Feedback Control

Improving the safety and efficacy of medical devices.

LOUIS C. SHEPPARD

is an Associate Professor and Computer Applications Engineer in the Department of Surgery. He received his B.S. degree in chemical engineering from the University of Arkansas in 1967. After six years' experience in petrochemicals, he was employed by IBM Corporation and worked primarily in the area of application of computers to the solution of medical problems at the Texas Medical Center and at the Mayo Clinic. In October 1968 he joined the faculty of the Department of Surgery at the University of Alabama Medical Center and since that time has been engaged in surgical intensive care automation. He is a registered professional engineer in the state of Alabama.

PATIENT ENVIRONMENT WITH TITRATOR® SYSTEM

Controller

Patient

Target

Controlled Variable

Controller

Patient

Controlled Variable

PROPORTIONAL INTEGRAL DERIVATIVE CONTROLLER

DECISION TABLE

AGENT

PUMP

PATIENT

MEAN ARTERIAL PRESSURE

ml/hr

Agent

Pump

Decision Table

Proportional Integral Derivative Controller

Mean Arterial Pressure

Blood Pressure Transducer and Catheter
Automated control of postoperative hypertension: a prospective, randomized multicenter study.

- 180 cardiac surgical patients
- blood pressure +/- 10% of the target
  – 83% of the time with the automatic system
  – 61% of the time with manual regulation
- hypertension: 9% versus 22%
- hypotension: 6% versus 22%;
- less requirement for nurse regulation of infusion rate.


Rapid Induction of Anesthesia

- Isoflurane 5.0 then 1.2%
- High Oxygen Flow - 10 L/min
- Rapid Ventilation - 8 L/min
- High Cardiac Output - 10 L/min

Zeus®
Decisively different...

Dräger Medical: Zeus
Time course of inhaled anaesthetic drug delivery using a new multifunctional closed-circuit anaesthesia ventilator. *In vitro* comparison with a classical anaesthesia machine


1Department of Anaesthesia, Ghent University Hospital, De Pintelaan 195, B-9000 Gent, Belgium, 2Research and Development, and 3Product Management Business Unit Anaesthesia, Dräger Medical, Lübeck, Germany.

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**CLINICAL INVESTIGATIONS**

Model-based automatic feedback control versus human control of end-tidal isoflurane concentration using low-flow anaesthesia

T. J. Sieber1, C. W. Frei2, M. Devigili2, P. Feigewinter1, D. Leibundgut1 and A. M. Zbinden1

1Department of Anaesthesiology, Research Section, University of Berne, Inselspital, 3010 Berne, Switzerland, 2Automatic Control Laboratory, Swiss Federal Institute of Technology (ETH), 8092 Zurich, Switzerland.
Was können Anästhesiesysteme in der Zukunft leisten am Beispiel der Sauerstoff-Dosierung und -Messung?

T. Simmener

Performance of Anesthesia Systems in the Future. O₂ delivery and O₂ measurement as Example
Hamilton Adaptive Support Ventilation

- Assess breath by breath the patient's lung mechanics.
- Optimize tidal volume/respiratory frequency combination based on lung mechanics.
- Achieve optimum tidal volume/respiratory frequency

Sulzer CF et al. Anesthesiology 2001;95:1339-45

Fuzzy logic control of mechanical ventilation during anaesthesia

J. Schaublin, M. Deiometti, P. Fegerswinter, S. Petersen-Felix and A. M. Zbinden

British Journal of Anaesthesia 1996; 77: 636-641

Model-based control of mechanical ventilation: design and clinical validation

E. P. Martinoni2, Ch. A. Pflieger2, K. S. Studler2, P. M. Schumacher3, D. Liebendum4, T. Bouillon5, T. Biasca2 and A. M. Zbinden2

BJA
Evaluation of a Closed-Loop Muscle Relaxation Control System

- Douglas J. Eleveld, MEng, Johannes H. Proost, PhD, and J. Mark K. H. Wierda, MD, PhD
Table 3. Controller Train-of-Four (TOF) Count
Performance During 39 h of Closed-Loop Control

<table>
<thead>
<tr>
<th>TOF count during closed-loop control</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0.8</td>
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<tr>
<td>1</td>
<td>38.5</td>
</tr>
<tr>
<td>2</td>
<td>57.6</td>
</tr>
<tr>
<td>3</td>
<td>2.0</td>
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<tr>
<td>4</td>
<td>1.1</td>
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</tbody>
</table>

Closed Loop Muscle Relaxation Control

- Adequate surgical relaxation without complete suppression of patient movement
  - Allowing patient grimacing or movement
- Constant level of relaxation
- Reversal drugs more effective
- Reduce anesthesiologists’ workload

DEVELOPMENT OF A STANDARD TO VALIDATE CLOSED LOOP CONTROL IN MEDICAL DEVICES

In 2002, an initiative began to prepare a standard for closed loop control systems for medical devices. The currently a draft includes three significant requirements specific to closed loop systems:

- Control system must assume a fallback mode in any single fault condition which creates unacceptable risk.
- The operator needs the ability to maintain awareness of the status of the control system consistent with the operator’s mental model.
- The System shall indicate the mode of operation.

The standard should be completed in 2007 with the expectation that some closed loop medical devices can be approved in the US through the 510(k) route.