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 feedback system for the anesthesia workstation to reduce repeated manual adjustments. Such a system may enable target control administration of O₂ and AA based on individual patient’s needs.

Objectives
After extensive lab testing, end-tidal control (EIC) 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 O₂ measured from the patient, as EIC may reflect patient's metabolism more closely than FiO₂ only. Likewise, optimal circle system characteristics were important for quick response time, for target control of both EIC 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 EtO₂ 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, SpO₂, NIBP, Entropy, NMT, spirometry, and airway gas concentrations of O₂, N₂O, CO₂ 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.

Results
Enrolled 20 patients met all inclusion 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 (=±15% from control) in 16/20 patients, in 4/16 patients the reason was clinical. In 18/20 cases SpO₂ 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 EIC unexpectedly. Technical assessment of control performance parameters (Fig. 3 and Table) included response and setting times, command overshoot and steady state deviations of both EtO₂ and EtAA.

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

Fig 2. Laparoscopic hysterectomy recording
ASA I, 75 kg, 170 cm. Duration over 3 h. BP decreased >15% at induction (Propofol, Fent). Thereafter maintenance of anesthesia was steady (Sevo, Fent, Rocur, O₂/Air). (ref. Case 1 by IK)

Table. Performance measurements (N=20)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Manual setting</th>
<th>Aisys Carestation</th>
<th>Average ±STD</th>
<th>Measured Average Time in this study (N=20 cases)</th>
</tr>
</thead>
<tbody>
<tr>
<td>EtAA response time</td>
<td>68 ± 28 s</td>
<td>69.29 s</td>
<td>59.29 s</td>
<td></td>
</tr>
<tr>
<td>EtAA setting time</td>
<td>126 ± 100 s</td>
<td>110.84 s</td>
<td>108.4 s</td>
<td></td>
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<tr>
<td>EtAA steady state deviation</td>
<td>0.2 ± 0.1%</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>EtAA overshoot</td>
<td>8.1 ± 4.8 %</td>
<td></td>
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</tr>
<tr>
<td>EtO₂ response time</td>
<td>130 ± 35 s on an increase</td>
<td>138.23 s</td>
<td>138.23 s</td>
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</tr>
<tr>
<td></td>
<td>228 ± 41 s on a decrease</td>
<td>228 ± 41 s</td>
<td>228 ± 41 s</td>
<td></td>
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<tr>
<td>EtO₂ setting time</td>
<td>136 ± 30 s on an increase</td>
<td>225.84 s</td>
<td>225.84 s</td>
<td></td>
</tr>
<tr>
<td></td>
<td>335 ± 146 s on a decrease</td>
<td>225.84 s</td>
<td>225.84 s</td>
<td></td>
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<tr>
<td>EtO₂ steady state deviation</td>
<td>1.3 ± 0.8%</td>
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<td></td>
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<tr>
<td>EtO₂ overshoot</td>
<td>1.2 ± 0.4%</td>
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</table>

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 feedback 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 anesthesia agent and oxygen (EIC) is based on real measured end-tidal concentrations of each individual patient.

Bibliography
2. Aisys ETCarestation Addendum (M1177874) by GE Healthcare [Note: TCI control not commercially available in all markets, not cleared or approved by the U.S. FDA]

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)

Table 3. Clinical deviations (BP or HR ±25%, SpO2≥90%) from the pre-induction baseline.
(Ref. clinical target range definition in the study protocol)

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)

Table 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.
• EtO2 is also continuously measured from the circuit. End-tidal oxygen may reflect patient’s metabolism more closely than FiO2 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.]