Clinical performance of electrical control for Aisys™ Carestation, to automatically adjust fresh gas, end-tidal agent and oxygen

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Introduction

Traditionally, anesthesiologists administer oxygen and anesthesia agent (AA) by manually adjusting vaporizer (VAP) and FGF settings, observing airway gas concentrations, and according to clinical judgment. However, it is technically possible to design a feed-back system for the anesthesia workstation to reduce repeated manual adjustments(1). Such a system may enable target control administration of O_2 and AA based on individual patient's needs.

Objectives

After extensive lab testing, end-tidal control (EtC) prototype designed for Aisys™ (GE Healthcare), was ready for evaluation on human subjects.

Technical design goals of this fuzzy logic target control system included administration of oxygen based on end-tidal O_2 measured from the patient, as EtO_2 may reflect patient's metabolism more closely than FiO_2 only. Likewise, optimal circle system characteristics were important for quick response time, for target control of both EtO_2 and AA.

The aim of this study on patients, was to access clinical performance vs. expectations of anesthesiologist, plus to compare behavior of the control system vs. technical specs by analyzing real time response data.

Methods

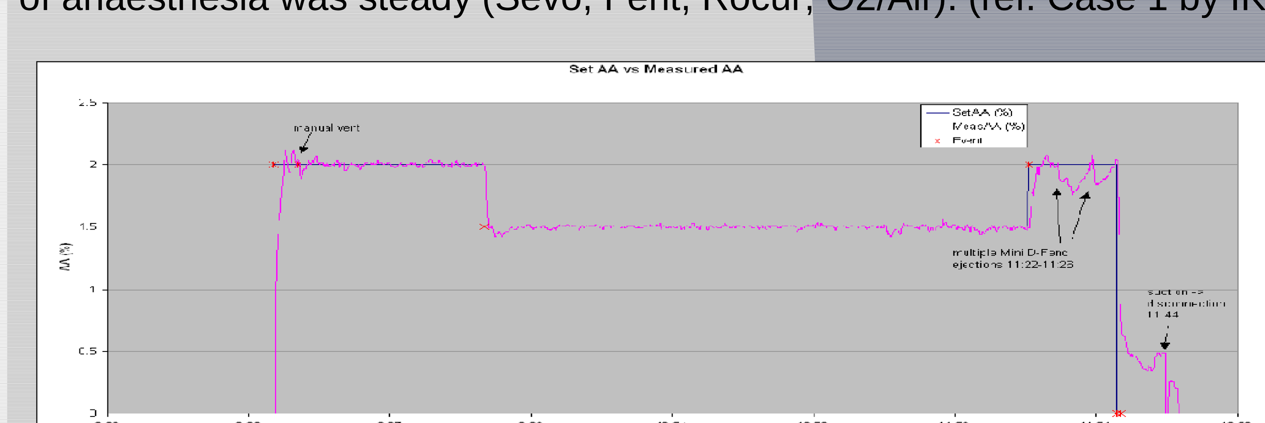
After approvals of ethical committee and authorities, written informed consent was obtained from 20 ASA 1-3 patients undergoing gynecological procedures according to hospital standards. Anesthesiologist responsible of patient care stayed in the O.R., continuously observing the control system. In addition, there was a technical observer to record time marked notes and comments. At induction, anesthesiologist deciding about target concentrations for EtAA and EtO_2 dialed them to the controller, thus enabling software algorithm to start adjusting FGF and VAP settings automatically.

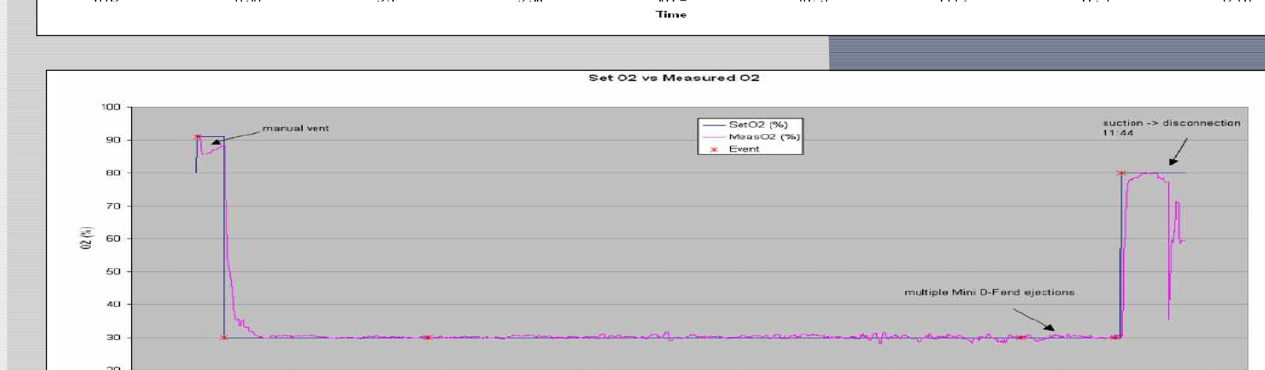
Non-invasive monitoring (S/5 AM, independent of the controller), collected ECG, SpO_2, NIBP, Entropy, NMT, spirometry, and airway gas concentrations of O_2, N_2O, CO_2 and AA. Clinical data were automatically stored. Control system's breath to breath data flow was also stored in real time. Clinical quality indications (e.g. hemodynamic variability) had been defined *a priori*. After each completed case, anesthesiologist estimated whether variability in monitored variables was due to technical or clinical reasons.

Fig 1. Aisys™ Carestation with automated end-tidal gas control

Fig 2. Laparoscopic hysterectomy recording

ASA 1, 75 kg, 170 cm. Duration over 3 h.
BP decreased >25% at induction (Propofol, Fent). Thereafter mainenance of anaesthesia was steady (Sevo, Fent, Rocur, O2/Air). (ref. Case 1 by IK)





Results

Enrolled 20 patients met all inclusions criteria; none had to exit during study. Five anesthesiologist administered sevoflurane general anesthesia with the system: three were senior staff and two were anesthesia residents.

There were no adverse effects. HR and BP remained stable (±25% from control) in 16/20 patients, in 4/16 patients the reason was clinical. In 18/20 cases SpO_2 was above 90% all the time, in 2/20 the reason for deviation was clinical.

None of the clinicians stopped using controller during the cases. Neither did controller exit from the EtC unexpectedly. Technical assessment of control performance parameters (Fig. 3 and Table) included response and setting times, command overshoot and steady state deviations of both EtO_2 and EtAA.

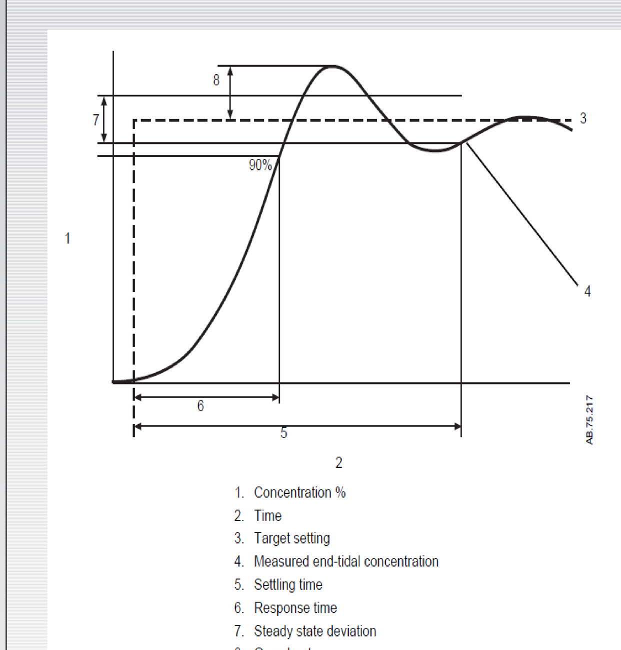


Fig 3. Variables used for analysis of gas setting change
(concentrations measured from the patient's airway)

Table. Performance measurements (N=20)

	Typical performance after setting change, Aisys manual (2). Average ±SD	Measured Average Time in this study (N=20 cases)
EtAA response time	68 ± 28 s	59.29 s
EtAA settling time	126 ± 100 s	110.84 s
EtAA steady state deviation	0.2 ± 0.1vol%	
EtAA overshoot	8.1 ± 4.8 % of setting	
EtO2 response time	130 ± 38 s on an increase 228 ± 41 s on a decrease	138.23 s
EtO2 settling time	136 ±30 s on an increase 335 ±146 s on a decrease	225.84 s
EtO2 steady state deviation	1.3 ± 0.8 vol%	
EtO2 overshoot	1.2 ± 0.4 vol%	

Conclusions

This open observational study was the first systematic comparison on human subjects, with the prototype end-tidal control designed for the Aisys™ Carestation by GE. Our measurements in gynecological anesthesia are in accordance with manufacturer's published information(2). Systematic feed-back collected from anesthesiologists using the system, indicated its suitability for everyday anesthesia.

Whereas, target control infusions (TCI) in intravenous anesthesia rely on predictions, or averages based on statistical algorithms, target control of anaesthesia agent and oxygen (EtC) is based on real measured end-tidal concentrations of each individual patient.

Bibliography

1. Absalom, A.R.; De Keyser, R.; Struys, M.M. Closed loop anesthesia: are we getting close to finding the Holy Grail? Anesth. Analg. 2011; 112: 516-
2. Aisys Et Control Addendum (M1177874) by GE Healthcare [Note: Et control not commercially available in all markets, not cleared or approved by the U.S. FDA.]

[1]**Disclosure**: Medical advisor of Datex-Ohmeda (1987-2005), thereafter consultant for medical industry incl. GE Healthcare.

Clinical performance of electrical control for Aisys™ Carestation, to automatically adjust fresh gas, end-tidal agent and oxygen (2)

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Clinical insight

Fig 4. Abdominal hysterectomy, asthmatic smoker needs periop. suction and recruitment

ASA 3. Abdominal hysterectomy. Duration > 3h.

Patient was heavy smoker with asthma (162 cm 66 kg), and her BP was variable (Case 3 in Table 2).

Note: **suction (S)** from the intubation tube (patient disconnected), and manual **recruitment (R)** of lungs.

Table 2. Study summary spreadsheet, 20 cases, 5 anesthesiologists (3 senior, 2 junior)

Case Number	Date	Clinician	Clinician Experience Level	Clinician Case Number	Case Report Form: Necessary to Exit EGC	HR/BP Stable	SpO2 > 90%	Adverse Events
1	7/21/2009	Dr. Ilkka	Sr MD	1	N	N - Not Et related	Y	N
2	7/22/2009	Dr. Ilkka	Sr MD	2	N	Y	Y	N
3	7/22/2009	Dr. Ilkka	Sr MD	3	N	Y	Y	N
4	7/23/2009	Dr. Risto	Sr MD	1	N	Y	Y	N
5	7/23/2009	Dr. Risto	Sr MD	2	N	Y	Y	N
6	7/27/2009	Dr. Anu	Jr MD	1	N	Y	Y	N
7	7/27/2009	Dr. Anu	Jr MD	2	N	Y	Y	N
8	7/28/2009	Dr Julia Kallio	Jr MD	1	N	N - Not Et related	Y	N
9	7/29/2009	Dr Julia	Jr MD	2	N	Y	Y	N
10	7/29/2009	Dr Julia	Jr MD	3	N	Y	Y	N
11	7/30/2009	Dr. Ilkka	Sr MD	4	N	Y	Y	N
12	7/31/2009	Dr. Anu	Jr MD	3	N	Y	Y	N
13	7/31/2009	Dr. Anu	Jr MD	4	N	N - Not Et related	N - Not Et related	N
14	7/31/2009	Dr. Anu	Jr MD	5	N	Y	Y	N
15	7/31/2009	Dr. Ilkka	Sr MD	5	N	N - Not Et related	N- Not EtC related	N
16	8/3/2009	Dr. Timo	Sr MD	1	N	Y	Y	N
17	8/4/2009	Dr Julia	Jr MD	4	N	Y	Y	N
18	8/4/2009	Dr Julia	Jr MD	5	N	Y	Y	N
19	8/5/2009	Dr. Ilkka	Jr MD	6	N	Y	Y	N
20	8/6/2009	Dr Julia	Jr MD	6	N	Y	Y	N

Table 3. Clinical deviations (BP or HR ±25%, $SpO_2 \geq 90\%$) from the pre-induction baseline.

(*Ref. clinical target range definition in the study protocol*)

Case #	ASA Agent	Patient and case	Clinical comments
1	1 Sevo	Laparoscopic hysterectomy Duration > 3h 170 cm 75 kg	BP low after induction with propofol, maintenance normal
8	3 Desf	Abdom.hysterectomy Duration > 3h 162 cm 66 kg	Heavy smoker with asthma Periop. hemodynamic instability
13	2 Sevo	Gyn. laparoscopy Duration ~1h 161 cm 90 kg BMI 35 (obese)	Brady before extubation (35/min ->atropin corrected) SpO2 low after extubation Extub: cough, wheezing, transient SpO2 low, up with mask ventil
15	1 Sevo	Gyn. laparoscopy Duration ~1h 153 cm 63	Prolonged intubation AirtraQ™ was needed. BP, SpO2 transient drops at ind.

Technology brief

Fig 5. Laparoscopic hysterectomy revisited

- After intubation, prolonged manual ventilation, with target EtC of 2%
- Near end the case, **water trap was ejected a few times (W)**
- This graph illustrates minimal effect on Etc and measured gas concentrations.

(ref. Case 1 by IK)

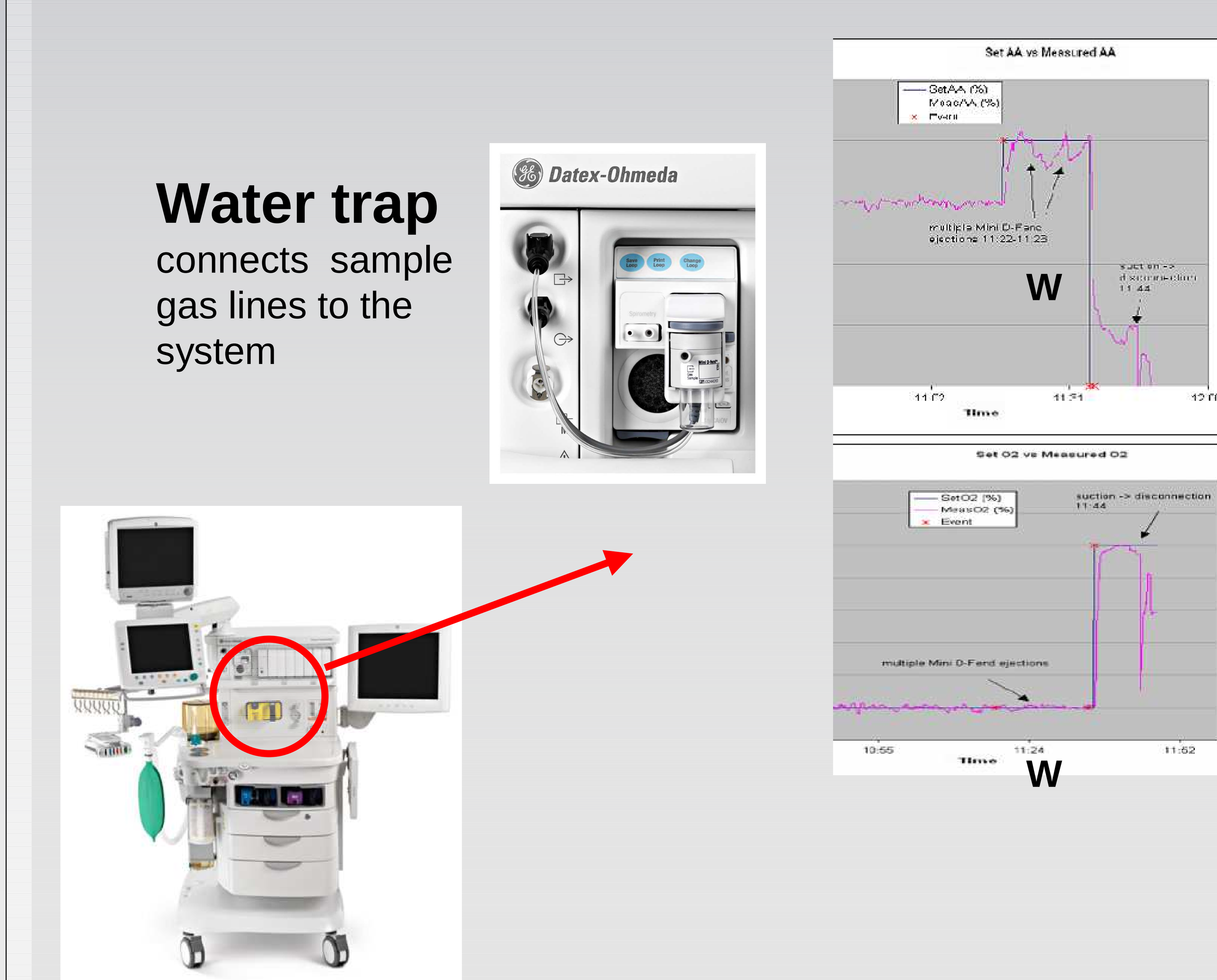
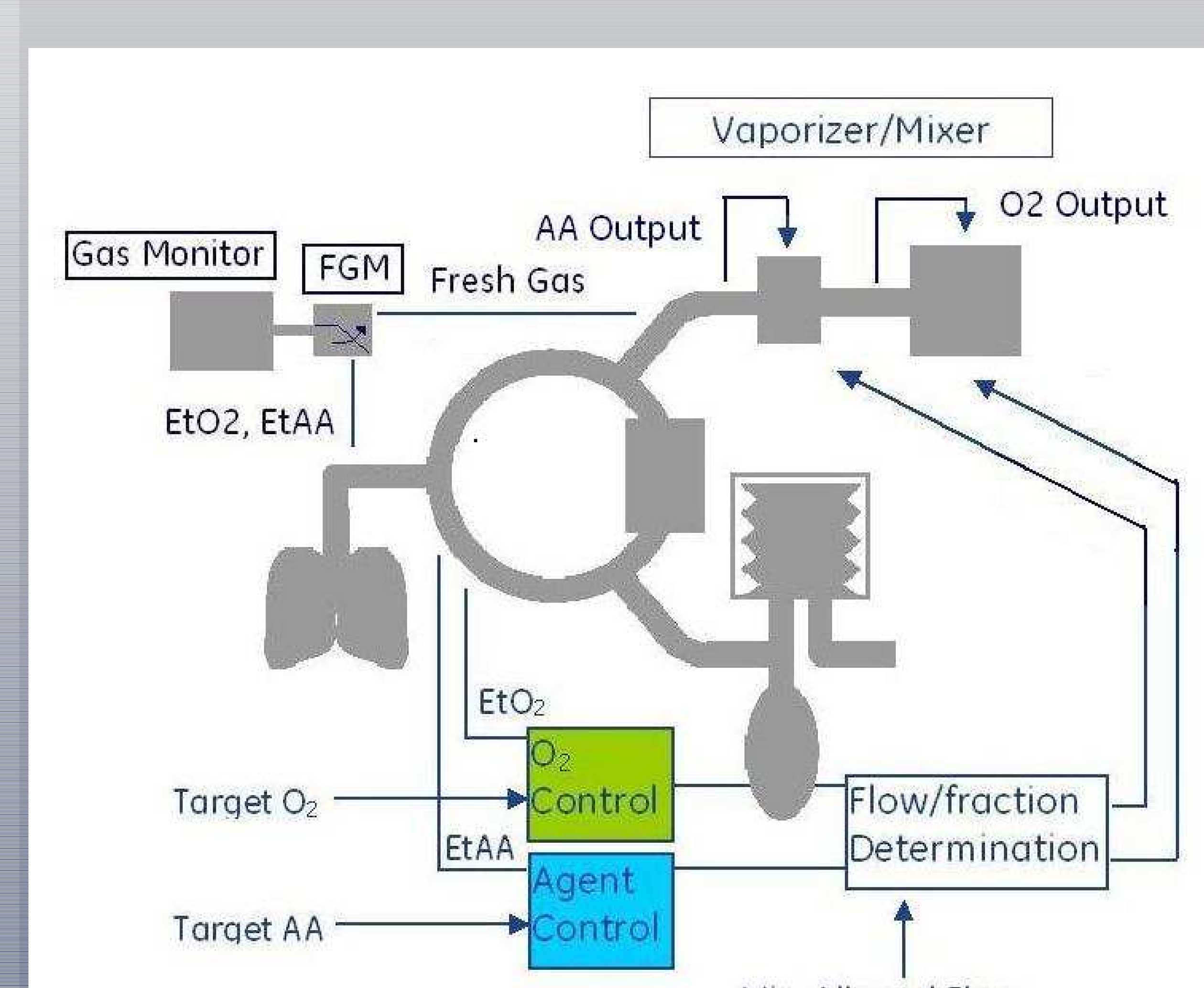


Fig 6. Technology behind Et Control, built onto the Aisys™ system

- Fresh gas connects to the circuit after absorber (near inspiratory limb to facilitate concentration changes in the circuit)
- Monitored EtAA compares with the target set by anesthesiologist.
- EtO_2 is also continuously measured from the circuit. End-tidal oxygen may reflect patient's metabolism more closely than FiO_2 only.



Tech. Figures courtesy of GE Healthcare

[Note: Et control not commercially available in all markets, not cleared or approved by the U.S. FDA.]