# Framework for Biosignal Interpretation in Intensive Care and Anesthesia

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Abstract **Improved monitoring improves outcomes of care. As critical care is 'critical', everything that can be done to detect and prevent complications as early as possible benefits the patient. In spite of major efforts by the research community to develop and apply sophisticated biosignal interpretation methods (BSI), the uptake of the results by industry has been poor. Consequently the BSI methods used in clinical routine are fairly simple. This paper postulates that the main reason for the poor uptake is the insufficient bridging between the actors (i.e. clinicians, industry and research). This makes it difficult for the BSI developers to understand what can be implemented into commercial systems and what will be accepted by clinicians as routine tools. A framework is suggested that enables improved interaction and cooperation between the actors. This framework is based on the emerging commercial patient monitoring and data management platforms which can be shared and utilized by all concerned from research to development and finally to clinical evaluation.**

Keywords: Biosignal Interpretation, Framework for BSI, Intensive Care, Anesthesia

## 1 Critical Care and BSI

Intensive care aims at normalizing the vital functions of the patient. Patient status is assessed continuously and treatment plans with goals are generated and updated based on that. Anesthesia in addition to providing the necessary sedation for the surgical procedure aims at maintaining body functions at a normal level and avoiding complications whereas in intensive care patients 'by default' already have complications.

The uniting features of these two domains are the cycle *'assess - plan - execute - evaluate'* and the need to monitor the progress in patient state. Monitoring provides data which when interpreted in its context gives information on what the patient status is, how the status is changing and whether these changes are as anticipated (i.e. in accordance with the goals of the current treatment plan) or whether a reassessment is required and/or adjustment of the treatment plan (and goals).

Control theory concepts fit well into critical care. Control is exercised by clinicians, other clinical staff and the patient. Data of the patient (process) status is provided by visual observations and technical devices comprising monitors, diagnostic equipment (located e.g. in laboratories and X-ray departments), therapeutic instruments such as IV-pumps.

This model approach although simplistic[1] shows that there are three 'actors'; the patient, the diagnostic, therapeutic and monitoring devices and the clinical staff. The challenge is to divide optimally the patient management tasks and to provide smooth interfaces between actors. As technology is progressing the role of technical devices in intensive care and in anesthesia has evolved from simple monitors to monitoring systems and further to patient data management systems (PDMS) networked with other hospital information systems (e.g. laboratory and pharmacy). Although the main reason in the increasing utilization of monitoring devices has been to relieve the clinical staff from routine tasks at the same time the amount of data collected has increased exponentially and clinical staff is faced with an information overload in interpreting signs and symptoms.

Consequently, a drive towards a layered approach can be distinguished in patient monitoring products

- The ‘first line of defense’ is based on biosignal interpretation methods (BSI) in acquiring clean and reliable data and generating alarms e.g. on faulty transducers
- More sophisticated interpretation facilities are provided by BSI methods that are based on models of vital organs and the whole patient.

The first practical applications of such models were limit alarms. The next step of sophistication were trend displays enabling clinical staff to observe & detect trends.

## 2 BSI Framework

The BSI framework comprises the process of developing a new BSI method, the actors involved in the process, and the technical platform on which the process takes place.

[1] One must bear in mind that a human being (patient) is not a machine and therefore data derived from the patient is context sensitive in addition to possibly being erroneous and faulty.

### 2.1 *Development and evaluation of a BSI method*

Before a new BSI method can diffuse into clinical practice it must pass a development and evaluation process of several stages:

- The development of a BSI solution to an existing problem
- Demonstration that the method works in *laboratory conditions* with a limited patient sample.
- After feasibility has been demonstrated *verification* against a more comprehensive set of patient cases. This normally leads to changes in the method requiring a new verification cycle.
- Once the method has been "tuned" with the available patient cases *validation* against a new independent set of patient cases to rule out biases in performance. Unfortunately only a few such reference signal libraries are available.
- After validation the procedure in which the method is embedded must be *evaluated*. Typical questions for this stage comprise: will it improve diagnostic accuracy, can treatment plans be generated and executed with greater accuracy, will it reduce false positive alarms in monitoring tasks, what are the implications to manpower and other resource requirements, will it replace an existing procedure or is it new, is it effective, and do users accept it.

The value of the method must be proven not only in the technical dimension but also in the dimensions of clinical outcomes and resource utilization. In real life BSI methods are rarely evaluated as completely as suggested above. This explains why so few of the research prototypes end in being used in clinical routine. A proof of principle is far from convincing evidence that the innovation should diffuse into clinical routine.

After the BSI method has passed the tests of above still one important test remains: Can it be implemented (embedded) into a commercial product? Examples of conditions that need to be met include ‘it may not consume too much computing power', ‘it may not be too slow', 'it may not consume too much memory', and above all 'it must be robust and reliable'.

### 2.2 *Actors*

The development and evaluation stages require a skill mixture that cannot be supplied by one person only. In problem definition the clinical staff has the central role. The biomedical engineers act as the interface in interpreting these needs into technical solutions. Once a prototype exists clinical staff is needed to guide the improvement of it and later to carry out its proper evaluation. In addition to clinical expertise evaluation also requires other skills which are related to e.g. cost-effectiveness assessment. The final actor of the industry which implements the new methods into commercial products.

The key is that for a positive outcome the needs of all these actors must be accommodated to ascertain that their interaction runs smoothly and stays focused on the goals.

### 2.3 *BSI platform*

As monitoring technology has progressed a technical platform is emerging which is able to support all the tasks from development of a BSI method to its evaluation and implementation. The schematic structure of such a platform is illustrated in Figure 1. The way that R&D utilizes this is through the ‘Add-on appl’s’ which allows prototypes to be developed, tested and evaluated with real-life data and signals. In the European Community funded IMPROVE project we have been able to utilize one such existing system in problem definition, collection of a data and signal library, and finally in evaluating the methods in a real-life environment.

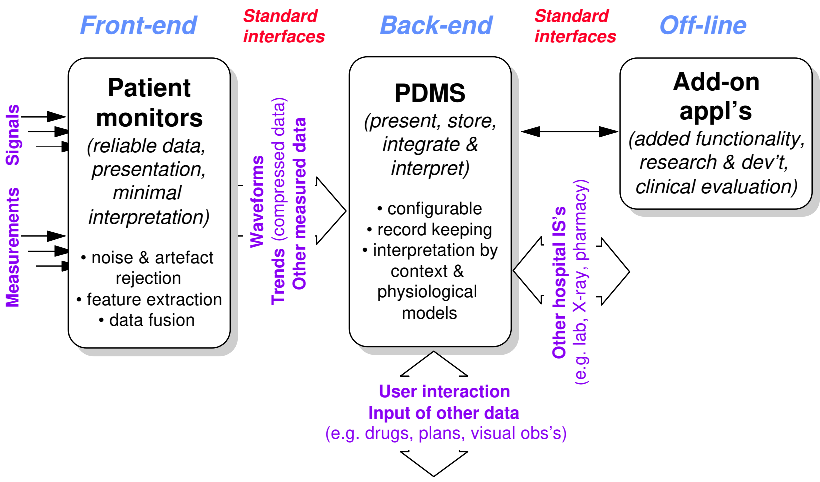


Figure 1. A schematic arrangement of functions in a future patient monitoring environment

## 3 State of the Art of Current BSI

### 3.1 *BSI in academic research*

Table 1 provides an indication of what BSI methods in signal acquisition, data processing, and information management have received most attention in the academic world in the last few years. It also assesses the ‘maturity’ of these techniques.

These include ‘traditional’ and well-established techniques like autoregressive modeling, ‘straightforward’ approaches like the use of FIR filters for artifact and noise removal from EEG signals, and techniques based on statistics such as the use of probability distributions for the removal of artifacts from auditory evoked potentials. Rule-based techniques have also been widely employed in a number of applications.

More novel signal analysis techniques that have potential in anesthesia and ICU comprise: multivariate modeling, which can account for interactions between signals of different origin; non-linear methods e.g. in the analysis of respiration; time-variant approaches, which are able to follow non-stationary signal changes; non-linear filters for preprocessing biosignals as an alternative to commonly used averaging filters that cannot adequately remove transients; and bispectral analysis of the EEG to predict patient movement in response to incision.

Artificial neural networks (ANN) are studied for a wide range of applications, just a few of the examples are: detecting clinically significant changes in haemodynamic variables, assessing the quality of blood pressure signals, detecting faults in breathing circuits, analyzing EEG to investigate the effects of anesthetics, and identifying features in auditory evoked potentials. Fuzzy logic techniques are investigated in the context of control tasks such as the administration of drugs for haemodynamic control. Other applications include the identification of peaks in brainstem auditory evoked potentials and a decision system for an alarm for cardiac anesthesia that produces patient-state variables such as blood volume, myocardial contractility, afterload, and anesthetic depth using haemodynamic data.

Another application field that has grown explosively in recent years concerns wavelet techniques. Examples include analyzing evoked potentials to detect ischemic neurological injury, recognizing cardiac patterns, analyzing pulmonary capillary pressure, and identifying characteristic points in ECG.

Examples of other, less frequently used, techniques include the use of genetic algorithms in closed-loop control and the use of chaos analysis to describe EEG.

Evaluation has mainly concentrated on the use of real data in an off-line (laboratory) situation and most systems have been built as proof-of-principle systems only. The number of systems that is actually evaluated clinically is extremely limited and no evaluations of the benefits of such systems for patient care exist. The lack of real clinical evaluation is very much due to the fact that virtually all systems are developed solely by academic researchers.

### *3.2 BSI in commercial products*

BSI methods that are used in commercial products are much more conservative as illustrated by Table 2. This reflects the real-life challenges of patient monitoring. Although in the main average values are used each patient is an individual. For instance a limit alarm for systolic blood pressure depends on the pathophysiological state of the patient, treatment goals, drugs, fluid balance etc. Methods must be reliable and robust for all patients not only for the average patient.

## 4 Discussion

It seems that although the framework as suggested above is at least implicitly understood it is not followed. The first problem it that of problem formulation. A lot of academic BSI research is technology driven 'what can I do with this technique'. Consequently, the emphasis is in the proof-of-principle stage and is not followed by the evaluation stages as suggested above.

The second problem centers around the lack of signals that can be used to develop and evaluate prototypes. Acquisition of comprehensive data of continuous and intermittent signals requires a large effort in terms of man power and also a serious commitment by the clinicians and the clinical staff. It is not enough the collect these signals they need also to be verified and annotated by the clinicians. In the IMPROVE project we have been able to collect such a large data library thanks to the enthusiasm of the project partners and the financial support of the European Union through the BIOMED-1 program.

The third problem deals with the overall evaluation of the impact of a new BSI method. How can it be implemented in a real-life environment without interruption and disturbance to patient care? The technical platform suggested in Figure 1 is the solution. It is possible to install the new set of methods on a separate PC, connect it to the patient monitoring environment and drive the new system in parallel with the existing one.

The final problem is one of exploitation. BSI research must be based on patient needs. In that respect user needs must be carefully assessed. Users in this case also include the manufacturing industry. Prototypes should been designed from the beginning to be implementable. Reverse-engineering is too expensive and time consuming.

## 5 Bridging the Gap

It seems that the propagation delay from research to products is at least 5-8 years. There is a lot of BSI research with potential but turning it into implementable results is a large effort. In doing so the need for the close interaction of the actors must be recognized.

The emerging technical platform enables these interactions and also allows a step further to really embark on research geared on data fusion. Since real-world problems usually involve a mixture of application fields, it may be expected that in solving such problems successfully also a mixture of techniques will have to be used.

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Table 1. BSI methods in the research stage

| Methods | Applications | Maturity | References |
|---|---|---|---|
| Autoregressive modeling | EEG analysis (assessment of anaesth. depth)<br>Ischaemia monitoring<br>Evoked potential analysis | Well established | [30; 10]<br>[6]<br>[15] |
| FIR filters | Artifact/noise removal from EEGs | Evaluated | [22] |
| Statistics (prob distrib) | Artifact removal from evoked potentials | Evaluated | [3] |
| Rule-base systems | Ventilator management<br>Patient monitoring<br>Evoked potential analysis<br>Appl's dealing with temporal aspects | Evaluated | [28; 24]<br>[17]<br>[7]<br>[5] |
| Multivariate modeling | Modeling of neural control mechanisms | Evaluated | [1] |
| Non-linear models | Interpretation of interactions of respiration | Evaluated | [16; 27] |
| Time-variant approaches | Detection of non-stationarities in signals | Evaluated | [4] |
| Non-linear filtering | Preprocessing of biosignals | Evaluated | [18] |
| Bispectral analysis | EEG analysis (predict patient response to incision) | Evaluated | [26] |
| Artificial neural networks | Detection of changes in haemodynamic variables<br>Assessment of quality of blood pressure curves<br>Fault detection in breathing circuits<br>EEG analysis (anesthetic depth)<br>Feature extraction in evoked potentials | Research (many applications but mostly 'proof of principle' studies only) | [8]<br>[21]<br>[19]<br>[25; 31]<br>[11] |
| Fuzzy logic | Control of drug administration<br>Feature extraction in evoked potentials<br>Decision system for alarms in anesthesia | Research | [33; 12]<br>[20]<br>[2] |
| Wavelet techniques | Evoked potential analysis (detection of ischaemic injury)<br>Recognition of cardiac patterns<br>Analysis of pulmonary capillary pressure<br>Identification of characteristic points in ECG signals | Research | [29]<br>[23]<br>[13]<br>[14] |
| Chaos analysis | Description of EEG signals | Experimental | [31; 9] |

Table 2. BSI methods implemented in commercial systems

| Methods | Task | Applications |
|---|---|---|
| Digital filters (FIR, IIR, median) | Filtering | Noise reduction of e.g. ECG and respiratory signals |
| Digital filters (median) | Artifact rejection | Peak rejection from SAP trend |
| Averaging | Stimulation | Averaging of evoked motor or cerebral responses |
| Data fusion | Feature extraction and detection | HR computed from ECG; if not possible, from SAP; if not possible from PAP;... |
| Physiological modeling | | Measurement of energy expenditure from respiratory gas measurements |
| Amplitude a/o Frequency analysis | | Detection of burst-suppression EEG power in frequency bands<br>Spectral edge frequency of EEG |
| Median filtering & downsampling | Information compression | Output of 10s. median values of monitored variables every 10s.<br>Storage of 120s median values of the monitor output every 120s. |
| Manual validation / data cleaning | | Storage of only those values validated by nurses |
| Limit alarms | Signal interpretation & alarming | Bradycardia alarm |
| Data fusion | | Detection of electrode disconnection<br>On-line measurement of electrode impedance |
| Scoring | | Automatic computation of APACHE or TISS scores |