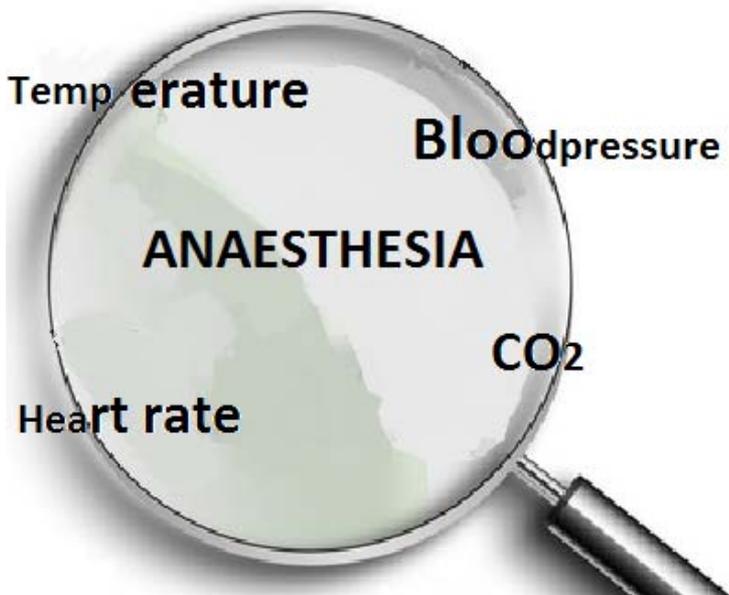


EBMi Manual

Evidence-Based Monitoring (interactive)

V 1.17.0

www.custos.co.nz



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Note: This system functions entirely on data already obtained by the anaesthetic monitor. It does not require additional patient monitoring hardware.

1 Introduction

Current anaesthetic monitors generate alerts from individual physiological variables using threshold values. For example, an alarm may be generated if the blood pressure falls below a set value, say 90 mmHg.

External or internal influences on the body result in organised physiological responses that compensate for the perturbation; different adverse events having different patterns of adaptation.

EBM stands for Evidence-Based Monitoring. The adverse events detected by the software are based on pieces of evidence extracted from your main anaesthetic monitoring system. Individual measurements are used as evidence, like parts of a jigsaw, to identify patterns pathognomic of an event.

The patterns are based on data from patients with known physiological profiles which allow the program to take advantage of past relevant history and present live data.

The program incorporates three processes:

- a. the input of specific patient information
- b. the collection and processing of all the usual physiological data
- c. the recognition of adverse changes and generation of alerts

Though existing alarms warn a user that there may be a problem, a signal such as a 'beep' does not identify its cause. Once the source is identified, and is determined to be relevant, the cause has to be determined.

With EBMi the alert is a clear statement in the user's language that suggests what condition may exist, based on all the evidence.

The patient and anesthesiologist both benefit.

2 Hardware and software requirements

a) Microsoft Windows 10 or previous versions or even XP. While XP will run the program it does not support the audible alert facility.

b) .net Framework v4

Can be downloaded free from

<http://www.microsoft.com/download/en/details.aspx?id=17718>

Check installation is complete after downloading.

c) Null modem cable - available from any computer store to attach to RS232 output from GE AS3/AS5 monitors

RS232 / USB adaptor if computer does not have RS232 connection.....try computer store again.

d) For Carescape – a USB connection

e) Carescape or GE (Datex-Ohmeda) AS3 or AS5 anaesthetic monitors.

f) Latest version of EBMi (www.custos.co.nz)

3 Setting up

The first time the program is run a screen appears indicating an evaluation period. If you wish to install a license please follow the instructions.

The next screen contains a disclaimer..

"Please accept responsibility for all actions or inactions in the management of the patient as EBMi is an aide and not yet a fully validated system."

License Agreement



The EBMI is an advisory system that uses the physiological changes during anaesthesia to suggest functional diagnoses.

It is for use by anaesthetists and the anaesthetist has total responsibility for the interpretation of the diagnostic output. Any clinical decision, action, or inaction will be the total responsibility of the user.

Each change in a physiological variable is used as a piece of evidence; that evidence is weighed and integrated with other changes to reflect the organised physiological response of the patient.

The user can interact with the device to set the patient's age (this device is for adult anaesthesia only), to indicate that some disease processes exist, and ultimately, to query the output.

I accept that any clinical decision, action, or inaction will be my responsibility.

I Accept

Decline and Close

The data processing and output of EBMI is designed to be a vigilant overseer with the ability to make suggestions about what is going on, "Please consider....". How you manage your patient is your responsibility.

On the next screen there is a choice of monitors. At present only the driver for the GE AS3 and GE AS5 monitors are available in v1.0. If you wish to run a 'demo', highlight the XL icon at the bottom of the screen.

NEXT will take you to the following screen...if you have chosen the 'demo' mode the Browse button allows you to search for an appropriately formatted c.s.v. file and a sliding cursor adjusts the speed at which the simulation will run...up to 100x normal speed.

Highlighting the GE monitor advances to a patient data entry page.

Patient Details Close

Approximate Age undeclared

15 100

Ischaemic heart disease / Recent stroke No

Aortic stenosis

None Mild Moderate Severe

Dysrhythmia No Pacemaker No Beta-blocker No

Type of Anaesthesia

Volatile TIVA LA

Next

Press NEXT and BEGIN and the software will run.

Please note that no processing of data will start until there has been five minutes of steady state respiration. This period can be skipped but the output should be considered less reliable as induction of anaesthesia gives rise to significant changes in many physiological variable which are very transient.

4 Use

In this trial period note that EBMi is not an extensively validated system and therefore the output should be very carefully appraised by experienced staff.

Note 1...v1.0 works using kPa units for EtCO₂ so please set monitor to kPa.

Note 2...the full functionality of the software is only achieved using an arterial pressure cannula for blood pressure measurement.

Note 3 ...RAPPV stands for respiratory associated pulse pressure variation and it will only be available if

- a) the ventilation is controlled and
- b) the arterial waveform is not damped.

There are algorithms to detect both conditions in the software. This is a delicate measurement and if the patient is being moved / turned/ or the limb with the pressure line is being moved the output will be invalid.

Note 4 ...The variables involved in the diagnosis of malignant hyperpyrexia have changes that are similar to those changes at the onset of laparoscopic surgery...blood pressure, heart rate and EtCO₂ all rise. It is unlikely that the presentation of MH would be so fast that it would occur right at the beginning of anaesthesia but if an MH alert should appear at the beginning of laparoscopic surgery take great care to review the situation.

Data for the modelling of MH is limited and so the algorithm to detect MH in this software should not be considered in any way definitive...the possibilities of both false positive and false negatives should be remembered.

Note 5 ...Be aware that once an alert has been generated **it (the same alert) will not be repeated for five minutes**. This means that, for example, a patient may continue to be hypotensive but there will be no notifications in this five minute period. This avoids repetitive intrusive alerts.

At this stage in the use of the software the only interaction that can be made by the user is by activating the audit buttons. When an alert appears (and new ones appear at the top of the column of alerts) you can press the appropriate button to register your view of the alert.

This data is automatically filed at the end of the case. **To ensure that the file is saved close down the program using the "End of operation button".**

To find the output files go to ...

C:\Users\Michael\AppData\Local\name-of-user

The screen you see will be as below.

The alerts with a relative time stamp are on the left and the newest alert is at the top.

There is a list of diagnoses with sets of coloured boxes beside them...in the boxes are labels indicating in which direction the variable has changed, i.e. BP ^ .

If all the boxes in one row change colour to an orange/red then an alert for that diagnosis is generated. The alert is also audible...but not if the XP operating system is being used.

The horizontal bar is a representation of the pulse pressure variability. The whole width of the bar encompasses the range 0%-20%. If the arterial waveform is damped or the ventilation is not satisfactory the word "Unavailable" appears on the bar.

EBMi v 1.0 has the following alerts.

Inadequate anaesthesia – low MAC calculated using age and temperature.

Damped arterial trace

Inappropriate ventilation

Sympathetic response

Achronotropic sympathetic response (lacks heart rate component due to pacemaker, β -blockade or high dose TIVA)

Hypovolaemia possible

Hypovolaemia likely (RAPPV)

Cardiac output down

Cushing response

Failure to ventilate after CPB

Malignant hyperpyrexia

5 Limitations

EBMi collects data from the user input and the monitor. It does not 'know' what is going on outside this limited data set. It is 'unaware' of patient position (head-up, head-down, lateral positioning, change of positioning); nor of change of operation technique – e.g. from laparoscopy to open surgery. The physiological changes associated with these states may temporarily mimic other adverse events. Take extra care in interpreting the output statements.

The EBMi software is dependent on the integrity of the anaesthetic monitor's output...if for example the arterial pressure transducer is incorrectly calibrated the resulting processing of the data will be affected.

The software is designed for use in adult patients only

The software has not been tested in the management of patients who are pregnant.

The algorithm for the detection of malignant hyperpyrexia is based on a limited dataset and has therefore limited reliability. As mentioned earlier the changes associated with the onset of laparoscopic surgery have the potential to be confused with malignant hyperpyrexia...but it is considered a low risk.

The alert for 'achronotropic sympathetic response' has to be evaluated knowing that this relies only on changes in blood pressure and pulse volume – the heart rate being fixed (fixed rate pacemaker, β -blockade, high dose opiate (TIVA)).

The data processing and output of EBMi is designed to be a vigilant overseer with the ability to make suggestions about what is going on, "Please consider....". How you manage your patient is your responsibility.

