Aisys CS² Et Control option

User's Reference Manual

Software Revision 12



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Et Control option

This addendum describes the function of Et Control mode. Use this addendum along with the product User's Reference manual.

The clinician sets the target end tidal O2 (EtO2) and target anesthetic agent (EtAA) values. The system monitors the EtO2 and EtAA values and adjusts the gas composition and total flow to maintain the set target values. The clinician prescribes and sets the dose target EtAA and EtO2 values for the patient based on the appropriate drug labeling and his or her clinical judgment. The Et Control feature does not provide dosing guidance or alter the dose that is prescribed by the clinician.

A patient airway (for example, endotracheal tube or laryngeal mask airway) must be in place and controlled while using Et Control mode. Et Control mode cannot be used with a mask airway. Et Control can be used in vent mode (mechanical ventilation) or bag mode (manual ventilation) as long as a patient airway is in place and ventilation meets the patient gas demand. Irregular ventilation patterns in bag mode involve increased risk for automatic exit of Et Control to Fresh Gas Control.

The system must have a supply of O2 and balance gas to enter Et Control mode. Safety checks run on the system while in Et Control mode. See "*Et Control theory of operation*" for specific check information.

Et Control cannot be used with halothane, enflurane, non-circle circuit, cardiac bypass, Alternate O2, and Air only modes. It is recommended that Et Control mode not be used during cases that have disturbances to the lungs such as chest surgery.

- **WARNING** The system may deliver 100% O2 while in Et Control mode. Do not use Et Control if delivery of 100% O2 could injure the patient.
 - Fire hazard. Do not use electrosurgical equipment that cannot be used in the presence of oxygen while in Et Control mode.
 - Et Control mode stops if an anesthetic agent type change is made while Et Control mode is active. Exit Et Control mode before changing an agent type.
 - Et Control mode repeatedly enters the increased flow state if a mask airway is used for the case and/or if the case has disturbances to the lungs such as chest surgery.

Information

Indications for use

The optional Et Control feature is designed to interface with the Aisys CS2 Anesthesia System to support clinicians in maintaining the targeted end tidal oxygen and end tidal anesthetic agent concentrations that the clinician sets during an anesthetic procedure, by making multiple, limited adjustments to the fresh gas composition and total flow. The Et Control feature is indicated for patients, 18 years of age and older.

Training

A GE approved training curriculum is provided for all US customers who use Aisys CS2 with Et Control. All users are required to complete the training curriculum which includes passing a knowledge assessment prior to the use of Aisys CS2 with Et Control.

Et Control setup and connections

WARNING Anesthetic agent can enter the room air due to a patient circuit leak or disconnection while Et Control mode is in use.

The system requirements to use Et Control mode include:

- Et Control option must be installed and enabled on the system.
- For CARESCAPE airway modules, a D-fend Pro must be installed in the airway module.
- Either no agent cassette installed in the system or an agent cassette properly installed in the system. Agent cassette type must be desflurane, sevoflurane, or isoflurane.
- Measured CO2 respiratory rate (RR) must be 35 breaths per minute or less. The system must be registering a minute volume.
- The specified airway module requirements must be met.

Airway module requirements for Et Control mode:

- Module type must be E-sCAiOE or E-sCAiOVE.
- Module must be installed and warmed up.
- Module must be properly calibrated.
- **Note** Use of airway modules E-series (E-CAiO, E-CAiOV, E-CAiOVX) or M-series (M-CAiO, M-CAiOV, M-CAiOVX) does not comply with IEC 60601-1-2:2014 standard.
- **Note** Proper connection of the fresh gas sample line is verified during the *Full Test*. A message displays in the test window if the test fails.

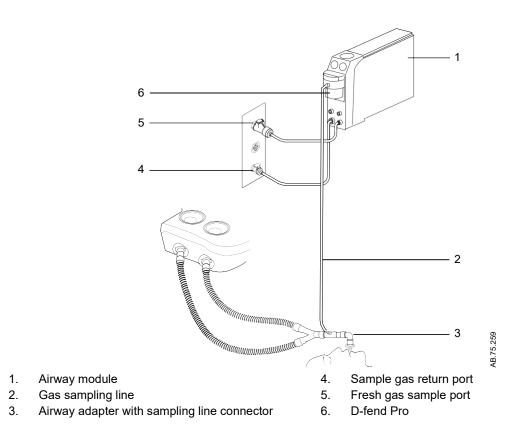


Figure 1 • CARESCAPE airway module setup with Et Control mode

- **Note** The preoperative checkout looks for the presence of an Et Control compatible airway module. A message displays in the checkout menu if the airway module is not present.
- **Note** When the Airway Module D-fend Pro water trap fills with water it can cause an alarm that transitions the system to the Et Control Increased Flow mode. To clear the alarm, drain/remove water from the D-fend Pro and reconnect D-fend Pro to Airway Module.

Symbols used in Et Control mode

Symbols replace words on the equipment, on the display, or in product manuals.

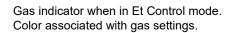
Warnings and Cautions tell you about dangerous conditions that can occur if you do not follow all instructions in this manual.

Cautions tell about a condition that can cause damage to the equipment. Read and follow all warnings and cautions.

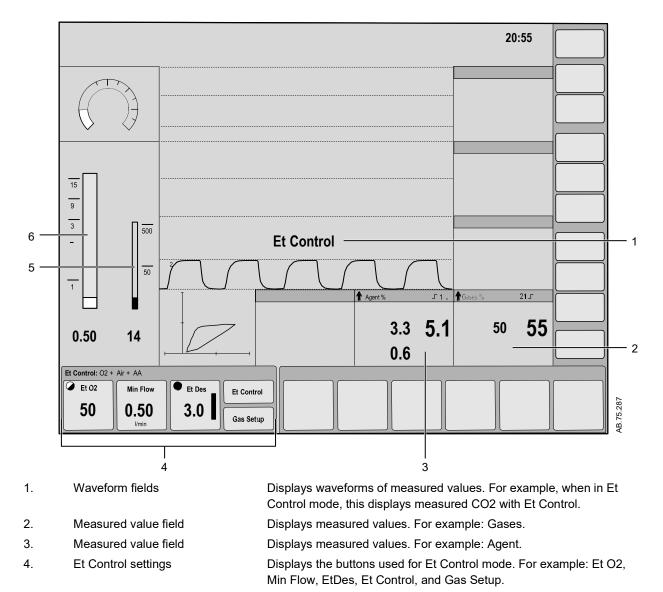


O2% indicator on left and balance gas indicator on right when in Et Control mode. Colors associated with gas settings.

Enhanced temperature sensing when in Et Control mode.



Et Control display



- 5. Vaporizer output
- 6. Electronic gas flow indicator
- Displays the measured value of agent output. Displays the measured value of total gas flow.

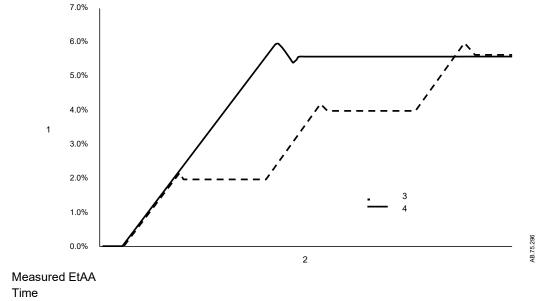
Figure 2 • Et Control view

Using Et Control

Use the *Et Control* menu to start, stop, and resume Et Control mode. Use the gas quick keys to adjust the Et Control settings. Return to fresh gas delivery at any time.

Important Rapid increases of desflurane concentrations have been associated with sympathetic activation. Et Control achieves the target settings quickly. The response time that Et Control takes to achieve the target settings is constant (not user adjustable). This behavior is intended to provide a similar response time for a wide range of patients and a variety of target setting changes. The target settings may be achieved in steps if a slower wash in is desired. For example, if a target EtDes of 6.0% is the desired end target setting, set the first target to 2.0%, then 4.0%, and ultimately 6.0%.

The maximum value within the "*Et Control algorithm and controller* Note range" (Des 18%, Iso 5%, Sev 8%) may be delivered in Et Control. The actual values inspired by the patient (FiAA) and expired by the patient (EtAA) will be considerably lower as the agent is diluted in the circuit. The Et Control algorithm is specified to not allow the measured EtAA value to overshoot the user set Target EtAA by more than 0.2 MAC or 30% of setting (whichever is greater). This ensures there is not a significant increase above the clinicians' desired values. When the user set Target EtAA value is achieved, the vaporizer setting is then lowered to maintain the user set Target EtAA value.



- 1.
- 2.
- 3. Step
- 4. Quick

Figure 3 • Steps to target EtAA

Starting Et Control

WARNING Ensure that alarm limits are appropriate for the patient before starting Et Control. If the alarm settings are incorrect a condition that requires immediate action by the user to prevent harm to the patient may not be recognized.

- 1. Select *Et Control*.
- 2. Select Start.

The target EtO2 and target EtAA are set to the current measured Et values.

Gas flows and agent delivery adjusts as needed to meet target EtO2 and target EtAA.

The target EtAA quick key is highlighted.

- 3. Confirm or adjust and confirm the target EtAA setting.
- **Note** If the conditions to enter Et Control are not met, instructions show in the window to help correct conditions to allow Et Control mode.

Stopping Et Control

- 1. Select Et Control.
- 2. Select **Stop**.

Fresh gas control mode resumes at values based on the target Et O2 and target EtAA settings.

The agent quick key is highlighted.

3. Confirm or adjust and confirm the agent setting.

Changing Et Control settings using quick keys

Gas quick keys while in Et Control mode show the target EtO2%, minimum flow I/min, and target EtAA%. Adjust these settings by pushing the corresponding quick key.

Note If target EtO2 is set to Max, the fresh gas is 100 % O2 and anesthetic agent is added and pushed to the circle breathing system. The measured EtO2 is less than 100 % because other gases (CO2 and agent) are present in the exhaled gas. If the measured EtO2 falls below 80 %, flows increase to attempt to maintain that level of EtO2.

- 1. Select the quick key to select the corresponding setting.
- 2. Turn the ComWheel to the desired value.
- 3. Push the ComWheel or select the quick key to confirm the change.
- **Note** After adjusting EtAA%, an estimated MAC (MACe) value is shown on the quick key. This is the corresponding age MAC adjusted value for the adjusted EtAA value. This estimated value is based on the current N2O value.

Vaporizer settings and output

The graphs below show the Vaporizer setting from controller at common Total Flow values used by Et Control. The Vaporizer Output shown on the Split Screen is the liquid anesthetic agent (ml/h) in use.

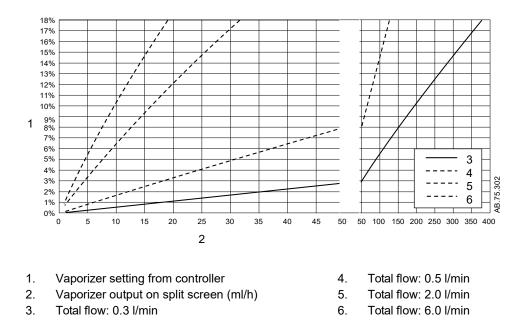


Figure 4 • Desflurane Vaporizer Setting (%) And Vaporizer Output On Split Screen (ml/h)

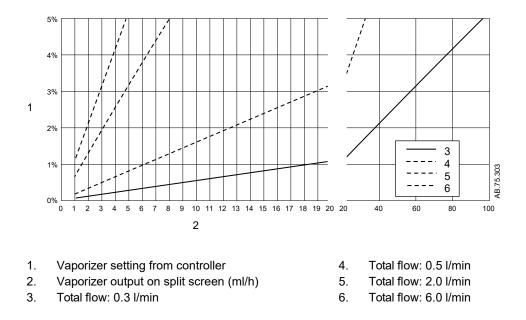
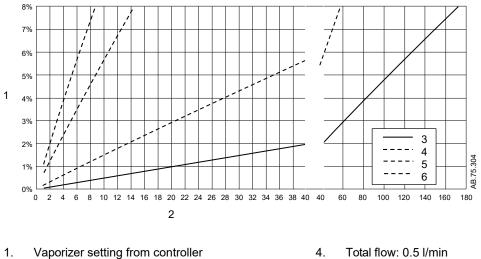


Figure 5 • Isoflurane Vaporizer Setting (%) And Vaporizer Output On Split Screen (ml/h)



2. Vaporizer output on split screen (ml/h) 3. Total flow: 0.3 l/min

- Total flow: 0.5 l/min
- 5. Total flow: 2.0 l/min
- 6. Total flow: 6.0 l/min

Figure 6 • Sevoflurane Vaporizer Setting (%) And Vaporizer Output On Split Screen (ml/h)

Washing agent out of the system

Turning agent off during Et Control

Use the **Off** setting in the target EtAA quick key to shut agent Off. This is equivalent to turning the vaporizer off without changing the fresh gas flow. When turning off the vaporizer, the anesthetic agent concentration will slowly decrease based on the fresh gas flow.

Et Control: O2 + Air + AA				
Et 02	Min Flow	Et Sev	Et Control	
50	∎ I/min	Off Target %	Gas Setup	AB.75.297

Figure 7 • EtAA Off quick key

- 1. Select the target EtAA quick key.
- 2. Select Off.

Agent delivery stops. No additional agent is added to the breathing system.

Flows are controlled based on oxygen and balance gas concentrations.

Purging agent during Et Control

Use the *Purge* setting in the target EtAA quick key to drive agent out of the system as fast as possible.

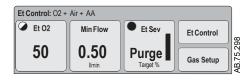
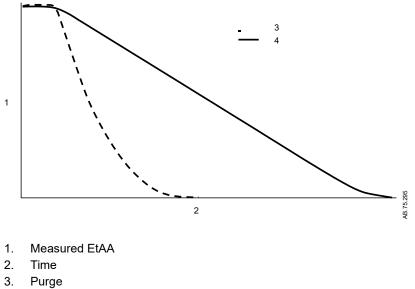


Figure 8 • EtAA Purge quick key

- **WARNING** Do not remove the agent cassette while the target EtAA is set to *Purge*. Removing the agent cassette causes the target EtAA to set to Off, resulting in slower removal of agent out of the system.
 - 1. Select the target EtAA quick key.
 - 2. Select *Purge*. Agent delivery stops.

Fresh gas flow is set at 10 l/min.



4. Off

Figure 9 • Purge versus off

Et Control log

Use the System Setup menu to access the Et Control log.

A record of the Et Control mode actions during a case can be viewed in the Et Control log. 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.

Entries are saved at event change. The log is capable of displaying up to 19 entries at a time with at least 2500 entries total. The log is cleared at the start of a case. When system power is shut off or lost, data from the most recent case is saved.

Viewing Et Control log

- 1. Select System Setup.
- 2. Select *Et Control Log*.
- 3. Select *Scroll*, *Next Page*, *First Entry*, *Last Entry*, or the cursor to scroll through the current log page.
- 4. Select *Close* to exit the Et Control Log.

Et Control alarms

Message	Priority	Cause	Action
Et Control stopped. Adjust settings.	Medium	Multiple possible causes.	Safeguard the patient. Verify that the gas delivery settings are appropriate. Go to the Et Control menu to view the actions needed to resolve the alarm.
Push Et Control. Flow is 6 l/min.	Medium	Multiple possible causes.	Safeguard the patient. Go to the Et Control menu to view the actions needed to resolve the alarm.
Sample line leak. Check sample line	Medium	Leak detected in the airway module sample line.	Check the airway module sample line connections. Replace the sample line if condition continues. Go to the Et Control menu. Select Resume Flow Control to restart Et Control.

Et Control error conditions

The following error conditions causes an automatic exit from Et Control to Fresh Gas Control:

- Alternate O2 mode active
- O2 or Air pipeline pressure is invalid
- O2, Air or N2O pipeline pressure is low
- Airway Module data missing or invalid
- Selectable Common Gas Outlet (SCGO) failure
- Ventilator Failure activate
- Vaporizer Failure active
- Invalid agent cassette detected
- Halothane or Enflurane agent cassette detected
- Multiple agent types detected
- **Note** The measured end-tidal value of the secondary agent must be greater than 0.35 MAC Age for automatic exit to occur.
 - Cardiac Bypass mode active
 - Non-Circle mode active
 - Et Control Fresh Gas Sample Check failure
 - Et Control Supervisor failure
 - Et Control Internal Error

The following error conditions will cause the software to transition to Et Control increased flow state:

- Measured CO2 RR is greater than 40
- Measured CO2 RR is less than 6
- No CO2 breaths detected for a period of time
- High FiCO2 detected
- Airway Module sample gas out blocked
- Airway Module sample line blocked
- Airway Module sample line disconnected
- Airway Module sample line leak
- Unknown agent detected
- Et Control System Check failed
- Et Control Leak Check failed

Et Control troubleshooting

Use the help information shown in the Et Control help window to resolve Et Control alarms. Select *Et Control* to access the Et Control help window.

Help message	Symptom	Problem	Solution
Use Fresh Gas Control. Start Et Control when previous agent is removed from the circuit.	Et Control has stopped during an agent change.	Et Control does not function during an agent change.	During an agent change, use fresh gas control mode until the previous agent is cleared out of the system before restarting Et Control mode. Use fresh gas control until previous agent registers less than 0.35 MAC. Re-enter Et Control.
Et Control requires sufficient gas supply pressure.	Et Control has stopped. Gas supply pressure alarms occur.	The O2 and/or the balance gas supply pressures are out of the allowable range for Et Control.	The O2 and balance gas pipeline pressures must be more than 252 kPa (36 psi). The O2 and balance gas cylinder pressures must be more than 2633 kPa (381 psi). Check that the pipelines and cylinders are properly connected. Use fresh gas control until the gas supply pressures are within the allowable range. Re-enter Et Control.
Et Control requires a Fresh Gas Module. Check gas module connections.	Et Control has stopped. Help information shows fresh gas module is required.	The fresh gas module used with E and M-series airway modules has become disconnected.	Check that the fresh gas module is properly connected. If the condition continues, contact an authorized service representative.
Use Fresh Gas Control. Calibrate gas module when possible.	Et Control has stopped. Help information indicates Fresh Gas Sample Check failure.	The fresh gas sample check failed.	Check the airway module sample line for kinks. After the case, calibrate the airway module. If multiple failures occur following an airway module calibration, contact an authorized service representative.
Target settings not achieved. Use Fresh Gas Control.	Et Control has stopped. Help information indicates Et Control supervisor failure.	Target EtO2 and/or target EtAA was not achieved.	The case conditions may not allow the use of Et Control. If multiple failures occur under different case conditions, contact an authorized service representative.
Enter Et Control again.	Et Control has stopped. Help information indicates enter Et Control again.	Multiple possible causes.	Re-enter Et Control. If issue continues, finish the case using fresh gas control. Contact an authorized service representative.
Sample line leak. Check sample line. Then select Resume Flow Control to continue with low flows.	Flow is 6 l/min during Et Control. Help information indicates a sample line leak.	Leak detected in the airway module sample line.	Check the airway module sample line connections. Replace the sample line if condition continues. Select Resume Flow Control to restart Et Control.

Help message	Symptom	Problem	Solution
Flow is 6 I/min until CO2 breaths are detected. Check gas module connections.	Flow is 6 l/min during Et Control. No breath detected.	No breath detected prevents Et Control.	Safeguard the patient. Check the airway module sample line connections. Check breathing circuit connections.
FiCO2 detected. Try replacing the CO2 absorber.	Flow is 6 l/min during Et Control. FiCO2 high. Absorbent OK? alarm already exists or occurs at the same time.	FiCO2 high issue is detected.	Determine if the FiCO2 level is appropriate. If the FiCO2 level is not appropriate or CO2 bypass is activated, replace the absorbent. If the FiCO2 level is appropriate, adjust the FiCO2 High alarm limit. Et Control enters increased flow mode if FiCO2 is greater than 1% or the alarm limit (whichever is higher) or greater than 2% if the alarm limit is set to Off.
Gas module valve malfunction. EtControl will not be available. Install a different gas module to use EtControl.	Unable to enter Et Control or Et Control has stopped. Help information indicates gas module valve malfunction.	The CARESCAPE airway module fresh gas sampling valve failed to function.	Contact an authorized service representative to fix the valve malfunction. Install a different gas module to use Et Control.

Help message	Symptom	Problem	Solution
Several possible messages	Unable to enter Et Control.	Blocked from entering Et Control.	Review the alarm conditions of any active alarms to resolve the alarm. Go to the Et Control menu to see the Et Control specific help information. Correct the conditions blocking Et Control. Try to enter Et Control again.
Several possible messages	Et Control has stopped. Additional system alarm occurs at the same time.	The alarm conditions prevent Et Control.	Review the alarm conditions to resolve the alarm. Go to the Et Control menu to see the Et Control specific help information.
Several possible messages.	Flow is 6 l/min during Et Control. An airway module alarm occurs at the same time.	Airway module condition prevents Et Control.	Review the alarm condition to resolve the alarm. The system check runs after the alarm is resolved.

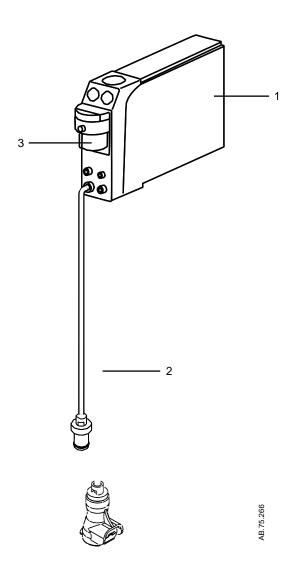
Et Control Checkout troubleshooting

Use the help information shown in the Checkout troubleshooting text to resolve Et Control related messages during Checkout.

Troubleshooting text	Symptom	Problem	Solution
To use Et Control, install the fresh gas module. Check gas module connections. Calibrate gas module?	The Airway Gas Module step in the Vent and Gas step of Checkout has ended with a Conditional Outcome.	The measured value for O2, Air and/or N2O did not fall within the specified limits during the Airway Gas Module step.	The airway module accuracy is not at full specification until it has been installed and powered for 20 minutes. If this Troubleshooting text was seen within 20 minutes of airway module installation, re-run the Vent and Gas test after the airway module has been installed for 20 minutes. If this troubleshooting text is seen after the airway module has been installed and running for 20 minutes, check all airway module connections and calibrate the airway module.
To use Et Control, use a gas module with fresh gas sampling.	The Airway Gas Module step in the Vent and Gas step has not detected an Et Control compatible airway module.	The airway module that is installed does not have a fresh gas valve (which is required for Et Control and indicated by an "E" in the airway module type).	Install an airway module with a fresh gas valve (which is required for Et Control and indicated by an "E" in the airway module type).

Et Control parts

CARESCAPE airway module



Item	Description	Stock Number
1	Airway module model E-sCAiOE	M1221474
	Airway module model E-sCAiOVE	M1199131
2	Fresh gas sample tubing and connector	2063483-001
3	D-fend Pro water trap (pack of 10)	M1182629

Et Control theory of operation

Et Control is an optional gas delivery mode. The clinician sets the target end tidal O2 (EtO2) and anesthetic agent (EtAA) values for the patient based on the drug labeling and the clinician's judgment. The Et Control feature does not provide dosing guidance or alter the dose that is prescribed by the clinician. The system monitors the EtO2 and EtAA values and adjusts the gas composition and total flow to maintain the set target values. The Et Control algorithm is updated for each new patient detected breath, as reported by the airway module.

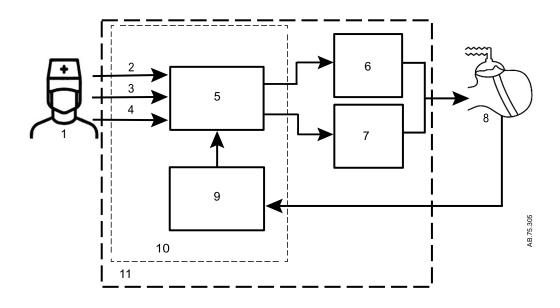
The minimum flow setting for Et Control mode safeguards the patient by maintaining at least the minimum set flow delivered to the patient. Increasing the minimum flow does not affect the speed of change to achieve target concentrations.

Safety mechanisms protect the patient during Et Control mode. Safety mechanisms include the delivery of increased flows when temporary issues arise. For example, a leak detected in the patient sampling system. Automatic return to active Et Control resumes when the issue is resolved.

Automatic exit from Et Control occurs for issues that require clinician interaction to resolve or cannot be resolved during a case. For example, airway module calibration required. Manual re-entry into Et Control is required.

Checks occur before active Et Control is allowed and continue to run while in Et Control. The Et Control fresh gas sample check guards against incorrect delivery due to faulty airway module readings. The Et Control system check and Et Control leak check guard against incorrect delivery due to sample line issues such as leaks. The Et Control supervisor is an additional safeguard to ensure that the system is able to control gas and agent delivery to meet the targets.

See "Safety mechanisms" for more information.



- 1. User
- 2. Target EtO2
- 3. Minimum flow
- 4. Target EtAA
- 5. Et Control algorithm
- 6. Electronic gas mixer
- 7. Electronic vaporizer
- 8. Patient
- 9. Airway module

- 10. Et Control safety mechanisms
- Et Control system check
- Et Control leak check
- Et Control fresh gas sample check
- Et Control supervisor
- Et Control increased flow
- Et Control auto exit
- 11. Anesthesia machine
- Figure 10 Et Control block diagram

Safety mechanisms

Safety mechanisms include Et Control system check, Et Control leak check, Et Control fresh gas sample check, and Et Control supervisor. The safety mechanisms function automatically when entering Et Control mode. These checks are run during Et Control mode independent of the tests performed during the preoperative checkout.

Et Control system check

The Et Control system check verifies 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. Otherwise, the check runs 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.

The Et Control system check fails during the following situations:

- The measured FiO2% is less than or equal to (92.1% 0.9* measured EtAA%).
- The measured leak in the sampling flow is greater than 30%.

The Et Control system check runs during the following situations:

- After selecting **Resume Flow Control** in Et Control increased flow state.
- After terminating a Pause Gas Flow procedure before timing out.
- When the 'Check sample gas out' alarm is removed.
- When the 'Sample line blocked' alarm is removed.
- When the 'Check D-Fend' alarm is removed.

When the Et Control system check passes, the Et Control leak check starts and active Et Control begins.

The system enters Et Control increased flow if the check does not pass. An Et Control system check may be needed to re-enter Et Control mode.

Et Control leak check

The Et Control leak check runs after the Et Control system check passes. The CO2 and O2 are tracked for movement toward ambient. (Ambient CO2 is 0% and ambient O2 is 21%.) If a leak is detected, the check fails and the system enters Et Control increased flow. The Et Control leak check fails if the measured leak in sampling flow is greater than 15% of the leak in sampling flow measured during the Et Control System Check.

Et Control fresh gas sample check

The Et Control fresh gas sample check verifies the calibration of the airway module. This check runs approximately every 3 minutes while in Et Control mode and lasts approximately 13.2 (+/- 0.2) seconds. Using the fresh gas sample port, a fresh gas sample is taken from the anesthesia system instead of from 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. The Et Control Fresh Gas Sample Check does not have any effect on the Apnea alarm timing.

Et Control supervisor

Et Control supervisor is a safety measure to prevent incorrect delivery of O2 and agent. The system enters fresh gas control in the event of an Et Control supervisor failure.

The Et Control supervisor fails during the following situations:

- The average measured EtO2 of the last three breaths is <18%.
- The EtAA measured is more than 1/2 MAC different from the set Target EtAA for 30 seconds (under most scenarios).

There are a few scenarios where the supervisor time limit is extended or an alternate limit is used to avoid nuisance scenarios that would unnecessarily exit the user from Et Control, when the system was in fact behaving as intended. These situations include scenarios such as:

- Target EtAA is set to OFF by the user (when EtAA is set to OFF, there is no "target" that the system is trying to achieve)
- O2 Flush is selected by the user (O2 Flush temporarily alters the O2 and agent levels in the circuit)
- During the initial period after a Target EtAA change or upon entering Et Control, limits are adjusted to allow appropriate time to reach the new targets (based on the expected response and settling times)

Et Control increased flow

Certain issues during Et Control cause the fresh gas flow to automatically be set to 6 l/min. Et Control remains active during this increased flow state. The fresh gas flow is set to 10 l/min when Vital Capacity or Cycling is active. This is done to prevent the bellows from collapsing during the procedure. The fresh gas concentrations

Et Control option

are delivered to maintain a steady state; therefore, changes to new Et target settings may be slower. Most of the 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.

Et Control algorithm and controller range

Parameter range used by the Et Control algorithm and the user setting range availble in fresh gas control.

Parameter	Et Control mode algorithm and controller range	Fresh gas control user setting range
Fresh gas flow	0.3 l/min to 10 l/min	0.2 l/min to 15 l/min
02%	25% to 100%	Balance gas Air: 21% to 100% Balance Gas N2O: 25% to 100%
AA% (Des)	0% to 18%	0% to 18%
AA% (Iso)	0% to 5%	0% to 5%
AA% (Sev)	0% to 8%	0% to 8%

Et Control mode examples

The display changes through a cycle of fresh gas control to Et Control mode and during a setting change in Et Control mode are shown in the following examples. The electronic flow tube, numerics, and quick key areas on the display are important areas to focus on during Et Control mode.

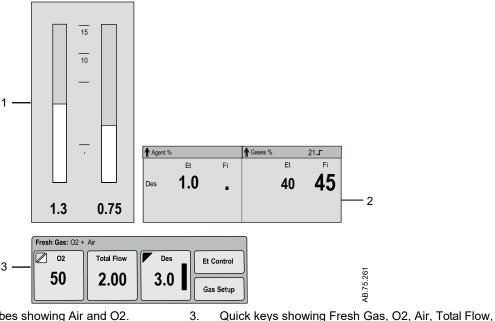
Fresh gas control example

During fresh gas control before entering Et Control mode, the total flow is set to 2.0 l/min with 50% O2 and agent is set at 3.0 of Des as shown in the quick keys.

The actual gas flow matches the set total flow. Notice that the patient inspired and expired desflurane (Fi Des and Et Des) and the inspired and expired oxygen (Fi O2 and Et O2) are different than what is set.

The flowing gas and agent mixes with the existing gas in the breathing system, enriching the mixture inspired by the patient (Fi Des and FiO2). Patient gas exchange affects the mixture expired by the patient (Et Des and Et O2).

Des, Et Control, and Gas Setup.



1. Electronic flow tubes showing Air and O2.

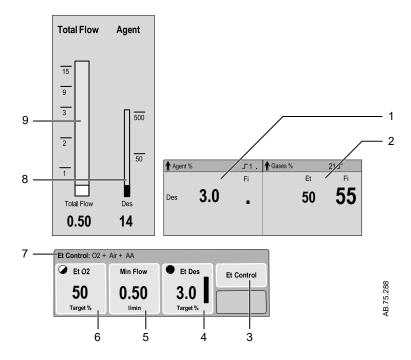
2. Measured values showing Agent, Et Des, Fi Des, Gases, Et O2, and Fi O2.

Figure 11 • Display during fresh gas control

Entering Et Control mode examples

On entering Et Control mode, the display changes. The system begins to adjust the delivery of gas and agent to reach the target settings. The Agent output displays next to the Total Flow tube. The quick keys show Et Control settings. The target EtO2 is 50%, the minimum flow is 0.5, and the target Et Des is 3.0.

Notice that after the system reaches the target gas concentration settings, the gas flow has changed to low flow. The patient expired desflurane (Et Des %) and expired O2 % (Et O2) are at the target settings.



6.

- 1. Expired agent measurements showing Agent, Et Des, and Fi Des.
- Expired oxygen measurements showing Gases, Et 7. O2, and Fi O2.
- 3. Et Control quick key.
- 4. Target agent setting showing Et Des and Target %.
- 5. Min Flow quick key.



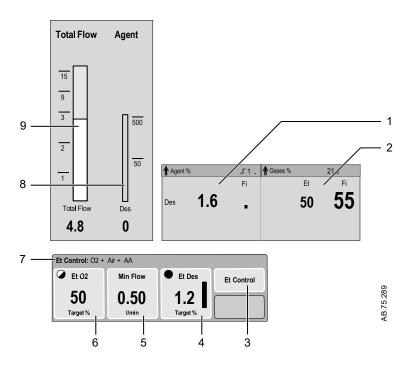
Target oxygen setting showing Et O2 and Target %.

Mode indicator showing Et Control, O2, Air, and agent.

- 8. Vaporizer output showing Agent and Des.
- 9. Total gas flow tube showing Total Flow.

Target values change example

The user makes a change to the Et Control settings. The target Et Des % is changed to 1.2 and the target Et O2 remains at 50%. Notice that the vaporizer has shut off. Gas flows have increased to get to an Et Des of 1.2% quickly.



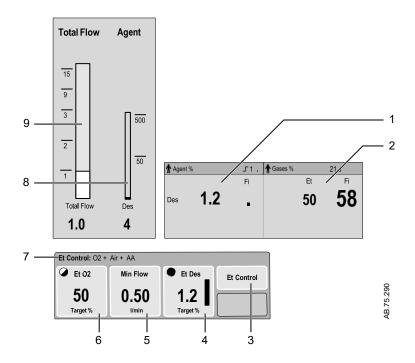
6.

- 1. Expired agent measurements showing Agent, Et Des, and Fi Des.
- Expired oxygen measurements showing Gases, Et 7. O2, and Fi O2.
- 3. Et Control quick key.
- 4. Target agent setting showing Et Des and Target %. 9.
- 5. Min Flow quick key.
- Figure 13 Display when target values are changed

- Target oxygen setting showing Et O2 and Target %.
- Mode indicator showing Et Control, O2, Air, and agent.
- 8. Vaporizer output showing Agent and Des.
 - Total gas flow tube showing Total Flow.

Target values achieved example

The Et Control settings are achieved. Notice that the vaporizer is now on. The gas flows are low. The Et Des% displays 1.2 and the Et O2 displays 50%. Notice now that the target settings are achieved. The gas flows are low for optimal delivery.



6.

- 1. Expired agent measurements showing Agent, Et Des, and Fi Des.
- 2. Expired oxygen measurements showing Gases, Et 7. O2, and Fi O2.
- 3. Et Control quick key.
- 4. Target agent setting showing Et Des and Target %. 9.
- 5. Min Flow quick key.

Target oxygen setting showing Et O2 and Target %.

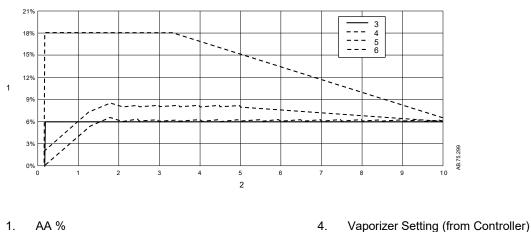
Mode indicator showing Et Control, O2, Air, and agent.

- 8. Vaporizer output showing Agent and Des.
 - Total gas flow tube showing Total Flow.

Figure 14 • Display when target values are reached during Et control mode

Typical agent delivery in Et Control cases

The data in these examples represents the agent values that may be seen in a typical case in which the Target EtAA is set from Off to 1 MAC.



5.

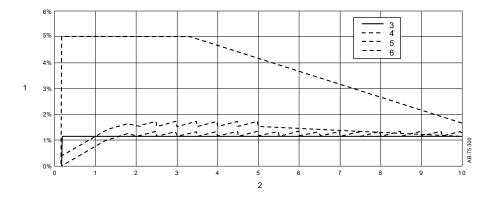
6.

Measured FiAA

Measured EtAA

- 1. AA %
- 2. Time (mins) since start of Et Control
- User Set Target EtAA 3.

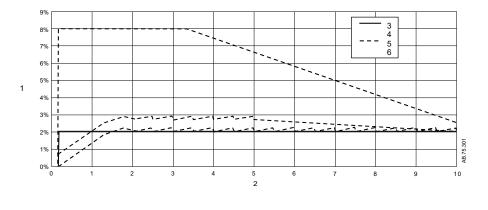
Figure 15 • Typical Desflurane Et Control Case



- AA % 1.
- 2. Time (mins) since start of Et Control
- User Set Target EtAA 3.

Vaporizer Setting (from Controller) 4. 5. Measured FiAA

- Measured EtAA 6.
- Figure 16 Typical Isoflurane Et Control Case



- 1. AA %
- 2. Time (mins) since start of Et Control
- 3. User Set Target EtAA

Figure 17 • Typical Sevoflurane Et Control Case

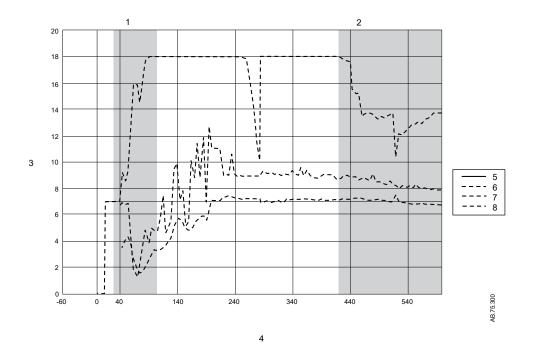
- 4. Vaporizer Setting (from Controller)
- 5. Measured FiAA
- 6. Measured EtAA

Desflurane case clinical trial example

The data in this example is from a case using Et Control as part of a clinical trial. The examples show the fresh gas flow, oxygen, and anesthetic agent data for one minute before entering Et Control mode and 10 minutes after entering Et Control mode.

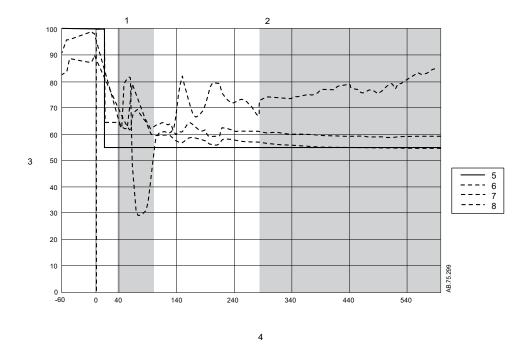
At entering Et Control mode:

- Min Flow set to Min (0.5 I/min, changing from previous setting for 6.0 I/min).
- Target EtO2 set to 55% (changing from previous setting of 100%).
- Target EtDES set to 7.0% (changing from previous setting of Off).



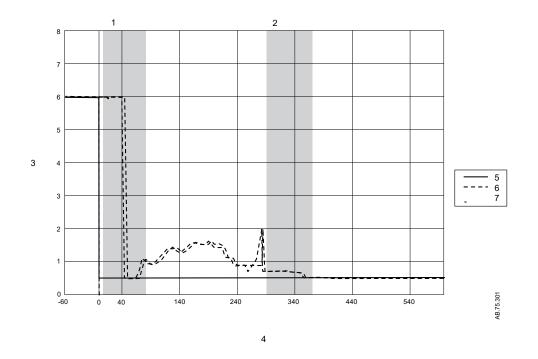
- 1. Vaporizer setting from controller rises to drive the Measured EtDES to meet user set Target EtDES (7.0%)
- 2. Measured EtDES reaches user set Target EtDES (steady state), vaporizer setting begins to fall
- 3. DES%
- 4. Time (in seconds) since start of Et Control
- 5. User set Target EtDES
- 6. Vaporizer setting from controller
- 7. Measured FiDES
- 8. Measured EtDES

Figure 18 • Agent data from desflurane case



- 1. O2 setting from controller drops to drive the Measured EtO2 to meet user set Target EtO2 (55%)
- 2. Measured EtO2 reaches user set Target EtO2 (steady state), O2 setting stabilizes at user set Target EtO2
- 3. O2%
- 4. Time (in seconds) since start of Et Control
- 5. User set Target EtO2
- 6. O2 setting from controller
- 7. Measured FiO2
- 8. Measured EtO2

Figure 19 • O2 data from desflurane case



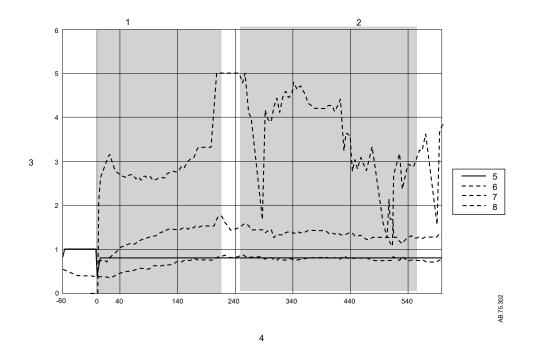
- 1. Fresh gas flow setting at 6.0 l/min as controller works to achieve the user set Target EtDES and user set Target EtO2
- 2. Target end-tidal values achieved, delivered fresh gas flow approaches user set Min Flow
- 3. Flow (l/min)
- 4. Time (in seconds) since start of Et Control
- 5. User set Min Flow
- 6. Fresh gas flow setting from controller
- 7. Delivered fresh gas flow
- Figure 20 Flow data from desflurane case

Isoflurane case clinical trial example

The data in this example is from a case using Et Control as part of a clinical trial. The graphs show the fresh gas flow, oxygen, and anesthetic agent data for one minute before entering Et Control mode and 10 minutes after entering Et Control mode.

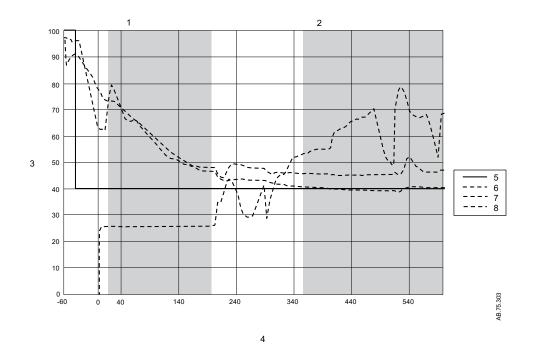
At entering Et Control mode:

- Min Flow set to Min (0.5 l/min, changing from previous setting for 15.0 l/min).
- Target EtO2 set to 40% (changing from previous setting of 100%).
- Target EtISO set to 0.8% (changing from previous setting of 1.0%).



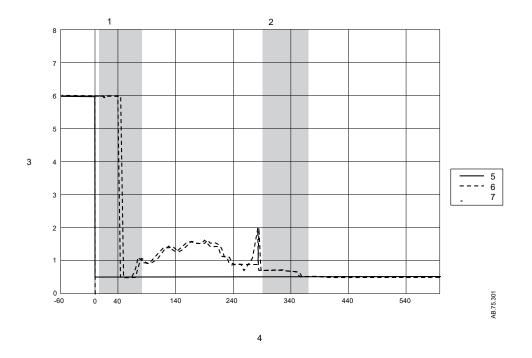
- 1. Vaporizer setting from controller rises to drive the Measured EtISO to meet user set Target EtISO (0.8%)
- 2. Measured EtISO reaches user set Target EtISO (steady state), vaporizer setting changes frequently to maintain user set Target EtISO
- 3. ISO(%)
- 4. Time (in seconds) since start of Et Control
- 5. User set Target EtISO
- 6. Vaporizer setting from controller
- 7. Measured FilSO
- 8. Measured EtISO

Figure 21 • Agent data from isoflurane case



- 1. O2 setting from controller remains low to drive the Measured EtO2 to meet user set Target EtO2 (40%)
- 2. Measured EtO2 reaches user set Target EtO2 (steady state), O2 setting changes frequently to maintain user set Target EtO2
- 3. O2%
- 4. Time (in seconds) since start of Et Control
- 5. User set Target EtO2
- 6. O2 setting from controller
- 7. Measured FiO2
- 8. Measured EtO2

Figure 22 • O2 data from isoflurane case



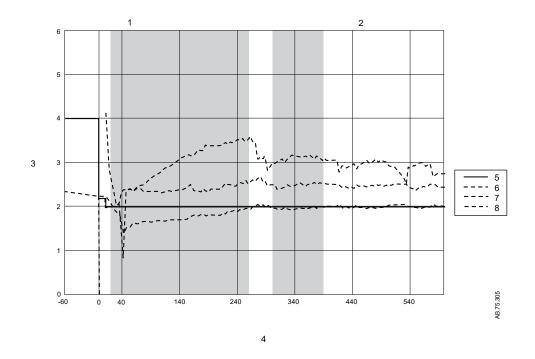
- 1. Fresh gas flow setting higher than user set Min Flow of 0.5 l/min as controller works to achieve the user set Target EtISO and user set Target EtO2
- 2. Target end-tidal values achieved set and delivered fresh gas flow approaches user set Min Flow
- 3. Flow (l/min)
- 4. Time (in seconds) since start of Et Control
- 5. User set Min Flow
- 6. Delivered fresh gas flow
- 7. Fresh gas flow setting from controller
- Figure 23 Flow data from isoflurane case

Sevoflurane case clinical trial example

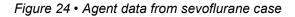
The data in this example is from a case using Et Control as part of a clinical trial. The graphs show the fresh gas flow, oxygen, and anesthetic agent data for one minute before entering Et Control mode and 10 minutes after entering Et Control mode.

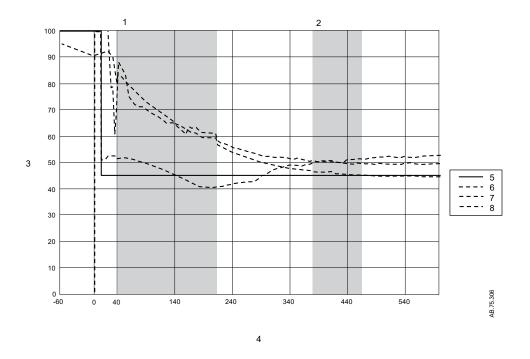
At entering Et Control mode:

- Min Flow set to 2.0 I/min (0.5 I/min, changing from previous setting for 8.0 I/min).
- Target EtO2 set to 45% (changing from previous setting of 100%).
- Target EtSEV set to 2.0% (changing from previous setting of 4.0%).



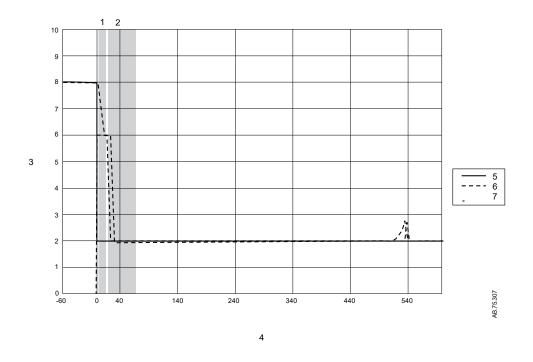
- 1. Vaporizer setting from controller rises to drive the Measured EtSEV to meet user set Target EtSEV (2.0%)
- 2. Measured EtSEV reaches user set Target EtSEV (steady state), vaporizer setting begins to fall and stablize
- 3. SEV(%)
- 4. Time (in seconds) since start of Et Control
- 5. User set Target EtSEV
- 6. Vaporizer setting from controller
- 7. Measured FiSEV
- 8. Measured EtSEV





- 1. O2 setting from controller dropped to drive the Measured EtO2 to meet user set Target EtO2 (45%)
- 2. Measured EtO2 reaches user set Target EtO2 (steady state), O2 setting begins stablize to maintain user set Target EtO2
- 3. O2%
- 4. Time (in seconds) since start of Et Control
- 5. User set Target EtO2
- 6. O2 setting from controller
- 7. Measured FiO2
- 8. Measured EtO2

Figure 25 • O2 data from sevoflurane case



- 1. Fresh gas flow setting 6.0 l/min (above user set Min Flow of 2.0 l/min) as controller works to achieve the user set Target EtSEV and user set Target EtO2
- 2. Target end-tidal values achieved set and delivered fresh gas flow approaches user set Min Flow
- 3. Flow (I/min)
- 4. Time (in seconds) since start of Et Control
- 5. User set Min Flow
- 6. Delivered fresh gas flow
- 7. Fresh gas flow setting from controller

Figure 26 • Flow data from sevoflurane case

Et Control performance data

Typical performance after setting change with minimum flow of 0.50 I/min			
Average	Standard deviation		
68 seconds	+/- 28 seconds		
126 seconds	+/- 100 seconds		
0.2 vol%	+/- 0.1 vol%		
8.1% of setting	+/- 4.8% of setting		
130 seconds on an increase, 228 seconds on a decrease	+/- 38 seconds on an increase, +/- 41 seconds on a decrease		
136 seconds on an increase, 335 seconds on a decrease	+/- 30 seconds on an increase, +/- 146 seconds on a decrease		
1.3 vol%	+/- 0.8 vol%		
1.2 vol%	+/- 0.4 vol%		
	Average 68 seconds 126 seconds 0.2 vol% 8.1% of setting 130 seconds on an increase, 228 seconds on a decrease 136 seconds on an increase, 335 seconds on a decrease 1.3 vol%		

Note: Data derived from performance testing. Depending on patient type, situation, and external disturbances the performance of the system may differ from the values given above. For example:

Patient dynamics could limit performance during wash out from high to low levels of agent.

Problem conditions during Et Control mode could limit performance.

Disconnects during Et Control mode could limit performance.

Typical performance after setting change with minimum flow of 0.30 l/min		
	Average	Standard deviation
EtAA response time	93 seconds	+/- 58 seconds
EtAA settling time	129 seconds	+/- 87 seconds
EtAA steady state deviation	0.09 vol%	+/- 0.11 vol%
EtAA overshoot	5.24% of setting	+/- 6% of setting
EtO2 response time	129 seconds on an increase, 332 seconds on a decrease	+/- 24 seconds on an increase, +/- 100 seconds on a decrease
EtO2 settling time	147 seconds on an increase, 390 seconds on a decrease	+/- 18 seconds on an increase, +/- 115 seconds on a decrease
EtO2 steady state deviation	1.02 vol%	+/- 0.58 vol%
EtO2 overshoot	1.15 vol%	+/- 0.29 vol%

Et Control option

Typical performance after setting change with minimum flow of 0.30 l/min		
	Average	Standard deviation
Note: Data derived from performance is performance of the system may differ to Patient dynamics could limit performan Problem conditions during Et Control ro Disconnects during Et Control mode co	from the values given above. For exam nee during wash out from high to low le node could limit performance.	nple:

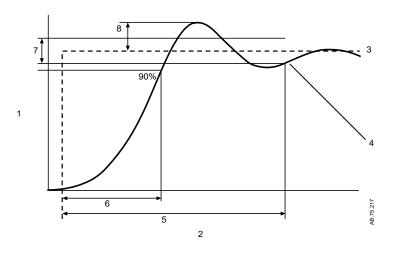
Clinical performance after setting change with minimum flow of 0.5 I/min				
Parameter	Average Value Observed in Clinical Trial	Value at Which 90% of Steady State Occurrences Were Reached	% of Steady State Occurrences Within Target Range*	Target Range
EtAA Response Time	23 seconds	60 seconds	99.6%	<= 240 seconds
EtAA Settling Time	31 seconds	85 seconds	99.6%	<= 600 seconds
EtAA Steady State Deviation	0.05 vol%	0.09 vol%	99.6%	< 0.15 MAC
EtAA Overshoot	5.1% of setting	9.6% of setting	99.8%	<= Greater of (0.2 MAC, 30% of setting)
EtO2 Response Time (Increase)	37 seconds	115 seconds	100.0%	<= 600 seconds
EtO2 Response Time (Decrease)	133 seconds	201 seconds	100.0%	<= 600 seconds
EtO2 Settling Time (Increase)	39 seconds	136 seconds	100.0%	<= 900 seconds
EtO2 Settling Time (Decrease)	159 seconds	240 seconds	100.0%	<= 900 seconds
EtO2 Steady State Deviation	0.7 vol%	1.3 vol%	100.0%	<= Greater of (3% vol, 5% of setting)
EtO2 Overshoot (Increase)**	2.2 vol%	4.6 vol%	95.8%	<= Greater of (5% vol, 20% of setting)
EtO2 Overshoot (Decrease)**	0.8 vol%	2.3 vol%	97.5%	<= Greater of (5% vol, 5% of setting)

Parameter	Average Value Observed in Clinical Trial	Value at Which 90% of Steady State Occurrences Were Reached	% of Steady State Occurrences Within Target Range*	Target Range
data presented in the "	Clinical Performance' ta Typical Performance' tab al Performance' data inc mance.	ole, as the 'Typical Perfo	ormance' data comes fro	om testing done in a
	ynamics could limit perf cts during Et Control mo	•	•	ls of agent. Problem

Note: Setting changes with a Target EtO2 of "MAX" were excluded from EtO2 calculations as "MAX" simply flows 100% O2 rather than targeting an EtO2 value.

*Any setting change that did not reach steady state within the target range was due to an external disturbance (e.g. circuit/sample line leak,patient cough, etc.) and not related to the performance of the Et Control algorithm.

**EtO2 Overshoots that occurred upon transition from Fresh Gas Control to Et Control were excluded from these calculations as they were a result of the Et Control System Check and not related to the performance of the Et Control algorithm.



- 1. Concentration %
- 2. Time
- 3. Target setting
- 4. Measured end-tidal concentration
- 5. Settling time
- 6. Response time
- 7. Steady state deviation
- 8. Overshoot

Figure 27 • Et Control accuracy graph

Et Control factory default settings

Setting	Range	Default
Target EtO2	25 - 80%, Max	Measured value upon entry *
Minimum flow	0.50, 0.55 - 6 l/min 0.30, 0.35 - 6 l/min (optional)	0.50 (Des, Iso, and no agent) 2.0 (Sev) **
Target EtDes	Off, Purge, 1.0 - 12.0%	Measured value upon entry. ***
Target Etlso	Off, Purge, 0.2 - 2.5%	Measured value upon entry. ***
Target EtSev	Off, Purge, 0.2 - 4.0%	Measured value upon entry. ***

Notes:

*If the measured EtO2 is less than 25%, the default is 25%. If the measured EtO2 is more than 80%, the default is Max.

**Minimum flow default is the Super user setting. See "Super user" for more information.

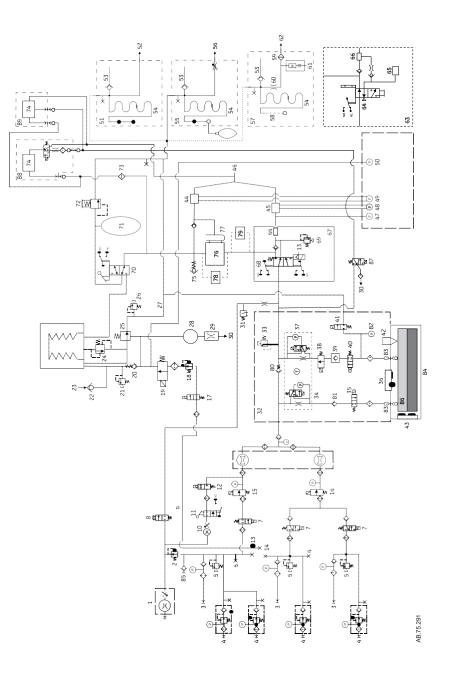
***If the EtDes, EtIso, or EtSev is less than the lowest %, the default is the setting value nearest to the measured EtAA value. If the EtDes, EtIso, or EtSev is more than the highest %, the default is the highest %.

Fresh gas control settings

The following settings are used for Fresh Gas Control after exiting Et Control.

Setting	Value
O2%	[(Set Target EtO2% + 5%) / (1 – Set Target EtAA% /100%)] or concentration required to get 500 ml/min of O2, whichever is greater
Total flow	Current commanded flow or 500 ml/min, whichever is greater
Agent%	Set Target EtAA%
Note: When the system transitions between Et Control and Fresh Gas Control, the fresh gas settings will be rounded to the nearest in-range value.	

System pneumatic circuit



- 1. Auxiliary O2, 0-10 l/min (optional)
- 2. 241 kPa (35 psi) secondary O2 regulator
- 3. Pipeline: O2, Air, N2O
- 4. Cylinder: O2, Air, N2O
- 5. 758 kPa (110 psi) relief
- 6. Venturi drive gas connection
- 7. Selector valve, O2, Air, N2O
- 8. O2 flush
- 9. 0-120 l/min flow
- 10. Alternate O2
- 11. System switch
- 12. Alternate O2 disable valve
- 13. ACGO/non-circle port
- 14. Vent drive gas select
- 15. O2 flow controller
- 16. Balance flow controller
- 17. Gas inlet valve
- 18. Vent drive gas regulator 172 kPa (25 psi) at 15 l/min 63.
- 19. Inspiratory flow control valve
- 20. Drive gas check valve (3.5 cmH2O bias)
- 21. Mechanical over pressure valve (110 cmH2O)
- 22. Free breathing check valve
- 23. Atmosphere
- 24. Pressure relief valve
- 25. Exhalation valve (2 cmH2O bias)
- 26. Relief valve 10 cmH2O
- 27. 0-10 l/min drive gas, 0-10 l/min patient and fresh gas, 0-10 l/min total typical flow
- 28. 200 ml reservoir
- 29. Control bleed to ambient approximately 1 l/min at 3 74. cmH2O if continuous (rate dependent)
- 30. Vent to ambient
- 31. Flush switch 37.2 kPa (5.4 psi)
- 32. Electronic vaporizer
- 33. ACGO port relief valve
- 34. Cassette inflow measure
- 35. Cassette inflow valve
- 36. Cassette identification
- 37. Cassette outflow measure
- 38. Cassette flow control valve
- 39. Liquid flow prevention valve
- 40. Cassette outflow valve
- 41. Scavenging valve
- 42. Cassette temperature sensor
- 43. Liquid level indicator (not available on all cassettes) 88.
- 44. Expiratory flow sensor
- 45. Inspiratory flow sensor

- 46. Patient wye (patient connection)
- 47. Airway transducer
- 48. Inspiratory flow transducer
- 49. Expiratory flow transducer
- 50. Manifold pressure transducer
- 51. Passive gas scavenging interface
- 52. 30 mm male to disposal system
- 53. 0.3 cmH2O entrainment
- 54. Reservoir
- 55. Adjustable gas scavenging interface
- 56. DISS EVAC connector
- 57. Active gas scavenging interface
- 58. Room air
- 59. Filter
- 60. High or low flow restrictor
- 61. Flow indicator
- 62. To disposal system
- 63. ACGO variant
- 64. Circle or ACGO mode switch
- 65. 22 mm ACGO port
- 66. O2 cell
- 67. Non-circle variant
- 68. Circle or non-circle mode switch
- 69. Non-circle circuit pressure limiting valve
- 70. Bag/Vent switch
- 71. Bag
- 72. APL valve 0-70 cmH2O
- 73. Bacterial filter
- 74. Gas monitor
- 75. Negative pressure relief valve
- 76. Absorber
- 77. Drain
- 78. EZchange canister
- 79. Condenser
- 80. Bypass back-pressure valve
- 81. Inflow check valve
- 82. Cassette pressure sensor
- 83. Cassette connection valve
- 84. Aladin cassette
- 85. Pneumatic power outlet
- 86. Embedded temperature sensor (not available on all cassettes)
- 87. Fresh gas sample relief valve
- 88. Single-width airway module bay

Super user

The initial minimum flow value can be set for Des, Iso, and Sev for Et Control mode. The default settings for Et Control mode are the same for all available case defaults. Refer to the "*Super user mode*" section in the User's Reference manual for additional information on setting the case defaults.

Default settings		
Minimum flow (None)	0.50	
Minimum flow (Des)	0.50	
Minimum flow (Iso)	0.50	
Minimum flow (Sev)	2.0	

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