



Aisys™ CS² Anesthesia Delivery System

End-tidal Control (Et Control) Software

Frequently Asked Questions

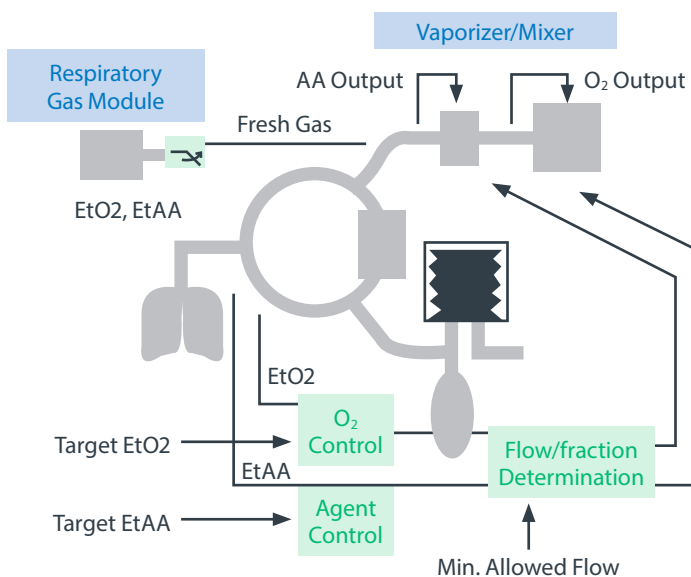


Product may not be available in all countries and regions. Et Control in the United States is indicated for patients 18 years of age and older.

Et Control Basics

How does Et Control work?

1. The user sets the target End-tidal oxygen (EtO₂) and target End-tidal anesthetic agent (EtAA) concentrations for the patient.
2. The CARESCAPE™ Respiratory Gas Module (airway module) measures current EtO₂ and EtAA concentrations at every breath.
3. Et Control compares the measured values from the airway module to the target concentrations.
4. Et Control adjusts the electronic gas mixer and vaporizer output accordingly to help achieve and maintain target concentrations.



How to make sure the system is working?

- All Aisys CS² normal self-tests continue to function.
- Before Et Control starts, the Et Control System Check makes sure that the sample line is connected to the circuit and not leaking (entraining room air). If you pre-oxygenate with 100% O₂, and there are no leaks detected, this check does not run when Et Control is entered. Otherwise, the check is run automatically when Et Control mode is entered at a total flow rate of 8 l/min at 100% O₂.
- Every 3 minutes, an Et Control Fresh Gas Sample Check verifies the calibration of the airway module. The fresh gas reading is compared to the expected fresh gas output.

What do I need to use Et Control?

- An Et Control compatible airway module must be properly installed.
 - Module type must be E-sCAiOE or E-sCAiOVE.
 - Module must be installed and warmed up.
 - Module must be properly calibrated.
- Et Control Option must be installed and enabled on the system.
- A controlled patient airway (LMA or ET Tube) – this will NOT work with face masks.
- Agent cassette type must be Desflurane, Sevoflurane and Isoflurane.
- Nominal breath rate (RR) must be between 6 and 35 breaths per minute.
- The system must register a Minute Volume.

When can I start Et Control?

- After the airway module is installed and warmed up.
- There are no failures or alarms that prevent Et Control use (any such alarms cause a message to appear when you push the Et Control button).

How long does it take to reach EtO₂ and EtAA targets?

- At a minimum flow of 0.50 l/min
 - On average, EtAA response time is 68 ± 28 seconds.
 - On average, EtO₂ response time is 130 ± 38 seconds on an increase and 228 ± 41 seconds on a decrease.
- At a minimum flow of 0.30 l/min
 - On average, EtAA response time is 93 ± 58 seconds.
 - On average, EtO₂ response time is 129 ± 24 seconds on an increase and 332 ± 100 seconds on a decrease.
 - A minimum flow option of 0.30 l/min requires that the airway module sample gas to be returned to the breathing circuit.
- Refer to the User's Reference Manual for more information on Et Control performance data.

How can I make adjustments to settings?

Adjustments can be made using the Et Control quick keys for target EtO₂, minimum flow, and target EtAA or using the facility default quick picks for EtO₂, minimum flow and EtAA.

Why do the flow meters move by themselves?

The system adjusts the flows to maintain the End-tidal targets that you set. If, for example, you push O₂ Flush, fresh gas flow increases temporarily until EtO₂ and EtAA return to set levels.

Et Control Basics *(cont.)*

What occurs during the Et Control System Check?

The system is checking to make sure the airway module sample line is connected to the circuit and not entraining room air. This is only done once during a case unless the system determines the integrity of the sample line is in question.

Where do initial settings come from?

Total flow comes from the minimum flow default set up by your facility. EtO₂ and EtAA are based on the measured values at the time you push the Et Control Start button.

What is the difference between Et Control and my current practice?

- Need to think in terms of End-tidal versus inspired settings
- Et Control includes **safety mechanisms**:
 - **Et Control System Check**
 - Verifies that there are no leaks in the patient sampling system
 - If the patient is pre-oxygenated prior to entering Et Control and no leaks are detected, this check does not run upon entering Et Control.
 - The check will run automatically when Et Control mode is entered.
 - During the check, the system delivers a high flow of O₂ with agent for up to 95 seconds to check for sample line leaks.
 - When it passes, the Et Control leak check starts, and active Et Control begins.
 - If the check does not pass, the system enters Et Control Increased Flow.
 - An Et Control System Check may be needed to re-enter Et Control Mode.
 - **Et Control Fresh Gas Sample Check**
 - Verifies the calibration of the airway module
 - Check runs approximately every 3 minutes while in Et Control Mode.
 - A fresh gas sample is taken from the anesthesia system instead of the sample line at the breathing circuit.
 - The fresh gas reading is compared to the expected fresh gas output.
 - If the reading is out of limit, the check fails.
 - The airway module may need calibration.
 - Automatic exit of Et Control occurs if the check does not pass.

– Et Control Supervisor

- Safety measure to prevent incorrect delivery of O₂ and Agent
- System enters Fresh Gas Control in the event of an Et Control Supervisor failure.
- Automatic exit of Et Control occurs if the target agent and target O₂ are not achieved.

– Et Control Increased Flow

- Certain issues cause the fresh gas flow to automatically be set to 6 l/min.
- Et Control remains active during the increased flow state.
 - Fresh gas concentrations are delivered to maintain a steady state; therefore, changes to new Et target settings may be slower.
- Most issues are temporary, and the normal flow control is resumed automatically when the issue is resolved.
- When an increased flow condition is caused by a sample line leak, resume flow control through the Et Control menu.
- For all increased flow conditions, help information is available in the Et Control menu.

What conditions cause Et Control to Auto Exit?

Malfunctions or conditions not likely to self-correct cause the system to alarm and exit Et Control. The settings upon exiting are: Agent% = set Et Agent; O₂% = Set EtO₂ + 5% (at the CGO); Total flow = flow at time the exit occurred. In practical terms, this helps ensure concentrations stay stable.

Auto Exit conditions:

- Detected agent does not match the vaporizer cassette (if not matching EtAA \geq 0.35 Mac).
- Vaporizer failure
- During the Et Control Fresh Gas Sample Check, the measured fresh gas concentration differs from the commanded value.
- Oxygen supply pressure low
- Balance gas supply pressure low
- Airway module disconnected
- Any other alternate O₂ delivery condition

Et Control Basics (cont.)

What conditions cause an additional Et Control System Check?

When valid information to continue Et Control is missing, the system goes to an increased flow (6 l/min at $O_2\% = \text{Set EtO}_2 + 5\%$ (at the CGO); $\text{Agent}\% = \text{Set EtAA}$). This is due to a potential sampling system leakage; a new Et Control System Check is required before re-activation of Et Control.

Below is a table of conditions that may cause the system to repeat the Et Control System Check following an increased flow state.

Condition	System Check?*
Monitor occlusion	Yes
Monitor air leak	Yes
Monitor check D-fend™ water trap	Yes
Sampling line leak	Yes
Performing sample line leak check	No
Sample line leak check failed	Yes
No breaths received (Apneic period)	No
Respiration rate <6 or >40	No
Average FiCO_2 of last 9 breaths $\geq 2\%$ if FiCO_2 alarm off or > alarm limit is set	No

*System Check is needed on recovery

What are the benefits of using Et Control?

- Improved workflow through fewer interventions with the anaesthesia machine
- Potential for significant cost savings due to conservation of volatile agent
- Lower environmental emissions due to conservation of volatile agent
- Agent delivery optimization
- Wider participation in low-flow anaesthesia

What can go wrong using Et Control?

There are a number of safety mechanisms in place when using End-tidal Control and these safety mechanisms aim to prevent anything from going wrong or notify the user if it does. These checks run independently of the pre-operative checks.

What clinical preparation or pre-use check is needed to use Et Control?

- An airway module must be properly installed and warmed up.
- Proper connection of the fresh gas sample line is verified during the Full Test that is run as part of the pre-operative checkout.

Et Control and the Patient

Can I use Et Control with a nasal cannula?

No. Et Control only functions with a controlled airway. It will not work with a face mask or non-invasive ventilation.

Additional changes made right after the initial Et Control settings are quite a bit slower - why?

The system waits 5 breaths between rapid step changes. During this time, normal adjustments happen via the algorithm, but there is no additional boost.

Which patient types can be used with Et Control?

- The maximum respiratory rate (<35 bpm) excludes very small preemies/neonates.
- In extremely obese patients, reaching set agent targets may take longer with fat soluble agents.
- Et Control in the United States is indicated for patients 18 years of age and older.

What happens if my patient's cardiac output changes?

The system adds more or less oxygen and agent to maintain the set targets.

What happens if my patient's dead space changes?

The system adds more or less oxygen and agent to maintain the set targets.

What happens with a patient who has atelectasis?

Et Control software attempts to maintain concentrations. Medical intervention may be required to treat atelectasis.

Can Et Control be used in one-lung ventilation patients?

Yes.

Can Et Control be used with a patient that has a chest tube or punctured lung?

No, as the circuit is now open to a potentially large leak.

What happens to Et Control during apnea?

Gradually Et Control goes to an increased flow state of 6 l/min.

Can Et Control be used during cardiac bypass?

It cannot be used during bypass since the system is not registering any respiratory rate.

Et Control and the Patient *(cont.)*

What happens with prone, supine, and lateral positional changes?

Transient changes in Et concentrations may cause flow and agent adjustments.

What happens when I place my patient in trendelenburg or reverse trendelenburg position?

It will continue to work as designed, but there will be some temporary fluctuations as the gas delivery adjusts to the likely changes in lung compliance as the position changes.

What happens if gases leak around the ET Tube or LMA?

- If the clinician notices the bellows are collapsing, he/she should increase the minimum flow setting. This will keep the system working correctly as long as the sum of the leak and patient uptake is less than 6 l/min. If this is exceeded, the bellows will go down and eventually collapse.
- Et Control will increase flows automatically if a higher flow rate is needed to achieve the correct EtO₂ and EtAA concentrations. Best way to overcome a large leak in the system is to exit Et Control and resume Fresh Gas Control.

What do I do at the end of the anesthesia case?

- If the patient breath rate falls to <6 bpm, the system will go to an increased flow state of 6 l/min. You may want to exit Et Control to avoid additional alarms.
- If you need to wake the patient as soon as possible, select **Purge**. Otherwise to continue, just turn the EtAA setting to **Off**.

What do I do when I use bronchodilator drugs?

Temporarily disconnect the gas sample line to inject or nebulize the drug. If the bellows collapse, push the flush button to fill the bellows, and the system will automatically return to equilibrium.

What happens if the surgeon asks to pause ventilation?

As long as the CO₂ respiratory rate remains >5 bpm, Et Control will function normally.

What happens when I disconnect my patient for suctioning?

- When the patient is disconnected from the breathing circuit for suctioning, the breath pattern is lost, and the Et Control algorithm enters an increased flow state of 6 l/min.
- Et Control returns to normal operation automatically when breaths are detected. If the bellows are collapsed, you can push the O₂ Flush button to fill the circuit and bellows. The algorithm corrects for excess O₂.

How does Et Control mitigate Desflurane changes that can cause profound changes in blood pressure?

- Maximum Desflurane setting is limited to 2 MAC as compared to 18% conventionally. Also, the algorithm ensures there will only be one large step change every 5 breaths.
- Since response time to achieve the End-tidal target is constant, the Et Control algorithm provides a similar response time across a wide range of patients and a variety of target setting changes. The clinician can then use a step approach (setting incrementally increasing targets of Desflurane) until the desired target is reached to help avoid blood pressure effects.



Et Control and Aisys CS²

Are EtAA and FiAA high/low alarms still active in Et Control?

Yes, if they are on and limits are violated.

Can I still use the D-lite™ sensor for spirometry?

Yes, no problem.

Can I change the D-fend water trap or swap airway modules in the middle of the case?

Yes, but the system will Auto Exit from Et Control to Fresh Gas Control. To start Et Control again select Et Control > Start > Confirm EtAA settings. Upon entering Et Control, the system will complete an Et Control System Check before resuming Et Control.

What percent savings can I expect on agent and gas?

Depends on your current practice.

Can the system measure VO₂ and VCO₂ when using Et Control?

No, metabolic measurements are not available.

How can I verify that Et Control is performing optimally?

- Use the Et Control log to view a record of Et Control actions during a case.
 - The log records date, event, target EtAA%, AA flow ml/h, EtAA%, target EtO₂%, mixer O₂%, EtO₂%, minimum flow, total flow, Air or N₂O, and Des, Sev, or Iso.
- Select the flow tube split screen to see real-time agent usage and gas flows.
- Verify that the measured EtO₂ and EtAA values are close to the settings.
 - The Et Control Supervisor will switch the system to Fresh Gas Control if the target settings are not able to be achieved for approximately 30 seconds.

Will Et Control work in manual ventilation?

Yes, so long as the patient breath rate remains above 5 bpm.

What is the difference between Off and Purge?

- **Purge** goes to 10 l/min and turns off the vaporizer to flush agent as rapidly as possible.
- **Off** lets agent decrease naturally by stopping any further delivery of agent to the circuit (e.g. closes the vaporizer). Flow is NOT automatically increased when **Off** is selected.

Will increasing minimum flow make the changes happen any faster?

No. The system automatically increases flows to achieve target settings regardless of the minimum flow setting.

What happens if the balance gas is changed from N₂O to air? Will the system maintain the O₂ target as set or try to wash out previous gas?

- System maintains set EtO₂ target despite secondary gas changes.
- In addition, flows are increased to drive out the previous balance gas.

What happens if one agent is used in the induction room and a different agent is used in the OR?

You cannot start Et Control if the measured agent is ≥ 0.25 MAC.

What happens if my O₂, N₂O or air supply fails?

- Et Control will stop. Use Fresh Gas Control until the gas supply pressures are within allowable range then re-enter Et Control.
 - Pipeline pressures must be more than 252 kPa (36 psi).
 - Cylinder pressures must be more than 2633 kPa (381 psi).

What happens if the airway module fails?

- Et Control stops. Check and/or replace the airway module.
- If replaced, allow airway module to warm up, complete Et Control System Check before re-entering Et Control mode.



Et Control and Aisys CS² (cont.)

Does it work with SIMV mode?

Yes, but the minimum breath rate applies.

Does it work in PSV mode?

Yes, but the minimum breath rate applies.

What happens with O₂ flush?

- Clinical uses of oxygen flush are:
 - Rapid increases of circuit O₂ concentration is associated with need to increase Set O₂.
 - Rapid filling of the circuit is associated with need to continue with the current settings.
 - Rapid circuit clearance from the anesthetic agent is associated with the need to reduce Set AA.
- Because the system cannot identify the need for pressing the oxygen flush, the algorithm continues with current targets.

What fresh gas flow rates should be used?

- The system automatically makes up for leaks, so set the lowest minimum fresh gas flow you are comfortable with.
- The factory defaults for minimum flow are 0.50 l/min for Isoflurane and Desflurane, and 2.00 l/min for Sevoflurane.

What do I have to do to swap or refill a vaporizer?

1. Turn the vaporizer off, and then remove it to fill.
2. Insert the refilled or replacement cassette of the same agent and confirm the EtAA target.

If changing to a different agent, you will not be able to continue with Et Control if the measured agent is ≥ 0.25 MAC.

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May 2022
JB00077XX

