Pain management portfolio: Alaris® PCA and EtCO$_2$ modules FAQs

Alaris® PCA module FAQs

1. **What criteria were used in the design of the Alaris PCA module?**

   The Alaris PCA module was carefully designed to meet the following criteria:

   - Lightweight (5.5 lbs).

   - Common user interface: Same front panel keys as other Alaris System modules.

   - Trending patient monitoring data: Ability to view a patient's PCA medication doses and/or %SpO$_2$, EtCO$_2$ and/or respiratory rate when the Alaris PCA module and monitoring module(s) are attached to the same Alaris PC unit. This feature may help improve compliance with the 2010 Joint Commission National Patient Safety Goals, "Improve, recognize and respond to changes in patient's condition" and "Improve clinician to clinician handoff procedures."

   - Patient safety: The Alaris PCA pause protocol algorithm promotes early detection of respiratory depression and pauses the PCA infusion if necessary.

   - Drug security: The Alaris PCA module has a channel release lever located behind the locked PCA door.

   - Security access levels: Ability to use code access or key access for subsequent programming changes and clinician boluses.

   - Optional locking IV pole clamp (sold separately).

   - Rate accuracy: +/- 2% of full-scale plunger travel (not including syringe variation).

2. **What are the leading competitive PCA syringe brands and manufacturers?**

   Hospira, B.Braun and Baxter.

3. **What makes the Alaris PCA module unique?**

   The Alaris system is the first and only modular system that includes dose error reduction software (DERS) for PCA therapy, continuous respiratory monitoring (SpO$_2$ and/or EtCO$_2$), a PCA pause protocol feature and barcoding capability (when used with the Alaris Auto-ID module) – all in on one platform using a single user interface.

   This advanced technology augments PCA safety throughout the duration of PCA therapy by:

   - Reducing the potential for harm before PCA therapy is initiated through DERS and confirming the right patient, drug and clinician (if used with the Alaris Auto-ID module).

   - Augmenting PCA therapy during administration through the Alaris PCA pause protocol with respiratory monitoring.

   - Providing continuous quality improvement data after PCA therapy completes.

   The Alaris System takes advantage of a fully-integrated, single platform and allows the clinician to view real-time PCA infusion dosing and monitoring trend data on the same screen. This feature provides an additional tool to help clinicians assess

the patient's physiological response to PCA therapy. The single user interface used for multiple devices (large volume pump, syringe, PCA and monitoring modules) reduces complexity and simplifies caregiver training because of the decreased number of devices the caregiver must learn to program.

4. **What is the Alaris PCA pause protocol feature?**

Due to the potential for opioid-induced respiratory depression, most hospitals require regularly monitoring and assessing patients during PCA therapy. By allowing interoperability and communication between the Alaris PCA module, Alaris $EtCO_2$ module and/or Alaris SpO_2 module on the same platform, the Alaris System provides the clinician a way to continuously monitor the patient's respiratory status in response to PCA therapy.

The Alaris PCA pause protocol is available when:

- The hospital enables the PCA pause protocol in the data set.

- An Alaris PCA module and Alaris $EtCO_2$ and/or Alaris SpO_2 modules are attached to the same Alaris PC unit.

The Alaris PCA module will pause the PCA infusion based on one or both of the following limits. These limits are determined by the hospital:

- Low respiratory rate: measured by the Alaris $EtCO_2$ module.

- Low oxygen saturation ($\%SpO_2$): measured by the Alaris SpO_2 module (Nellcor or Masimo technology).

When the Alaris PCA pause protocol feature is activated by a decline in the patient's respiratory status:

- The Alaris PCA module alarms.

- The PCA infusion automatically pauses.

- The patient dose request cored becomes inactive.

The Alaris PCA module will remain paused until the clinician physically addresses the alarm on the pump and the patient's respiratory parameters return to the limits set by the hospital.

The Alaris PCA pause protocol adds a safety net for the clinician and patient at the point of care – it does not replace clinician assessment or decision making.

5. **How many hospitals are using the PCA pause protocol feature?**

At the time of printing this document, more than 90 hospitals are using the PCA pause protocol with the Alaris $EtCO_2$ module and more than 30 hospitals with the Alaris SpO_2 module.

6. **What settings should I be aware of when configuring the PCA pause protocol, and how does this feature work?**

When developing the data set, it is necessary to consider several limits related to the PCA pause protocol.

First, it is necessary to set:

- The Respiratory Rate Low limit on the Alaris $EtCO_2$, and/or

- The $\%SpO_2$ Low oxygen saturation limit on the Alaris SpO_2 module.

When these limits are exceeded, the Alaris System alarms provide an early warning to the clinician of the potential decline in the patient's respiratory status. **The Alaris PCA module will not pause when these alarm limits are exceeded.**

These values must be set higher than the PCA pause protocol initial values.

Secondly, the PCA pause protocol initial value(s) must be set for the respiratory rate and/or the %SpO$_2$.

- This is a default value that, when exceeded, will cause the Alaris PCA module to alarm and pause.

- The initial value(s) can be edited by the clinician at the bedside. (The ability to edit this limit was designed to allow the clinician to individualize the Alaris PCA pause limit(s) to be specific to the patient's needs).

- The PCA pause protocol initial value(s) must be greater than or equal to the %SpO$_2$ Low Limit and/or the Respiratory Rate Lower Limit.

Thirdly, hard limits for the PCA pause protocol values must be set: %SpO$_2$ Low Limit and/or Respiratory Rate Lower Limit.

- These limits are the hospital's absolute lowest acceptable PCA pause value(s). These limits can be thought of as hard limits.

- These limits cannot be edited by the clinician at the bedside.

- These limits will restrict how low the PCA pause protocol initial value(s) can be set.

Note: To provide an early alarm warning that the patient's respiratory status is declining and prevent further decline:

- The Respiratory Rate Low limit on the Alaris EtCO$_2$ module must be set higher than the PCA pause protocol Respiratory Rate Initial Value and the PCA pause protocol Respiratory Rate Lower Limit.

- The %SpO$_2$ Low Limit on the Alaris SpO$_2$ module must be set higher than the PCA pause protocol %SpO$_2$ Initial Value and the PCA pause protocol %SpO$_2$ Low Limit.

Example 1
If the PCA pause protocol Respiratory Rate Lower Limit is set at 3, the following parameters can be set at the bedside:

- The PCA pause protocol Respiratory Rate Initial Value can be set to 3 or higher.

- The Respiratory Rate Low limit can be set to 4 or higher. (This value must be higher than the PCA pause protocol Respiratory Rate Initial Value.)

Example 2
If the PCA pause protocol %SpO$_2$ Low Limit is set to 88%, the following parameters can be set at the bedside:

- The PCA pause protocol %SpO$_2$ Initial Value can be set to 88% or higher.

- The %SpO$_2$ Low value can be set to 89% or higher. (This value must be higher than the PCA pause protocol %SpO$_2$ Initial Value.)

7. **What default respiratory and EtCO$_2$ monitoring parameters have other CareFusion customers used?**

At the time of printing this document, our customers have implemented the following device default settings:

Monitoring parameter	Adult default setting ranges±	Pediatric default setting ranges±
EtCO$_2$ high	50 to 60 mmHg**	45 to 60 mmHg**
EtCO$_2$ Low	8 to 20 mmHg**	10 to 15 mmHg**
Respiratory Rate High	30 to 35 bpm***	35 to 120 bpm***
Respiratory Rate Low	6 to 8 bpm***	8 to 12 bpm***
No Breath Alarm	20 to 30 sec	15 to 20 sec
FiCO$_2$ High*	6 to 8 mmHg	6 to 8 mmHg
%SpO$_2$ High	Off	Off to 100%
%SpO$_2$ Low	88% to 92%	88% to 92%

±data on file
*fractional-inspired CO_2 concentration
**mmHg-millimeters mercury
***breaths per minute

8. **What PCA pause parameters have other CareFusion customers used?**

At the time of printing this document, our customers have implemented the following PCA pause parameters:

PCA pause parameter	Adult PCA pause protocol setting ranges±	Pediatric PCA pause protocol setting ranges±
Respiratory Rate Initial Value	4 to 5 bpm*	5 to 12 bpm*
Respiratory Rate Lower Limit	4 to 5 bpm*	4 to 10 bpm*
%SpO_2 Initial Value	85% to 87%	85% to 89%
%SpO_2 Low Limit	80% to 87%	84% to 89%

±data on file
*breaths per minute

The Respiratory Rate Low value and/or %SpO_2 Low value (see #6 and #7) will trigger an alarm first to alert the clinician of possible respiratory depression. If the patient's respiratory rate and/or oxygen saturation continue to decline below the hospital-established PCA pause protocol parameters initial values (see #6 and #8), the Alaris PCA module will pause and alarm.

9. **Which settings are configurable in the data set for the Alaris PCA module?**

- Security access level
- Security code (four-digit code, profile-specific)
- Bolus delivery rate (mL/hr)
- Dose request cord configuration (visual and auditory queues)
- PCA module location enforcement
- Max dose limit time window

- Max rate mL/hr (for continuous dose)
- Near end of infusion alert time (%)
- Occlusion pressure limit
- Priming
- PCA pause protocol (Enable/Disable)
  — PCA pause protocol enables for $EtCO_2$, SpO_2 or both
  — Monitoring module attach enforcement
  — PCA pause protocol alarm text (advisory text developed by the hospital)

10. **Which settings are configurable in the data set for drugs in the PCA library?**

- Drug setup name
- Dosing units
- Supports PCA pause protocol
- Max accumulated dose range parameters (per 1, 2 or 4 hours)
  — Soft minimum (min)/#hr
  — Soft maximum (max)/#hr
  — Hard max/#hr
  — Initial value
- PCA dose parameters
— Soft minimum
— Soft maximum
— Hard max
— Initial value
— Lockout hard min
— Lockout soft min

![CareFusion logo]

- — Lockout soft max

- — Lockout initial value

- Continuous dose parameters

  - — Soft min/h

  - — Soft max/h

  - — Hard max/h

  - — Initial value

- Bolus dose parameters

  - — Soft min

  - — Soft max

  - — Hard max

  - — Choice to include (clinician-activated) bolus doses in max accumulated dose

- Loading dose parameters

  - — Soft min

  - — Soft max

  - — Hard max

- Concentration limits

  - — Concentration units

  - — Hard min

  - — Soft min

  - — Soft max

- Clinical advisory

11. **How can the PCA pause protocol be set up based on the PCA medication I choose, or must the PCA pause protocol be active for all PCA medications?**

Each hospital can choose which PCA medications the PCA pause protocol will be active for. The Guardrails® Editor software is used to associate the PCA medications with the PCA pause protocol.

Note: It is very important to enable the PCA pause protocol feature for the PCA medication when building the PCA drug library. If this feature is **not** enabled in the PCA drug library, the Alaris PCA module will **not** pause.

12. **Does the Alaris PCA module offer a priming feature?**

Yes. The priming feature allows a limited volume of fluid to be delivered in order to prime the administration set prior to being connected to a patient. When priming, a single continuous press of the PRIME soft key delivers up to 2 mL of priming fluid. If more than 2 mL of fluid is needed to prime, the PRIME soft key can be pressed multiple times.

13. **How many Alaris PCA modules can be attached to one Alaris PC unit?**

One.

14. **Does the Alaris PCA module offer weight-based dosing?**

No. To the best of our knowledge, PCA devices on the market today do not offer weight-based dosing. The Alaris PCA module offers a feature called Therapies. Therapies are not true weight-based dosing, but this feature allows you to set up weight-range dosing.

15. **Can the Alaris PCA module be used for epidural and subcutaneous infusions?**

Yes. The Alaris PCA module is approved for delivering intravenous, subcutaneous and epidural medications. Also, the Alaris PCA module can be used in adult, pediatric and neonatal patient populations.

16. **Does the Alaris PCA module offer air-in-line detection capabilities like the Alaris Pump module?**

    No. To the best of our knowledge, syringe-based PCA pumps on the U.S. market or abroad do not include air-in-line detection capabilities. If the syringe is purged of air before it is loaded into the Alaris PCA module and the administration set is primed properly, removing all air, there is no need for air-in-line detection.

17. **What is NEOI?**

    NEOI is "near end of infusion." NEOI is a configurable option per patient profile. When enabled, NEOI allows an alert to sound when the remaining syringe volume is anywhere between 5% and 25%. NEOI is intended to provide the clinician with an alert that the syringe may need to be changed soon.

18. **Will the Alaris PCA module allow for different drugs and concentrations in the data set?**

    Yes. Your hospital has control over which drugs and concentrations are added to the customizable drug library. The drug library can be tailored to each patient care area.

19. **What are the Alaris PCA module's occlusion alarm thresholds?**

    Occlusion alarm threshold can be set to low (200 mmHg), medium (500 mmHG) or high (800 mmHg).

20. **How quickly will the occlusion alarm sound when using a 50 mL syringe at 1 mL/hr?**

    The following chart outlines the time to alarm. We believe that CareFusion is at par or better with our competitor's time-to-occlusion alarm measurement.

Rate (mL/hr)	High-pressure limit setting (min)	Low-pressure limit setting (min)
1	120	37
5	30	7

21. **Can the Alaris PCA module automatically identify the syringe size when it is loaded?**

    The Alaris PCA module automatically identifies the size of an approved syringe (see #22). However, the user needs to confirm the brand of syringe being used.

22. **What syringe brands and sizes does the Alaris PCA module accept?**

    Note: The Alaris PCA module uses standard or pre-filled disposable syringes (with luer lock connections) and non-dedicated administration sets.

Syringe brand	Syringe size
BD Plastipak	20 mL, 30 mL, 50/60 mL
Monoject™	20 mL, 35 mL,* 60 mL
Terumo	20 mL, 30 mL, 50/60 mL
IMS** Pump Jet	30 mL pre-filled syringe

    *Includes detachable 35 mL Monoject PCA syringe.
    **International Medication Systems

23. **How does the Alaris PCA module recognize a syringe size?**

    The syringe clamp assesses the syringe's outer diameter and compares it to syringe size profiles/configurations stored in memory.

24. **Why can't the Alaris PCA module recognize the syringe brand?**

    The variance in outer diameters between syringes of the same size but made by different manufacturers is often too slight to accurately and reliably identify the syringe brand.

25. **Can the Alaris PCA module detect the volume in a syringe?**

    Yes. The Alaris PCA module is designed to detect the exact amount of fluid in a syringe.

26. Can the hospital enable and disable specific syringe sizes and brands?

Yes. Your hospital can define a "favorites" syringe list to limit syringe sizes/brands that appear on the Alaris PC unit screen for selection.

27. Does the syringe size have any effect on infusion accuracy?

Yes. Rate accuracy is +/- 2% of full-scale plunger travel (not including syringe to syringe variation). Syringe size and running force, variations of back pressure or any combination of these may affect rate accuracy.

28. What is unique about using the IMS syringe brand with the Alaris PCA module?

The Alaris PCA module can be configured through the data set to display **only** morphine 1 mg/1 mL on the drug library selection page when an IMS pre-filled syringe is loaded.

29. Are the 35 mL Monoject detachable PCA syringe barrel and its reusable plunger rod compatible with the Alaris PCA module?

Yes. The 35 mL Monoject pCA syringe barrel and its reusable plunger rod are compatible with the Alaris PCA module.

30. Why did CareFusion partner with Monoject to develop the 35 mL Monoject detachable PCA syringe barrel product?

The new detachable syringe barrel (with a reusable plunger rod) was developed in a partnership between Covidien and CareFusion in response to customer demand for improved storage capabilities at the point of care. This compact packaging design of the syringe is intended to fit in automated dispensing machines (e.g., Pyxis MedStation® system) pocket types, thereby improving storage and access to PCA syringes on the nursing unit.

31. Can I purchase the 35 mL Monoject detachable PCA syringe barrel with compounded and ready-to-use PCA admixtures?

Yes. Ready-to-use custom compounded PCA admixtures are available from PharMEDium Service. PharMEDium follows a rigorous approach to quality, including real-time stability testing for all of its compounded preparations. The ready-to-use syringes from PharMEDium offer a labeling design with integral warning statements and unique shapes to differentiate between drug families and support the "right drug, right concentration and right route" of the medication administration process. The new ready-to-use syringes from PharMEDium save time for the pharmacy, and custom PCA admixtures in compact containers support proper administration while facilitating storage at the point of care.

32. Can I purchase empty 35 mL Monoject detachable syringe barrels and fill them in my pharmacy?

Yes. Hospitals that compound and fill their own PCA syringes can order these new syringe barrels directly from CareFusion. This new PCA syringe barrel with a reusable plunger rod is an alternative to the standard (pre-assembled) Monoject 35 mL syringes used with the Alaris PCA module.

Note: Currently, the 35 mL Monoject syringe barrel is available in a quantity of 150 and is packaged in units of 10. The order number is 8881135609.

33. How is the reusable plunger packaged?

The reusable plunger is packaged with one of five PCA administration sets in a PCA administration kit. The new PCA administration kit model numbers and descriptions are listed in #35.

34. Can I use non-dedicated PCA administration sets and extension sets?

Yes. The Alaris PCA module accepts non-dedicated administration sets and extension sets. CareFusion recommends using non-dedicated administration sets with integrated anti-siphon valves. CareFusion also recommends using check valves on the primary IV set.

35. What dedicated PCA administration kits, administration sets and extension sets does CareFusion offer?

The charts below list the model numbers and descriptions for administration kits, administration sets and extension sets that can be used with the Alaris PCA module. All administration kits, administration sets and extension sets are latex-free and DEHP-free.

Note: All of the PCA administration kits and administration sets listed next have microbore tubing and incorporate an anti-siphon valve.

Administration sets and extension sets

Model Number	Description	Length (in)	Priming volume (mL)
30843E	Extension set with SmartSite® valve, with small bore tubing segment and check valve	12	1
30853	Administration set with microbore tubing, anti-siphon valve, Y-connector, with check valve	70	2.6
30863	Administration set with microbore tubing, anti-siphon valve, Y-connector, with check	63	1.4

Model Number	Description	Length (in)	Priming volume (mL)
	valve		
30873	Administration set with microbore tubing, anti-siphon valve, Y-connector with check valve	90	3
30883	Administration set with microbore tubing, anti-siphon valve	92	2.1
30893	Administration set with microbore yellow identification stripe tubing, with anti-siphon valve	113	2.6

Administration kits (content includes Monoject detachable reusable plunger rod and tubing)

Model Number	Description	Length (in)	Priming volume (mL)
10800173	Administration set with microbore tubing, anti-siphon valve, Y-connector, with check valve and reusable Monoject plunger rod	70	2.6
10800174	Administration set with microbore tubing, anti-siphon valve and reusable Monoject plunger rod	63	1.4
10800175	Administration set with microbore tubing, anti-siphon valve, Y-connector, with check valve and	90	3

	reusable Monoject plunger rod		
10800176	Administration set with microbore tubing, anti-siphon valve and reusable Monoject plunger rod	92	2.1
10800177	Administration set with microbore tubing with yellow identification stripe, anti-siphon valve and reusable Monoject plunger rod	113	2.6

36. How can the Alaris PCA module help prevent free-flow or siphoning?

If the syringe plunger head is not captured by the Alaris PCA module plunger grippers within 30 seconds of loading the syringe, the Alaris PCA module will indicate a potential siphoning condition and a syringe picture bitmap message will display on the main screen, guiding the user to load the syringe properly. Once the syringe is properly loaded, the syringe plunger is held in place, preventing uncontrolled flow. Flow of the fluid is achieved by the positive displacement motion of the mechanical motor during Alaris PCA module usage. When the Alaris PCA module is off, the mechanical motor is not active and therefore, there is no flow.

Also, the Alaris PCA administration kits and administration sets incorporate an anti-siphon valve. This anti-siphon valve helps prevent uncontrolled flow of opioid into the line. Within the PCA administration kits and administration sets, a Y-connector allows the connection of the maintenance/primary administration set. The check valve (integrated with the Y-connector) ensures that the PCA opioid does not backflow into the maintenance/primary administration set.

37. What are the Alaris PCA module configurable settings that are shared with the Alaris Syringe module?

The Alaris PCA and Alaris Syringe modules share a Maximum Flow Rate (for continuous dose). The flow rate programming increments are as follows:

Rate range (mL)	User selectable increments (mL/hr)
0.10 to 9.99	0.01
10 to 99.9	0.1
100 to 999	1

38. What is the maximum flow rate of the Alaris PCA module?

Maximum flow rate for the Alaris PCA module is 999 mL/hr, but it will be syringe-size dependent as listed below:

Syringe size (mL)	Flow rate range (mL/hr)
20	0.1 to 500
30/35	0.1 to 650
50/60	0.1 to 999

39. What is the minimum flow rate for the Alaris PCA module?

The minimum flow rate for the Alaris PCA module is 0.1 mL/hr.

40. What programming display resolution does the Alaris PCA module offer?

Programming for the Alaris PCA module on the Alaris PC unit goes to the thousandth decimal place (or three decimal points e.g., 0.222).

The digital rate display on the Alaris PCA module displays to the hundredth decimal place (or two decimal points e.g., 0.22).

The message display on the Alaris PCA module displays to the thousandth decimal place.

41. Does the Alaris PCA module deliver the exact dose programmed by the clinician (e.g., 0.222)?

The Alaris PCA module system software calculates and commands the pump to deliver the exact dose programmed by the clinician. In some cases, the volume infused is rounded to the hundredth decimal place for display purposes.

Note: It is also important to be aware of other technical features of the Alaris PCA module that can affect rate accuracy such as the length of administration set, rate accuracy of +/- 2%, syringe size variation, flow uniformity and rate restrictions based on syringe size. These factors can also affect the actual amount of fluid/medication administered.

42. What is the Alaris PCA module's critical volume?

Maximum over-infusion, which can occur in event of a single-fault condition, will not exceed 2% of nominal syringe fill volume during loading and 1% of maximum syringe travel after syringe loading.

43. What type of motor does the Alaris PCA module use?

The Alaris PCA module has a stepper motor and uses positive displacement.

44. What is the Alaris PCA module accuracy?

The accuracy of the Alaris PCA module is +/- 2% of full-scale plunger travel (not including syringe variation).

45. What is the continuity for the Alaris PCA module?

Flow continuity is driven by the mechanism step size of the PCA pump. In other words, every time a signal is sent to the motor to move, the head moves by a "set" distance. For the Alaris PCA module, the average "set" distance is 2.5 millionths of an inch (0.0000025 in). Thinking of it in terms of fluid delivered from an actual syringe gives us an idea of how great the flow continuity is. For example, a BD 60 cc syringe at a rate of 0.1 mL/hr:

At this very low rate, our mechanism is making 1 step (of 0.0000025 in) every 1.25 seconds.

For this syringe, there are 28,333 steps/mL.

For a given flow rate, the greater the number of steps per mL, the closer together in time each step will occur. No formal industry standards exist specifying a particular time interval; however, the Emergency Care Research Institute (ECRI) recently asserted that "no more than a 20 second interval" between steps was deemed "excellent" in flow continuity.

46. What is the flow uniformity for the Alaris PCA module?

Flow uniformity is mainly driven by the mechanical accuracy of the entire mechanism. In other words, the average "set" distance is not a perfect 0.0000025 in every time. A good tool to "visualize" or quantify flow uniformity is the trumpet curve and the associated start-up curve. For the trumpet curve, the "tighter" the trumpet shape is the better. For the start-up curve, the more steady the line is or the smaller the fluctuations are, the better. Please review the trumpet and start-up curves located in the back of the PCA section of the directions for use.

47. What are the Alaris PCA module's dimensions?

4.5" W x 15.0" H x 7.5" D (exclusive of security door).

48. Does the Alaris PCA module have a battery?

The Alaris PCA module requires an Alaris PC unit for power and operation. The Alaris System can run on battery power when unplugged.

49. How will the Alaris PCA module respond when downward force is applied to the plunger during operation?

We measure two different characteristics of how mechanically solid the Alaris PCA module is – compliance and slack.

Compliance is the small amount the head moves when the split nut is engaged as a load is applied (by a hand on the head or by backpressure from a loaded syringe). The Alaris PCA module moves about 0.05 in when 20 lbs is applied to the head (this is about 0.9 mL with a 60 mL syringe when 20 lbs is applied).

Slack is the small amount the head wiggles when the split nut is engaged with a very small amount of lead applied. We believe that CareFusion is at par or better than our competitors in this mechanical measurement. The Alaris PCA module has about 0.014 in of slack at the end. This is equivalent to about 0.25 mL with a 60 mL syringe.

50. Can the Alaris PCA module be used during MRI?

No.

51. Does the Alaris PCA module work in anesthesia mode?

No. Anesthesia mode does not apply to the Alaris PCA module. This design was based on the clinical practice of discontinuing PCA therapy when a patient undergoes anesthesia for surgical interventions.

52. Does the Alaris PCA module offer a keep vein open (KVO) option?

No.

53. Does the Alaris PCA module have a restore feature?

Yes. This feature allows clinicians to simplify programming by recalling previous programming parameters for the same patient.

54. Does the Alaris PCA module have the ability to display patient history?

Yes. The Alaris PCA module records and displays patient history for up to 24 hours, and may be displayed in the intervals 1hr, 2hr, 4hr, 8hr, 12hr and 24hr. Patient history includes the following information:

- Total demands
- Delivered demands
- Total drug delivered
- Time and date patient history last cleared
- Average drug per hour
- Total amount of drug delivered via:
  - PCA dose
  - Continuous infusion
  - Loading dose
  - Clinician bolus dose

55. Can the patient history be downloaded to a printer? Can it be sent electronically to the flowsheet or patient record?

No, not at this time. However, CareFusion is actively exploring ways to make the patient history available to other hospital information systems through our Alaris enterprise applications. Our product vision[*] includes the ability to download this data to a patient's flowsheet, patient record, electronic medication administration record (eMAR) or other information sources as needed for documentation and analysis purposes.

*CareFusion does not guarantee the availability of products identified as future vision.

56. **What type(s) of patient and family education does CareFusion provide for the patient and family?**

CareFusion provides patient and family education sheets in both English and Spanish. Also, CareFusion can provide a sticker (English/Spanish) to place on the patient dose request cord alerting the family that the patient dose request cord is for patient use only.

The can be ordered by calling Customer Care at 800-482-4822. Please see the order numbers below:

Patient information guide (English): Order #10273267

Patient information guide (Spanish): Order #10210839

Patient dose request cord stickers (English/Spanish): Order #10210838

Alaris EtCO$_2$ module FAQs

1. **How is the Alaris EtCO$_2$ module used?**

The Alaris EtCO$_2$ module is an easy-to-use capnograph that displays waveforms and numeric values of the patient's exhaled breath. It uses Oridion patented Microstream® circuit technology in conjunction with FilterLine® disposables to offer real-time ventilator status of the patient. The breath sample is captured externally from nose or mouth via cannula and transported to the device for sampling. It measures ventilation and is indicated for continuous non-invasive monitoring of end-tidal carbon dioxide (EtCO$_2$), fractional-inspired carbon dioxide (FiCO$_2$), respiratory rate and no breath indication. It is used to help identify adverse ventilation events and may help clinicians diagnose specific medical conditions, leading to important treatment decisions. The Alaris EtCO$_2$ module and FilterLine disposable (patient sampling cannula) are indicated for use with intubated and non-intubated adults, geriatric, pediatric and neonatal patients.

2. **What is the Oridion FilterLine disposable (patient sampling cannula)?**

The FilterLine cannula collects the EtCO$_2$ sample during exhalation and transports it to the Alaris EtCO$_2$ module, where it is measured and displayed. The FilterLine cannula is unique because it collects a sample by nose or mouth breathing. Moisture handling is accomplished by Nafion® material, and it minimizes the complications caused by clogged sample lines. This will increase the length of time you can use one FilterLine cannula before it displays occluded.[3] This same Oridion FilterLine can deliver up to 5L of oxygen. The oxygen is delivered through the small pinholes under the nose prongs and in a cloud instead of through the nasal prongs.

Note: For more information on the FilterLine product, please contact the manufacturer, Oridion.

3. **How many Alaris EtCO$_2$ modules can be attached to one Alaris PC unit?**

Only one Alaris EtCO$_2$ module can be attached to the Alaris PC unit.

4. **What are the principles of operations for the Alaris ETCO$_2$ module?**

The Alaris EtCO$_2$ module uses Oridion patented Microstream nondispersive infrared (NDIR) spectroscopy to continuously measure the amount of CO$_2$ during every breath, the amount of CO$_2$ present at the end of exhalation (EtCO$_2$) and during inhalation (FiCO$_2$),and the respiratory rate. The Alaris EtCO$_2$ module is a side stream capnograph that uses the FilterLine disposable to deliver a sample of the inhaled and exhaled gases from the patient or ventilator disposable to the EtCO$_2$ module. Moisture and patient secretions are extracted from the sample by the inline filter while maintaining the shape of the CO$_2$ waveform.

The 50mL/min sampling flow rate reduces liquid and secretion accumulation, decreasing the risk of obstruction in the sample pathway in humid ICU environments. The small sample size

eliminates the need for water traps and prevents excess fluid accumulation. No operator intervention is required for routine moisture or condensate. The Alaris $EtCO_2$ module draws a gas sample through a microsample cell (15 μL). This extremely small volume is quickly flushed, allowing for a rise time of approximately 190 ms and accurate CO^2 readings, even at high respiration rates.

The Microbeam infrared (IR) source illuminates the microsample cell and the reference channel. This proprietary IR light source generates only the specific wavelengths characteristic of the CO_2 absorption spectrum. The IR light that passes through the microsample cell and the IR light that passes through the reference channel are measured by IR detectors.

5. **What are some of the features and definitions related to using the Alaris $EtCO_2$ module?**

Below are some features and definitions to be familiar with when using the Alaris $EtCO_2$ module.

- BPM = Breaths per minute

- CO_2 = Carbon dioxide

- Capnography waveform = The real-time graphical display of CO_2 concentration throughout respiration

- $EtCO_2$ = The concentration of CO_2 in mmHg at the end of exhalation

- $FiCO_2$ = Fractional inspired CO_2; concentration of CO_2 present during inhalation

- Pre-silence-alarms = The Alaris $EtCO_2$ module can be silenced or pre-silenced for 120 sec. The silenced alarm can be cancelled before the 120 sec are complete

- Programmable alarm limits = The Alaris $EtCO_2$ module features programmable alarm limits for

$EtCO_2$, $FiCO_2$, respiration rates and no breath time periods

- Respiratory rate = The patient's respiratory rate in breaths per minute (breaths/minute)

- Trend data = The trend data is a tabular display of $EtCO_2$ and respiratory rate

6. **What are the configurable settings for the Alaris $EtCO_2$ module?**

Configurable settings for the Alaris $EtCO_2$ module include:

- $EtCO_2$ High (5 to 99 mmHg)

- $EtCO_2$ Low (0 to 98 mmHg)

- $FiCO_2$ high (2 to 99 mmHg)

- No Breath Alarm (10 to 60 sec)

- Respiratory Rate High (1 to 150 bpm)

- Respiratory Rate Low (0 to 149 bpm)

- Waveform time scale (5 or 10 sec)

- PCA pause protocol settings:

  — Respiratory Rate Lower Limit (bpm)

  — Respiratory Rate Initial Value (bpm)

*See the Alaris PCA module FAQs #4 and #8 for further explanation.

7. **How many hospitals are using the Alaris $EtCO_2$ module with the PCA pause protocol feature?**

At the time of printing this document, CareFusion has, to our knowledge, more than 90 hospitals using the Alaris $EtCO_2$ module to pause the Alaris PCA module. Keep in mind that these customer usage numbers are subject to change.

8. **What default respiratory and EtCO$_2$ monitoring parameters have other CareFusion customers used?**

At the time of printing this document, our customers have implemented the following device default settings:

Monitoring parameter	Adults default setting ranges$^{\pm}$	Pediatrics default setting ranges$^{\pm}$
EtCO$_2$ High	50 to 60 mmHg**	45 to 60 mmHg**
EtCO$_2$ Low	8 to 20 mmHg	10 to 15 mmHg
Respiratory Rate High	30 to 35 bpm***	35 to 120 bpm***
Respiratory Rate Low	6 to 8 bpm	8 to 12 bpm
No Breath Alarm	20 to 30 sec	15 to 20 sec
FiCO$_2$ High*	6 to 8 mmHg	6 to 8 mmHg

±data on file
*fractional-inspired CO2 concentration
**mmHg-mm mercury
***breaths per minute

9. **What respiratory rate PCA pause limits have other CareFusion customers used?**

At the time of printing this document, our customers have implemented the following PCA pause device default settings:

PCA pause parameter	Adult PCA pause protocol setting ranges$^{\pm}$	Pediatric PCA pause protocol setting ranges$^{\pm}$
Respiratory Rate Initial Value	4 to 5 bpm*	5 to 12 bpm*
Respiratory Rate Lower Limit	4 to 5 bpm*	4 to 10 bpm*

±data on file
*breaths per minute

10. **Does the Alaris EtCO$_2$ module have the ability to display the EtCO2 trend data?**

Yes. The Alaris EtCO$_2$ module displays patient trend data for up to 24 hours at one time and may be viewed in the time increments 1 min, 5 min, 30 min, 60 min and 120 min. Trend data displays the following information:

- Time period of data review

- Average EtCO$_2$ with high and low values

- Average respiratory rate (RR) with high and low values

- Alarm icon ( ) with Fi to indicate high FiCO$_2$ alarm limit has been exceeded

- Alarm icon ( ) to indicate alarm limit has been exceeded

- Alarm icon ( ) in RR column to indicate a no breath alarm limit has been triggered

11. **Does the Alaris System have the ability to display PCA and EtCO$_2$ trend data side by side?**

Yes. The Alaris System is the only system that displays PCA and EtCO$_2$ trend data for up to 24 hours at one time. The PCA and EtCO$_2$ trend data can be displayed when the two modules are on and attached to the same Alaris PC unit. The following information can be viewed:

- Data and time increments 1 min, 5 min, 30 min, 60 min and 120 min

- Average EtCO$_2$

- Average respiratory rate (RR)

- Alarm icon ( )

- Total dose of medication infused through the Alaris PCA module (includes continuous infusion, loading dose, bolus dose and PCA dose)

12. Does the Alaris EtCO₂ module have the ability to adjust the EtCO₂ waveform display?

Yes. The Alaris EtCO₂ module can display a continuous waveform, a waveform range of 1 to 60 mmHg or 0 to 90 mmHg, or in a waveform time scale of 5 sec or 10 sec.

13. What are the common myths with the measurement of respiratory rate?

A common myth is that all respiratory rate assessments are the same. Current respiratory rate monitoring requires the clinician's presence in the room to observe the patient's chest rise and fall and/or listen to breath sounds. Blankets or patient position can limit visualization of chest movement and, even with complete airway obstruction, there may continue to be chest movement as the patient attempts to breathe.

The Alaris EtCO₂ module can display the patient's respiratory rate and alarm if the patient's respiratory status declines when the clinician is not in the room.

Impedance Pneumography, measuring respiratory rate with ECG leads, provides a respiratory rate based on respiratory effort, the attempt to breathe or any other sufficient movement of the chest. However, the Alaris EtCO₂ module measures the effective breath; the actual exhales breath.

Remember, the monitoring objective during PCA is to monitor airway patency and breathing quality, and to detect the onset of respiratory depression. EtCO₂ provides the most accurate respiratory rate and monitors airway patency and breathing quality. Thus EtCO₂ monitoring is a breath-by-breath measurement of ventilatory status.[4]

14. What are the differences between conventional capnography technologies: Mainstream, Sidestream and Microstream?

Note: All capnographs—including Microstream—measure CO₂ concentration

using either Mainstream or Sidestream configurations.

Capnography technology	Definition
Mainstream	In mainstream capnographs, the sensor is located on a special airway adapter so that CO₂ is measured directly in the patient's breathing circuit (endotracheal tube). The main drawbacks are the weight of the sensor is on the airway, which is significant with neonates; external sensors that are vulnerable to damage and inability to monitor non-intubated patients easily.
Sidestream	In sidestream capnographs, a sample of exhaled breath is aspirated from the breathing circuit and carried to a sensor residing inside the monitor. Sidestream configurations are appropriate for both intubated and non-intubated patients. They require external filters to prevent liquids and secretions from reaching the sidestream sampling system. Drawbacks of sidestream include liquid and secretion handling a large breath sample rate and the use of low-flow applications (neonates) is precluded.
Microstream	Microstream improves on conventional sidestream technology because there is no sensor at the airway. IT can work for both intubated and non-intubated patients of all ages. Microstream uses laser-based molecular correlation spectroscopy (MCS) as the infrared emission source. The Microstream emitter operates at room temperature and is electronically activated and self-modulating. This eliminates the need for moving parts that are used on some competitive systems and increases the reliability of the Microstream system.

15. **Can we use humidification with the oxygen for the patient?**

    Yes.

16. **What is the accuracy of the Alaris EtCO$_2$ module?**

    Due to the relatively small sampling size needed for EtCO$_2$ readings, partial pressure does not affect the ability of the Alaris EtCO$_2$ module to measure EtCO$_2$, as long as the 50 mL/min rate can be achieved.

    EtCO2 readings

CO$_2$ partial pressure (at sea level)	Accuracy
0 to 38 mmHg	± 2 mmHg
39 to 99 mmHg	± (5% of reading + 0.08% for every 1 mmHg above 38 mmHg)

    Above 55°C module temperature, ± mmHg or 2.5% (whichever is greater) has to be added to tolerance of accuracy specifications.

    Respiration Rate

Measured in range of 0 to 150 bpm with the following accuracy:
0 to 70 bpm: ±1 bpm
71 to 120 bpm: ±2 bpm
121 to 150 bpm: ±3 bpm

17. **Does the Alaris EtCO$_2$ module have specifications for environmental conditions?**

    Yes. The specifications are listed below.

	Operating	Storage/ transport
Altitude	-380 to 4,570 m (-1,250 to 15,000 ft)	-380 to 4,570 m (-1,250 to 15,000 ft)
Atmospheric pressure	525 to 795 mmHg (700 to 1060 hPa)	375 to 760 mmHg (500 to 1013 hPa)
Relative humidity	20% to 90% Noncondensing	5% to 85% Noncondensing

Sound pressure	34.9 db	Not applicable
Temperature range	41°F to 104°F (5°C to 40°C)	-4°F to 140°F (-20°C to 60°C)

18. **Does CareFusion have a list of gases that were tested with the Alaris EtCO$_2$ module?**

    Yes. The following gases have been tested and were found to have no effect on EtCO$_2$ measurement:

    - Desflurane
    - Enflurane
    - Halothane
    - Isoflurane
    - Sevoflurane

19. **Does CareFusion have an example of a normal EtCO$_2$ waveform tracing with a brief description of the waveform anatomy?**

    Yes. The Alaris EtCO$_2$ module provides the option to display EtCO$_2$ readings as a waveform. The following graph is an example of a normal waveform (normal ventilation, 35 to 45 mmHg). In the event the EtCO$_2$ value is above the waveform display range, the top of the waveform will be slipped. Numerical EtCO$_2$ values continue to display on both the Alaris EtCO$_2$ module and Alaris PC unit.
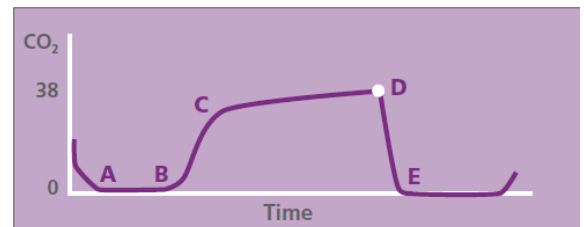
    A-B: Baseline period of no CO$_2$; end of inhalation
    B-C: Rapid rise in CO$_2$
    C-D: Alveolar plateau
    D: End of expiration; EtCO$_2$
    D-E: Inhalation

20. **What type of Alaris EtCO$_2$ module patient and family education does CareFusion provide?**

CareFusion provides patient and family education sheets in both English and Spanish. They can be ordered by calling Customer Care at 800-482-4822. Please see the order numbers below:

Patient information guide (English): Order #10273268

Patient information guide (Spanish): Order #10210840

21. **What is Smart Alarm for Respiratory Analysis (SARA™)?**

SARA is an alarm management technology developed by Oridion. The SARA technology, which recognizes and reduces respiratory rate nuisance alarms while accurately reflecting the patient's condition and preserving caregiver alarm vigilance[5], is embedded into the Alaris EtCO$_2$ module.

References

1   American Society of Anesthesiologists (ASA). *Basic Standards for Intraoperative Monitoring*. 1999, Joint Commission 2007.
2   Anesthesia Patient Safety Foundation. *Opioid Safety*. 2005, 2009.
3   Oridion directions for use, 2005
4   Oridion-Guide for implementing capnography for pain management, 2006.
5   Oridion. http://www.oridion.com.