in fault detection and diagnosis (FDD) in anaesthesia. It detects problems that can occur during anaesthesia by analysing physiological signals on-line. The advantage of this system over others is that it provides a measure of objectivity and vigilance. It uses a fuzzy time-domain pattern matching technique, termed fuzzy trend templates, to detect vaguely specified patterns in multiple physiological data streams. As an expert system, it incorporates the knowledge of many consultant anaesthetists. SENTINEL has achieved sensitivity and specificity accuracy above 90% in the diagnosis of seven common or serious conditions that can arise during anaesthesia.

Lowe and Harrison [19] developed a fuzzy logic based algorithm for detecting a rare pathological condition called malignant hyperpyrexia (MH). In this study, rule-based diagnoses were performed to detect the changes in the patterns of symptoms. In an offline validation of the algorithm, the system detected MH nine minutes before the anaesthetist diagnosed it. The work and its proven results show how expert systems can be implemented to facilitate and enhance anaesthetists' performance in the clinical environment, thus improving patient safety.

Esmaeili et al. [20] designed a fuzzy rule based system which integrates the features of an electroencephalogram (EEG) to quantitatively estimate the depth of anaesthesia. Reference data is divided into four well-defined anaesthetic states: awake, moderate anaesthesia, surgical anaesthesia, and isoelectric (deeply unconscious). Statistical analysis of features was used to design input membership functions (MFs). The training data was used in ANFIS to label the partitions and extract efficient fuzzy IF-THEN rules; the fuzzy rule-base index (FRI) is calibrated between 0 (isoelectric) and 100 (fully awake) using the fuzzy inference system (FIS) engine and designed output MFs. The main focus in this study was to simplify the mutual knowledge exchange between the human expert and the machine, and achieve enhancement of both the interpretability of the results and the performance of the system.

Mahfouf et al. [21] developed a Mamdani type of fuzzy model using anaesthetists' knowledge described by fuzzy IF-THEN rules. Clinical data were used to construct the patient model. An ANFIS was then used to train fuzzy Takagi–Sugeno–Kang (TSK) models so as to describe different signals. A stimulus model was used to establish the effects of surgical stimulus on HR and SAP according to the level of analgesia used to model different signals.

Harrison and Connor [22] developed an anaesthesia alarm system that detects the changes in

Systolic Arterial Pressure (SAP) and states that a decrease in SAP of 10 mmHg from a previous value of 70 mmHg has a greater clinical significance than a decrease of 10 mmHg from 150 mmHg. They processed SAP data to create a mathematically straightforward statistical tool for sampling intervals up to five minutes. Using Pythagoras's theorem, they combined the value for the standard deviation of SAP and the standard deviation of the change in SAP, so instead of alarms being set in mmHg, they would be set in standard deviations. This technique was developed further using Principal Component Analysis to isolate uncommon deviations from normal, clinically unimportant, physiological variations. This may turn out to be clinically useful.

Most of the reviewed expert systems demonstrated a significant improvement in diagnosis systems which can facilitate practitioners' performances in the clinical environment. However, using only off-line data with a set of conditions may cause some degradation and errors in these systems for on-line applications. Furthermore, due to their broad-spectrum application, these systems may generate lots of false alarms when dealing with a specific pathological event such as hypovolaemia.

Numerous intelligent techniques have been proposed in the past and some were employed for developing diagnostic alarm systems [23],[24],[25],[26]. Bhupendra et al. [27]developed the diagnostic system, Real Time – Smart Alarms for Anaesthesia Monitoring (RT-SAAM); it has two modules: probabilistic alarms (Probabilistic Module) and respiration-induced systolic pressure variations (SPV Module). The accuracy of the diagnostic results from RT-SAAM was analyzed using Kappa analysis. The results showed that the developed diagnostic system (RT-SAAM) is capable of diagnosing the pathological events with a moderate level of agreement between RT-SAAM and the anaesthetist.

The recent work in the fuzzy logic based approach shows rapid growth, such as; the work towards the classification of driver's drowsiness [28], underwater vehicle [29] and aircraft engine monitoring [30]. In patient monitoring using fuzzy logic [31]-[35], wireless [36],[37],[38], mobile [36],[39] and internet technologies [40].

2.3 Decision support systems in anaesthesia monitoring

Decision support systems (DSS) are an emerging and potentially beneficial technology that shows great promise for reducing medical errors and delivering improvements in the quality, safety, and

efficiency of health care. DSS are designed to integrate a patient monitoring information system: a computerised medical knowledge base and an inference engine to generate case-specific and situation-specific advice [41],[42].

These systems should also help the anaesthetists make decisions in complex situations where continuous monitoring of highly critical physiological parameters such as BP, HR, end-tidal carbon-dioxide (ETCO2), and PV require immediate response [43]. Many expert decision support systems have been proposed in the past to enhance the anaesthetist's performance [19],[44] thus aiding the anaesthetist and, in some cases, even outperforming the anaesthetist.

The challenge is to develop a computer application that will accumulate all the information in a variable, or several variables, over time, and identify when the trend in observations has changed. In recent years, there has been rapid growth in the patient monitoring approach by DSS, smart alarm monitoring systems, expert systems, and many other computer-aided protocols and designing tools [34], [45],[46],[47],[48].

2.4 False alarms in the operation theatre

The focus was also towards the low false alarm generation because the alarms of medical devices are a matter of concern in critical and preoperative care. The frequent false alarms are not only a nuisance for patients and caregivers, but can also compromise patient safety and the effectiveness of care. Intensive care unit (ICU) alarms have been designed to call attention to the patient, to alert a change in their physiology, or to alert staff to a device problem. Alarms are triggered when a physiologic variable crosses a set threshold. In their excellent literature review, Imhoff and Kuhls report alarm frequencies of 1.6 to 14.6 alarms/h and a false alarm rate of up to 90 percent [49]. Chambrin et al. [50] reported the lowest rate of alarms at 1.6 alarms/h. Tsien and Fackler [51] reported one of the highest alarm rates at 9.8 alarms/h in the noisier environment, but limited their study to alarms from the cardiac patient monitor. The problem with simple threshold alarms is that up to 94.5 percent of the alarms that sound in the ICU are either false or provider-induced [52] and frequently sound unnecessarily [49],[50],[52]. Default settings by the equipment manufacturers are set to avoid missing a single false negative alarm, and thereby result in many false positive alarms [53].

3 Participants and Data

3.1 Data collection

The physiological data were collected from the S/5 Datex-Ohmeda (GE, Datex-Ohmeda, Helsinki, Finland) anaesthesia monitor for patients undergoing major surgery. The data were collected with informed consent from 30 patients in the Auckland City Hospital operating theatre suite in New Zealand, with the respective local ethical approvals obtained. Some of the data were recorded using a software program called S/5 Collect from GE Healthcare Ltd.

However, the S/5 Collect software application can only collect data from the S/5 monitor and download it into the data collection computer; the data have then to be saved into a digital data file, in DOF format, which can then be used for offline analysis. There is no provision for relaying data to any other device or application; therefore, it cannot be used for real time data collection and testing. The data collection methodology had to be changed when the hospital's anaesthesia data logging system (IDAS) (SaferSleep Ltd) was introduced which occupied the only serial port. Some of the data which were collected using S/5 Collect in the past were used for offline testing of this project as shown in Fig. 1.
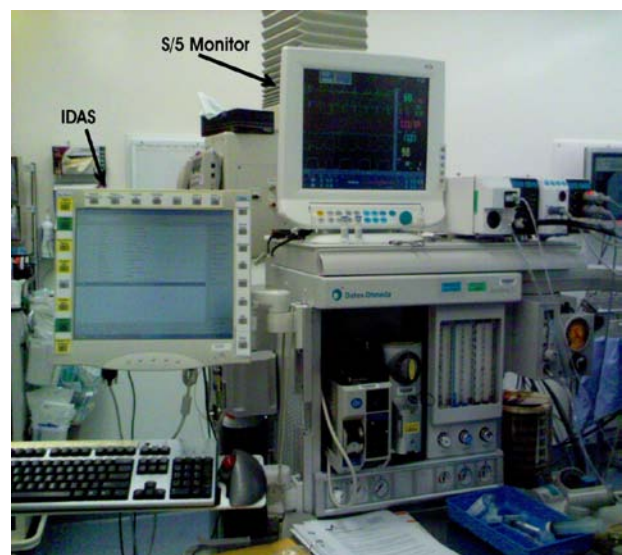

Fig. 1. Operation theatre setup with Datex S/5 monitor and IDAS system

3.2 Data conversion

DOMonitor.Net [6] is a JAVA.NET-based data collection application. Originally, it was used to acquire data from the S/5 monitor, save captured

data to a digital file, and simultaneously relay the data over another serial port. The digital file saved by the application can be used for offline analysis. DOMonitor had to be modified so that the acquired data could be relayed for real-time analysis. This application served as a very handy tool for testing as it performed the tasks simultaneously; this streamlined the whole process. It acquires data from the S/5 monitor and relays it to IDAS over another serial port, and also transmits the required data signals over a transmission control protocol (TCP) port. It saves the selected waveform data to a readable digital file that can be accessed in offline mode for retrospective analysis.

3.3 Pre-processing

3.3.1 Preparing data for analysis
After we employed the DOMonitor.net application to convert the (.dof) format data to readable text files (.txt).

- Removing/deleting missing values (values with zero or negative) in order to have a unique data set throughout the processing.
- Sampling data: The collected raw data contains sampling period of 10sec to 30sec, the sampling period was set at 30sec.
- Checking and removing outliers in the data plot; there are some points which appear to dramatically differ from the rest of data, such points are outliers.
- Calculating descriptive statistics: minimum, maximum, mean, median, mode, standard deviation and range.
- Smoothing/filtering data using a combination of variance based filtering, low pass filtering and threshold based noise rejection techniques to remove unwanted noise and disturbance.

3.3.2 Data analysis
Data analysis was carried out by using a time series technique in Matlab; this stored data and time values as well as the metadata information that included

units, events, data quality and decimation methods. Data analysis consisted of:

- Creating time series objects, which allow the monitoring system to work with real time.
- Time plots – morphological features can be extracted from the plotted data versus time. Some of these features can be used for the development of monitoring system such as managing outliers in the data set, discontinuity in data, and trends in the data set can be de-trended at any time interval containing the data of interest.
- Plotting time series in real time – different types of plots in the time series tools are; time plot, histogram, spectral plot, correlation plot and XY plot.

4 Fuzzy Logic Monitoring System-2 (FLMS-2) Development
Fuzzy logic modeling and working has been done in the Matlab and its related tool boxes. Fig. 2. shows a hierarchical block diagram for FLMS-2, each major component works as follows:

4.1 Signal processing
Multirate data processing i.e. using decimation technique to increase the sampling period from 10 sec to 30 sec to have a unique data set. Smoothing and filtering techniques are applied to reduce noise and major artefacts and to provide the cleaned data for the diagnosis process.

4.2 Adaptive Neuro-Fuzzy Inference System
ANFIS – is used to train the model with 10 patients' data and testing with 20 patients' data selected randomly (Mamdani type model) [46].

4.3 Fuzzy Inference System
FIS – is used to train the fuzzy model (Sugeno type model) [54]. Output from FIS training data when compared to FIS output (patient testing data) is shown in the Fig. 3.
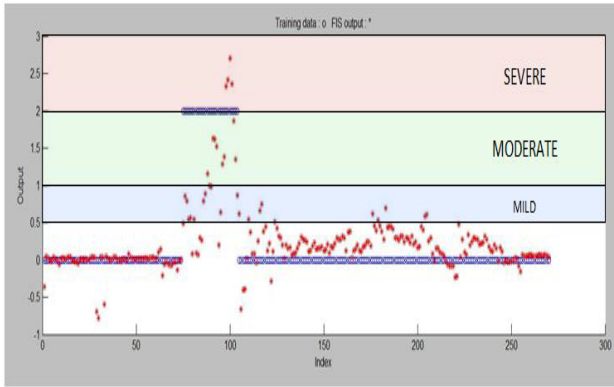
Fig. 3. FIS output window with classification of Hypovolemia as mild, moderate and severe

4.4 Membership Functions

MFs – The MFs for each input are set as mild, moderate, and severe. The selection of the MF's limits is set after analysing the data statistics, time series analysis and ANFIS outputs.

4.5 Rules

Rules – The rules are derived from all MFs and all possible levels of hypovolaemia which were detected throughout the training sessions. Ten different possible conditions/rules have been mapped in the fuzzy system after analyzing ten patient data during the training sessions, initially started with seven different rules and at the end of

training, ten different rules are considered as shown in Fig. 4. If no rules are executed then, this will only be the normal condition. In this case system will not generate any alert or warning and goes to next data batch.
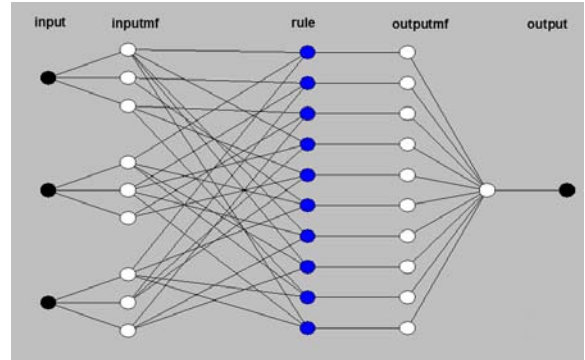

Fig. 4. Rules structure for ten different rules

5 FLMS-2 Configuration

The test conditions for the detection of hypovolaemia were classified as: mild, moderate, and severe. The following four principles were set before the generation of alarms in the system:

Principle 1- Sampling period: The system checks the sampling period of the input data which should be 30sec.

Principle 2- Three Inputs: The system is set to accept only three inputs which are HR, BP, and PV.
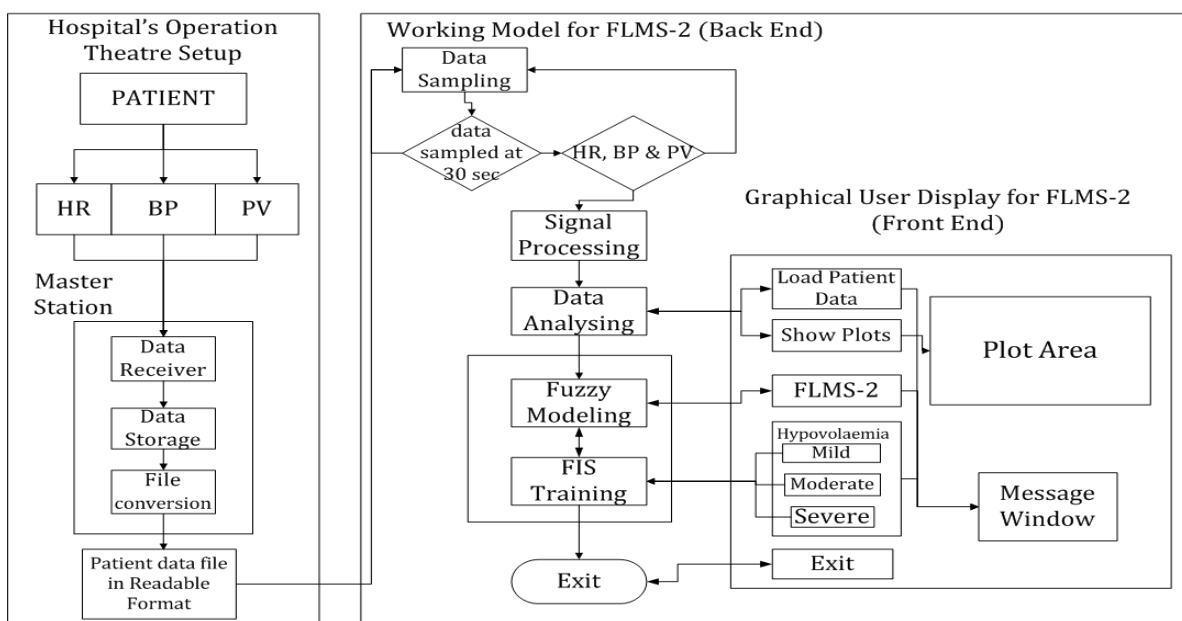

Fig. 2. A hierarchical block diagram for FLMS-2

Therefore, if any input data set is missing, the system will return the present alarm status as false, and wait for the next 15 minutes of the data set.

Principle 3- Membership Functions: The limits of the membership functions were set after considering the following points:

- The limits are set so that the FLMS-2 can detect the changes in the parameters, rather than the crisp numerical values and filtered data were divided into five-minute intervals.
- The relative value of each parameter (such as HR) is found by removing its average and dividing the result by its standard deviation (SD) for each five-minute interval.
- Considering the limits of SD in the whole data set as indicated in Table 1.

Table 1. Principle-3 testing SD values and limits

Hypovolaemia (SD)	Mild	Moderate	Severe
Heart Rate	1.75-3	3-5	5&>
Blood Pressure	2.75-5	5-6	6&>
Pulse Volume	4-6	6-8	8&>

Principle 4- Ten Rules: The rules are set for testing of the patients' data with their MFs. Fig. 5 shows all 10 rules with rule number four is executed to alert/warn the moderate level of Hypovolaemia.

1. If (HR is mild) and (BP is mild) and (PV is mild) then (Hypovolaemia is mild)
2. If (HR is moderate) and (BP is moderate) and (PV is moderate) then (Hypovolaemia is moderate)
3. If (HR is severe) and (BP is severe) and (PV is severe) then (Hypovolaemia is severe)
4. If (HR is mild) and (BP is moderate) and (PV is moderate) then (Hypovolaemia is moderate)
5. If (HR is severe) and (BP is severe) and (PV is moderate) then (Hypovolaemia is severe)
6. If (HR is moderate) and (BP is mild) and (PV is mild) then (Hypovolaemia is mild)
7. If (HR is mild) and (BP is moderate) and (PV is severe) then (Hypovolaemia is moderate)
8. If (HR is mild) and (BP is mild) and (PV is severe) then (Hypovolaemia is moderate)
9. If (HR is severe) and (BP is mild) and (PV is mild) then (Hypovolaemia is moderate)
10. If (HR is mild) and (BP is moderate) and (PV is mild) then (Hypovolaemia is mild)

Fig. 5. Rules viewer window of FLMS-2 with 10 different rules and rule number four is executed to alert the moderate hypovolaemia

Flowchart diagram of FLMS-2 and the four principles (conditions) is shown in Fig. 6. According to these principles, the system checks whether each parameter is true with the input values (principle 1 & 2) and each parameter exceeds the SD limit (principle-3). If those conditions are true, then principle-4 with ten rules will be checked and executed. The system generates alarm/warning in one of the three hypovolaemia levels of; mild, moderate, or severe.
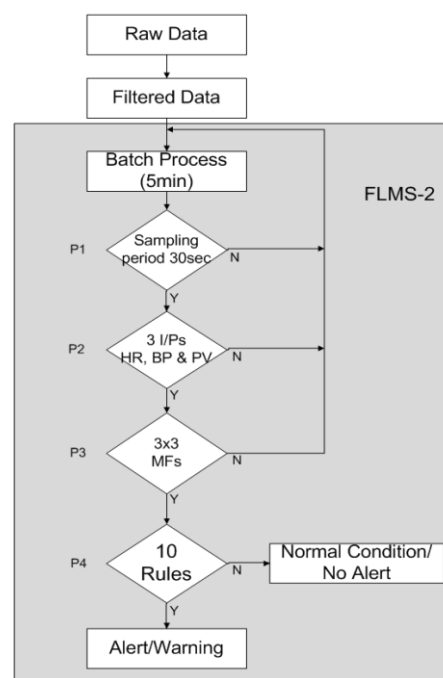

Fig. 6. Flow chart diagram of FLMS-2, where P1, P2, P3 and P4 are the four principles (conditions) respectively

5.1 System diagnosis

The patient data were used for offline data-simulation, and analysed retrospectively by revisiting all the available patient information for each record. The analysis of the data set in offline mode is identical to the real-time analysis as the same diagnostic algorithms are used for both analyses. The physiological data from 30 patients were divided into sub intervals of five minutes, and every three intervals re-combined to a 15 minute time slot. Epochs of 15-minute durations were used for offline analysis to match the anaesthetist's diagnosis which is made at 15-minute intervals.

FLMS's offline version is capable of reading the given patient data files. It analyses and generates the alarm levels for the complete data set. The data from the digital (Excel) patient files were fed to FLMS-2 and the corresponding computer-generated diagnostic alarm levels were produced by the system. The output has been classified into three categories: mild, moderate, and severe. These criteria were used and applied to the system, to generation of alerts from the given data (patient) sets.

5.2 Graphical User Interface

Fig. 7 shows the graphic user interface (GUI) of FLMS-2 front end simple display, major components of GUI display window with pushbuttons are;

- Load Patient Data – This will load the original patient data and a message window will appear with 'Patient data loaded successfully!!!'
- Show Plots – This will plot the complete waveform of BP, HR and PV.
- FLMS-2 – By clicking this, the 'FLMS2' system will test the loaded data and check for Hypovolaemia, and display the message 'FUZZY LOGIC MONITORING SYSTEM has detected hypovolaemia'
- Hypovolaemia (mild, moderate and severe) – These buttons will check for the level of hypovolaemia detected by the monitoring system and displays the message with its real time. Fig. 8 shows the alert window for moderate hypovolaemia detected by FLMS-2 at 09:46 am
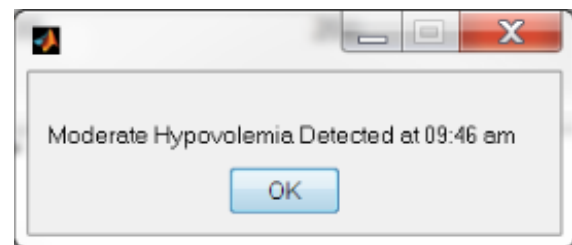

Fig. 8. Moderate hypovolaemia alert window

6 Testing and Validation

6.1 Testing

Evaluating FLMS-2's diagnostic performance was done by measuring the level of agreement between FLMS-2 and the anaesthetists; using Kappa analysis [7]. The value of the computed Kappa in the following section indicates the level of
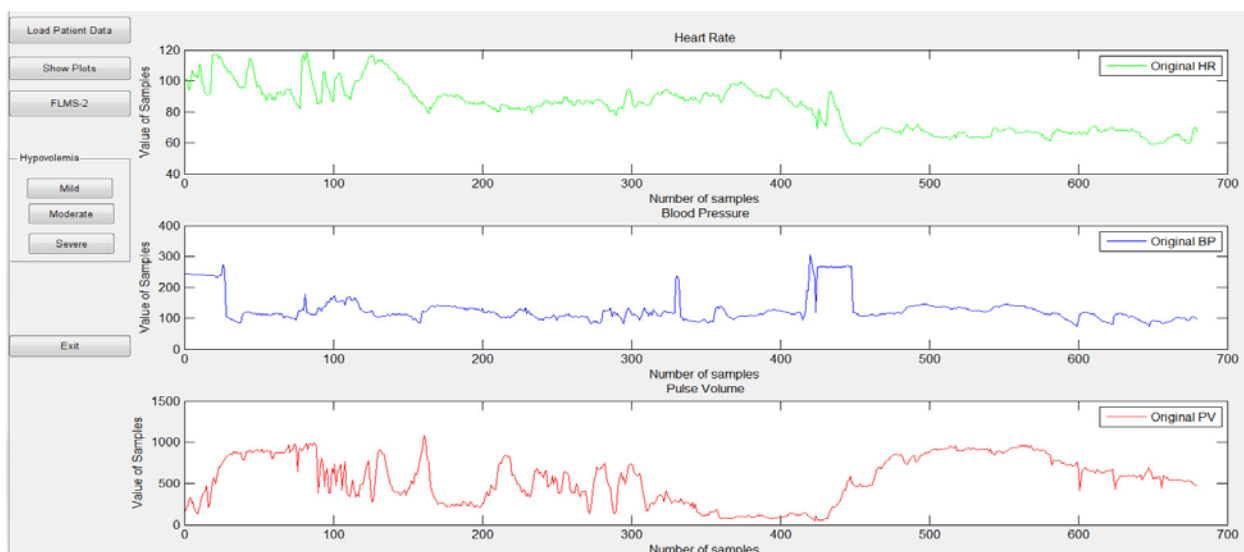

Fig. 7. FLMS-2 graphical user interface window

agreement/disagreement between the two. The diagnostic performance of the FLMS-2 was verified through a series of offline (retrospective) tests in a simulation environment. In off-line analysis the FLMS-2 was tested with data from 20 patients. Fig. 9 shows the testing and validation structure.
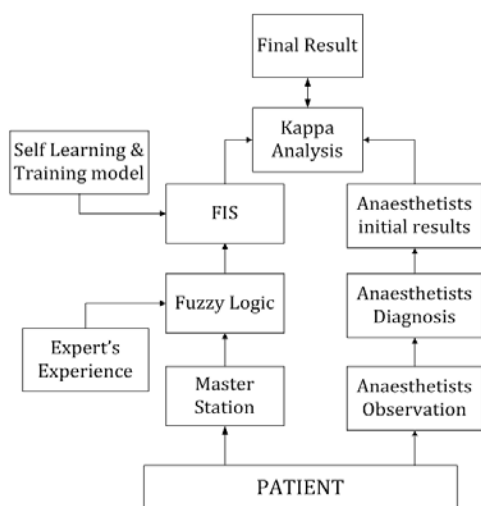

Fig. 9. FLMS-2 testing and validation

6.2 Results and Discussion

The FLMS-2 was tested with 20 patients using off-line data divided into15-minute epochs. Table 2 summarizes the kappa analysis results for performance validation of system. Po, Ppos, and Pneg are overall, positive, and negative agreements respectively. SE represents the standard error, CI95% is 95% Confidence Intervals for kappa and K is the kappa value.

Table 2. Results from FLMS-2 validation tests

Monitoring System	Po	Ppos	Pneg	Pe	SE	CI95%	K
FLMS-2	0.91	0.82	0.94	0.64	0.03	0.82-0.67	0.75

It shows the system has sensitivity of 94%, specificity of 90% and predictability of 72%. The developed diagnostic system is capable of diagnosing the pathological events with a substantial level of agreement between FLMS-2 and the anaesthetist. The level of disagreement needs further analysis and a more definitive study is required.

6.3 Result Comparison

Table 3 shows the results of FLMS-2, comparing with similar monitoring systems available today.

Table 3. FLMS-2 Result comparison with other monitoring systems

Monitoring Systems	Po	Ppos	Pneg	Pe	SE	CI95%	K
RT-SAAM [27]	0.81	0.83	0.79	0.50	0.06	0.73-0.51	0.62
SMS [4]	0.87	0.79	0.91	0.57	0.06	0.82-0.58	0.70
FLMS [3]	0.89	0.80	0.92	0.59	0.06	0.85-0.61	0.73
FLMS-2	**0.91**	**0.82**	**0.94**	**0.64**	**0.03**	**0.82-0.67**	**0.75**

7 Conclusion

The developed diagnostic alarm system (FLMS-2) has shown that evidence-based expert diagnostic systems can accurately diagnose a hypovolaemia event in anaesthetized patients and could be useful in providing decision support to anaesthetists. It is shown that the proposed FLMS-2 performs better in comparison with similar systems available today (Table 3). The complete validation of the system, as a clinically useful diagnostic alarm system, can only be verified after real-time testing. This system is ready to be tested in the real-time environment, although it may need further refinement and enhancement with additional features for routine clinical use. This system may be a clinically useful tool as shown by the overall results, and when compared with other monitoring systems.

8 Acknowledgment

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