological smart sensors with personalized, mobile computing systems. With this project, we are developing a generic platform for mobile telemedical applications. Basically, it consists of wearable, external sensors (or an array of sensors) with integrated signal processing and communication abilities, where a personal digital assistant (PDA) acts as mobile base station and a Bluetooth-enabled mobile phone allows for Internet connection. This Internet connection is used to instantaneously and directly transmit vital signs monitoring data into a web-based electronic patient record (EPR).

All data are transferred into a relational data base except of the XML formatted measuring data which are stored separately. Client access is realized via Java Server Pages and servlets (which are capable of accessing the JDBC API) with Tomcat as servlet container.

Communication is an important component in developing the personal health monitoring system. The widespread availability of wireless cellular networks provides a meaningful platform for mobile telemetry applications. Employing Bluetooth technology, embedded vital sensors can easily access mobile phone networks with low or even minimal performance and power requirements.

The base station is acting as user-interface and as a communication gateway. Simultaneously, it provides for rapid data analysis, alerting the patient in case monitoring parameters move beyond acceptable limits. In order to improve the interfacing of sensors, actors, and the EPR, the further development will combine the mobile phone and the PDA into a smartphone.

To date a demonstrator has been developed to evaluate manifold aspects of the concept underlying the personal health monitoring system. Implementing an initial scenario, we utilized a wearable multi-channel ECG-sensor, a weight scale, and a novel device for non-invasive and continuous blood pressure measurement as prototype sensors. This sensor profile was selected to monitor patients suffering from cardiac or cardiovascular diseases, since the remote monitoring of vital parameters is capable of improving the diagnostic-therapeutic process, and more importantly, allows for early recognition of adverse drug effects etc. All sensors come along with a Bluetooth interface for wireless transmission of medical and administrative data to the PDA.

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