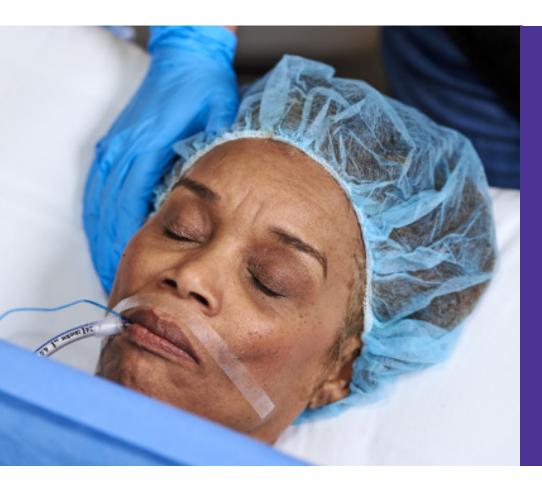


End-tidal Control software

Scientific highlights



Data demonstrates that Et Control supports safe and effective low-flow anesthesia by automating O₂ and anesthetic agent delivery.

Discover End-tidal (Et) Control software

Exclusively designed by GE HealthCare, Et Control brings a new level of automation, efficiency, and sustainability to United States anesthesia practices.

Introduction

The impact of the innovative technology behind Et Control has been demonstrated through widespread adoption outside the U.S., helping improve workflow efficiencies, reduce costs, decrease environmental impact, and drive consistency of anesthesia practices.

In this white paper, we will explore the impact and benefits of using Et Control through GE HealthCare internal data, peer-reviewed literature, and the results of a multicenter U.S. clinical trial, which was used to support the FDA Premarket Approval (PMA) process.

Specifically, we will analyze the benefits of Et Control for:

- Patients: Improved efficiency and precision of anesthetic administration.
- Clinicians: Workflow improvements, reduced cognitive load, and improved accuracy of anesthetic delivery.
- Purchasers: Reduced agent usage, reduced waste, and reduced anesthetic cost.
- Environment: Lower greenhouse gas emissions (eco-friendly)

Legacy of efficacy

Et Control was launched outside the United States in 2010 and is used in over 100 countries. Et Control has been designed, manufactured, and tested to meet the stringent U.S. regulatory requirements of a Class III medical device.

Et Control delivers individualized therapy to patients and appeals to clinicians and hospitals for its clinical efficacy, safety, cost reduction potential, and contributions to environmental sustainability.

What is Et Control?

Et Control is anesthesia delivery software* that automates repetitive, manual tasks during inhaled anesthetic administration. Using the Aisys™ CS² Anesthesia Delivery System with Et Control software (Figure 1) enables anesthesia providers to:

- 1. Set targets for end-tidal oxygen (EtO2) and anesthetic agent (EtAA).
- Automatically adjust fresh gas concentrations to quickly achieve these targets, even as the patient's metabolic and hemodynamic status changes.
- 3. Adjust anesthesia end-tidal targets during a case to meet any patient requirements.

Et Control Targets (Aisys CS² anesthesia machine)

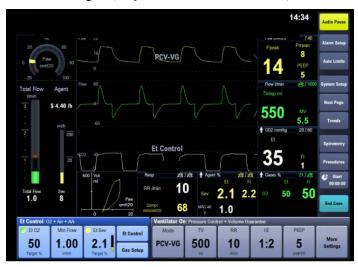


Figure 1. Aisys CS² anesthesia machine display showing end-tidal targets (bottom left panel) of EtO2 = 50%, Minimum flow rate = 1.00 l/min and Et Sevoflurane = 2.1%.



"Et Control reduces workload yet facilitates low-flow inhalational anesthesia and improves stability of vapor concentration. This allows the anesthesia provider to concentrate on patient care rather than the minutiae of vapor delivery."

Dr. Ross KennedyAnesthesiologist
Te Whatu Ora – Waitaha, Christchurch Hospital

^{*} Et Control in the United States is indicated for patients 18 years of age and older.

Safety first

To enter the U.S. market with Et Control, GE HealthCare was required to submit clinical data demonstrating equivalent safety to manual fresh gas control. The GE HealthCare Et Control Pivotal Study (Report DOC2163005) found no statistically significant difference in adverse effects.¹

In addition, supporting evidence showing the safety and efficacy of Et Control has been substantiated from multiple international peer-reviewed studies.^{2,3,5}

One study of 321 patients revealed that Et Control solves the problem of low vapor recirculation during low-flow anesthesia by "continuously monitoring vaporizer output to confirm that a safe and accurate quantity of vapor is administered". Another study added to these findings, indicating that there was "No statistical difference in the number of adverse effects between semi-automated Et Control and manual gas control."

Contributing to these safety results is proprietary Et Control technology that continually monitors and adjusts oxygen and anesthetic delivery, which removes repetitive manual tasks and reduces the cognitive burden on anesthesia providers.⁴

"The controller doesn't get distracted...This is especially true as fresh gas flow is reduced significantly below minute ventilation... Et Control adjusts delivery to maintain a constant EtO2 and EtAA."

Dr. Ross KennedyAnesthesiologist
Te Whatu Ora – Waitaha, Christchurch Hospital

In addition, Et Control provides an extra layer of protection (electronic hypoxic guard) against possible anesthetic complications due to hypoxic gas mixtures as well as under- or overdosing of the inhalational anesthetic agent.⁵

Rapid response with improved accuracy and efficiency

Anesthesia administration requires a high degree of vigilance, precision, and frequent adjustments to inhalational anesthetic agent and oxygen delivery levels. Et Control is more efficient than manual gas control for two primary reasons:

- 1. End-tidal gas monitoring and flow changes are automated and continuous.
- 2. Fewer manual adjustments to oxygen and anesthetic levels are required to maintain clinician-set targets.

Clinical studies have shown that Et Control significantly streamlines anesthesia delivery by reducing the number of keystrokes and user adjustments needed when compared to manual control.^{5,6}

One study has shown that Et Control requires 50% fewer key presses to reach target EtO2 and EtAA levels and achieves targets significantly faster than manual processes.³

As part of the GE HealthCare Pivotal study, Et Control has been shown to be twice as accurate at maintaining the desired concentration of EtO2 and EtAA (within 5%) compared to manual control (Figure 2).¹ Et Control has also shown to have a significantly smaller overshoot percentage compared to manual control.¹

According to the U.S. GE HealthCare Et Control Pivotal Study, Et Control was found to "exhibit a quicker response with a faster settling time [while maintaining] the desired steady-state concentration better than observed with the manual control group." This demonstrates that Et Control can maintain these targets at a faster rate, because breath-by-breath data captured on the anesthesia machine allows the system algorithms to respond faster than manual control to maintain target levels of O₂ and agent.



Et Control was twice as fast as manual control at reaching 90% of the target EtAA.¹



Et Control was three times faster than manual control at reaching 90% of the target EtO2.¹



Et Control is 50% faster than manual control at reaching the desired EtAA and EtO2 steady-state concentrations.¹

% Duration within acceptable limits

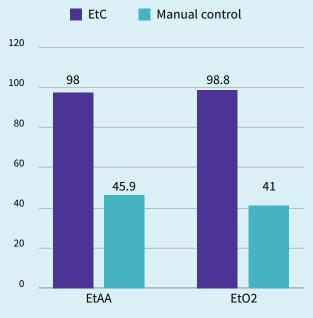


Figure 2. Et Control is twice as accurate at maintaining the set target EtO2 and EtAA concentrations (within 5%) compared to manual control.¹

Usability simplified

Et Control "provided the same clinical stability and avoided the continuous manual adjustment of delivered sevoflurane and oxygen concentrations." Therefore, anesthetists can focus on the patient and the general procedure.⁵

In fact, over 80% of the clinicians surveyed in the End-tidal Control MASTER Pivotal study reported that Et Control was easier to use with fewer adjustments to obtain the desired result.¹



of Et Control users reported it was easier to use than manual control¹ "As with many aspects of automation, a well-motivated user, concentrating only on control of vapor concentration may be able to do as well as Et Control. However, this is not a normal situation. With Et Control, we see rapid changes in vapor concentration, with changes in fresh gas flow being just enough to facilitate the change."

Dr. Ross KennedyAnesthesiologist
Te Whatu Ora – Waitaha, Christchurch Hospital

Environmentally friendly solution

Operating rooms are a significant contributor to greenhouse gas emissions within hospitals, and in some cases account for nearly two-thirds of the regulated medical waste from healthcare facilities.⁷

Using Et Control may help curb greenhouse gas emissions compared to manual control based on the ability of Et Control to optimize the delivery of volatile anesthetic agents during low-flow anesthesia, thus reducing the use of volatile agents (Figure 3).^{3,8,9}

The amount of greenhouse gas emissions that Et Control can reduce depends on the anesthesia provider's volatile agent of choice (nitrous oxide, desflurane, isoflurane, sevoflurane). Greenhouse gas emission reductions have been reported up to 44% in one study.⁸



According to Reuters, the greenhouse gases emitted by American healthcare facilities exceed those emitted by the United Kingdom as a whole. In fact, if U.S. healthcare facilities were compared to other nations, they would rank as the 13th-largest emitter of greenhouse gases globally. Here are a few more statistics that put the environmental impact into perspective:

- Using desflurane for an hour has a comparable environmental impact to driving a car 235–470 miles¹¹
- N₂O has an atmospheric lifetime of 114 years¹²
- Anesthetic gases currently represent 5% of the carbon footprint for all acute UK National Health System (NHS) organisations¹³

Given these figures, a growing contingency of anesthesia providers support a more environmentally friendly approach to general anesthesia delivery.

Et Control targets (Aisys CS² anesthesia machine)

Duration in minutes	Et Control		Manual Control	
	Mean (95% CI)	n	Mean (95% CI)	n
Fresh gas flow (liter min-1)				
<20	1.4 (1.1 - 1.7)	41	3.6 (3.3 - 3.9)	86
20 - 40	1.2 (1.1 - 1.4)	76	3.1 (2.7 - 3.5)	42
20 - 40	0.9 (0.8 - 1)	87	1.9 (1.7 - 2.1)	20
>60	0.7 (0.7 - 0.8)	117	1.5 (1.3 - 1.7)	20
Liquid sevoflurane usage (ml h ⁻¹)				
<20	15 (12 - 17)	31	33 (30 - 37)	79
20 - 40	14 (13 - 16)	55	30 (26 - 35)	34
20 - 40	11 (10 - 12)	52	20 (14 - 27)	14
>60	9 (8 - 9)	43	14 (12 - 17)	16
Liquid desflurane usage (ml h ⁻¹)				
<20	32 (25 - 39)	10	75 (50 - 100)	7
20 - 40	27 (21 - 33)	21	45 (29 - 62)	8
20 - 40	19 (17 - 20)	35	33 (30 - 35)	6
>60	17 (15 - 18)	74	33 (23 - 43)	4

Figure 3. Fresh gas flow and liquid volatile anesthetic usage categorized by duration of anesthetic. Data is presented as mean (95% CI), with anesthesia duration in minutes.³

Assessing cost reductions

Today's anesthesia providers also face rising expectations for improving the quality of patient care, practicing responsible environmental stewardship, and enhancing financial efficiencies when planning and administering an anesthetic.

Mean cost of volatile liquid agents per hour of anesthesia

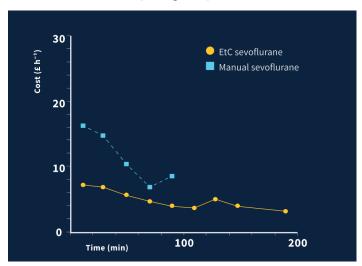


Figure 4A. Mean 2013 cost of volatile liquid agent per hour of anesthesia (£h-1) by duration of anesthetic agent using Et Control (EtC) vs. manual control with sevoflurane (A) and desflurane (B). 3

Mean cost of volatile liquid agents per hour of anesthesia

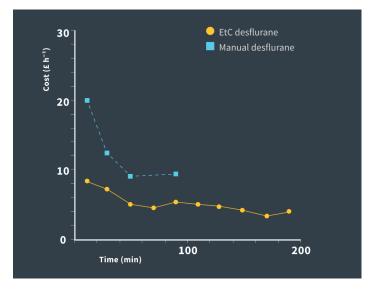


Figure 4B. Mean 2013 cost of volatile liquid agent per hour of anesthesia (£h-1) by duration of anesthetic agent using Et Control (EtC) vs manual control with sevoflurane (A) and desflurane (B).³

To meet these expectations, using Et Control to practice low-flow anesthesia can be a cost-effective option when measured against manual anesthesia procedures. Et Control has been shown to lower the anesthetic usage of sevoflurane, desflurane, and isoflurane, which translates to reduced costs for organizations (Figures 4A and 4B).^{3,8}

As one study reported, when Et Control was used instead of manual control, Et Control led to a >40% reduction in desflurane usage and a >50% reduction in sevoflurane usage. This resulted in the average cost per hour being lowered by 41% for desflurane and 53% for sevoflurane when compared to manual control.³

Simplifying the practice of low-flow anesthesia with the use of Et Control can offer significant economic benefits, with one study showing "automated control reduced costs by 27%."8

"Because of the way Et Control facilitates lower fresh gas flow (FGF), the savings in volatile consumption can be considerable. When we installed machines with Et Control, we found a payback time of about a year. Et Control truly facilitates the reduction of FGF. Early use of Et Control optimizes FGF & vapor dial setting through this phase leading to additional savings in vapor and, hence, cost."

Dr. Ross Kennedy

Anesthesiologist Te Whatu Ora – Waitaha, Christchurch Hospital

Conclusions

Et Control software on the Aisys CS² anesthesia workstation is a transformational anesthesia delivery technology for anesthesia providers in the United States. Its safety and efficacy have been validated globally for over a decade by practicing physicians, anesthesiologists, and researchers.

More recently the multicenter, clinical study GE HealthCare conducted¹ in the U.S. validated the safety and efficacy of using Et Control compared to manual control of fresh gas flows.

Et Control offers an automated and efficient method compared to manual control for administering and maintaining patient-specific end-tidal oxygen and anesthetic agent concentrations to help providers practice confident low-flow anesthesia with its many benefits.

Et Control can help drive cost savings with the benefit of having a positive environmental impact. It supports healthcare facilities around the United States – and around the world – in achieving their anesthesia delivery goals focused on safety, efficiency and sustainability.

For more information on the Aisys CS² Anesthesia Delivery System with Et Control software, please visit:

www.gehealthcare.com/etc

Et Control in the United States is indicated for patients 18 years of age and older.

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Et Control in the United States is indicated for patients 18 years of age and older. Not all products or features are available in all markets. Contact a GE HealthCare representative for more information. Please visit www.gehealthcare.com. Data subject to change.

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