Pain Management Portfolio FAQs

FAQs for the Alaris™ PCA, EtCO$_2$ and SpO$_2$ modules

Alaris™ PCA module FAQs

1. **What criteria were used in the Alaris PCA Module?**

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

- Lightweight: 5.5 lbs
- **Common user interface with Alaris System:** Same front panel keys as other Alaris System modules.
- **Patient safety:** The Alaris PCA Pause Protocol algorithm using the integrated Alaris EtCO$_2$ and/or Alaris SpO$_2$ promotes early detection of respiratory depression and pauses the PCA infusion when the patient's respiratory status falls outside the hospital's pre-set limits.
- **Drug security:** The Alaris PCA module has a channel release lever located behind the locked PCA door.
- **Trending patient monitoring data:** Ability to view a patient's PCA medication doses. When using the integrated monitoring modules -Alaris EtCO$_2$ (*capnography*) or Alaris SpO$_2$ (*oximetry*) modules attached to the same Alaris PCU, can also view the patient's respiratory rate, ventilatory waveform and oxygen saturation.
- **Security access levels:** The Alaris PCA module has the ability to use a code 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 Alaris PCA module's dimensions?**

The dimensions are: 4.5" x 15.0" x 7.5" (*exclusive of security door*).

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 (EtCO$_2$ and/or SpO$_2$), a PCA Pause Protocol feature and barcoding capability (*when used with the Alaris Auto-ID module*) all in one platform using a single user interface. This advanced technology augments PCA safety throughout the duration of PCA therapy by the following:

- Reducing the potential for harm before PCA therapy is initiated through DERS and confirming the intended drug and concentration chosen from the drug library (*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 completion.

The Alaris System takes advantage of a fully integrated single platform and allows the clinician to view real-time PCA infusion dosing plus monitor trend data on the same screen. This feature provides an additional tool to help the clinician 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 due to the decreased number of devices the caregiver must learn to program.

4. **What is the Alaris PCA Pause Protocol feature?**

Most hospitals require regular monitoring and assessment of patients during PCA therapy due to the potential for opioid-induced respiratory depression. By allowing integration 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 with the ability to continuously monitor the patient's respiratory status in response to PCA therapy.

To provide an additional safety net, the Alaris PCA Pause Protocol is available when:

- The hospital enables the PCA Pause Protocol in the dataset.
- An Alaris PCA module and Alaris $EtCO_2$ and/or Alaris SpO_2 module 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. The following 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 cord 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.

Note: 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. **What settings should be considered when configuring the PCA Pause Protocol? How does this feature work?**

When developing the dataset, 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.

Second, 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 the patient's status falls below the minimum threshold, 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 individual patient need.

- 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.

Third, hard limits for the PCA Pause Protocol values must be set: $\%SpO_2$ Low Limit and/or Respiratory Rate Low 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 to prevent further decline, follow these guidelines:

- 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.

The Respiratory Rate High or Low value and/or $\%SpO_2$ Low value will first trigger an alarm 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, then the Alaris PCA module will alarm and pause the PCA infusion.

6. **Which settings are configurable in the dataset 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
- Maximum dose limit time window
- Maximum rate mL/hr (for continuous dose)
- Near end of infusion alert time (%)
- Occlusion pressure limit
- Priming
- PCA Pause Protocol (enable/disable)
  — PCA Pause Protocol enabled for $EtCO_2$, SpO_2 or both
  — Monitoring module attach enforcement
  — PCA Pause Protocol alarm text (advisory text developed by the hospital)

7. **Which settings are configurable in the dataset for drugs in the PCA library?**

- Drug set-up name

- Dosing units

- Supports PCA Pause Protocol

- Maximum accumulated dose range parameters (per one, two or four hours)
  — Soft minimum/per hour
  — Soft maximum/per hour
  — Hard max/per hour
  — Initial value

- PCA dose parameters
  — Soft minimum
  — Soft maximum
  — Hard maximum
  — Initial value
  — Lockout hard minimum
  — Lockout soft minimum
  — Lockout soft maximum
  — Lockout initial value

- Continuous dose parameters
  — Soft minimum/per hour
  — Soft maximum/per hour
  — Hard maximum/per hour
  — Initial value

- Bolus dose parameters
  — Soft minimum
  — Soft maximum
  — Hard maximum
  — Choice to include (*clinician-activated*) bolus doses in maximum accumulated dose

- Loading dose parameters
  — Soft minimum
  — Soft maximum
  — Hard maximum

- Concentration limits
  — Concentration units
  — Hard minimum
  — Soft minimum
  — Soft maximum

- Clinical advisory

8. **Can the PCA Pause Protocol be set up based on a PCA-specific medication, or must the PCA Pause Protocol be active for all PCA medications?**

Each hospital can choose which PCA medications will activate the PCA Pause Protocol. Alaris Guardrails Editor software is used to associate the PCA medications with the PCA Pause Protocol.

Note: When building the PCA drug library, it is very important to enable the PCA Pause Protocol feature for each intended PCA medication. If this feature is **not** enabled in the PCA drug library, the Alaris PCA module will **not** pause.

9. **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 PCA 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.

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

Only one Alaris PCA module can be used with a single Alaris PCU.

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

No, not at this time. The Alaris PCA module offers a "therapies" feature. Therapies are not true weight-based dosing, but this feature allows the setup of weight-range dosing.

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

Yes. The Alaris PCA module is approved for delivering IV, subcutaneous and epidural medications. Also, the Alaris PCA module can be used in adult, pediatric and neonatal patient populations. Note: The hospital should determine the use of the PCA module for epidural and subcutaneous infusions.

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

No. If the syringe is purged of air before it is loaded into the Alaris PCA module and the PCA administration set is primed properly, removing all air, there is no need for air-in-line detection.

14. **What is Near End of Infusion (NEOI)?**

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

15. **Will the Alaris PCA module allow for different drugs and concentrations in the dataset?**

Yes. The 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.

16. **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*).

17. **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. However, the user must confirm the brand of syringe and size being used.

18. **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 PCA administration sets.

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

*Monoject 35 mL PCA syringe includes detachable plunger version
**International Medication Systems

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

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

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

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

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

Yes. Based on the syringe brand, the Alaris PCA module is designed to detect the exact amount of fluid in a syringe.

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

Yes. Hospitals can define a subset of syringe brands and sizes available as a "favorites" syringe list to limit the selection of syringe sizes/brands that appear on the Alaris PC unit screen.

23. **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*). Note: Syringe size and running force, variations of back pressure or any combination of these may affect rate accuracy.

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

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

25. **Is the 35 mL Monoject syringe barrel with detachable, reusable syringe 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.

26. **Why did BD partner with Monoject to develop the 35 mL Monoject PCA syringe barrel with detachable, reusable plunger rod?**

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

27. **Can the 35 mL Monoject with separate barrel and syringe plunger rod be purchased with compounded and ready-to-use PCA admixtures?**

Yes. Ready-to-use custom compounded PCA admixtures are available from PharMEDium Service.

28. **Can the 35 mL Monoject syringe barrel with detachable, reusable syringe plunger rod be purchased empty for filling by the hospital pharmacy?**

Yes. Hospitals that compound and fill their own PCA syringes can order the 35 ml Monoject syringe directly from BD. The 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. The empty barrel is part number 8881135609. To order or ask questions, call BD Customer Support: (888) 876-4287.

29. **How is the reusable plunger rod packaged?**

The reusable plunger is packaged with one of five PCA syringe administration sets in a PCA administration kit.

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

Yes. The Alaris PCA module accepts non- dedicated PCA administration sets and extension sets. BD recommends using non-dedicated administration sets with integrated anti-siphon valves. BD also recommends using check valves on the primary IV set to prevent PCA medication from backing up into the primary line.

31. **What dedicated PCA administration kits, administration sets and extension sets does BD offer?**

BD offers a broad range of PCA administration kits, administration sets and extension sets. Please refer to the online Infusion Disposables Catalog available on the website. All administration kits, administration sets and extension sets are latex-free. To order or ask questions, call BD Customer Support: (888) 876-4287.

32. **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 display a syringe picture message 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. The Alaris PCA administration kits and administration sets incorporate an anti-siphon valve. This anti-siphon valve helps prevent uncontrolled flow of fluid into the line. BD offers PCA administration kits and administration sets with a Y-connector allowing the connection of the maintenance/primary administration set. The check valve (integrated with the Y-connector) ensures that the PCA drug does not backflow into the maintenance/primary administration set.

33. **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/h*)	User selectable increments (*mL/h*)
0.10–9.99	0.01
10–99.9	0.1
100–999	1

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

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

Syringe size (*mL*)	Flow rate range (*mL/h*)
20	0.1–500
30/35	0.1–650
60	0.1–999

35. **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.

36. **What is the Alaris PCA module rate accuracy?**

The rate accuracy of the Alaris PCA module is +/- 2% of full-scale plunger travel (not including syringe variation).
Warning: Syringe size and running force, variations of back pressure, or any combination of these can affect rate accuracy. Factors that can influence back pressure are: Administration set configuration, IV solution viscosity, and IV solution temperature. Back pressure can also be affected by type of catheter.

37. **What is the Alaris PCA module critical volume?**

Maximum over-infusion, which can occur in the 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.

38. **What is the flow continuity for the Alaris PCA module?**

Flow continuity is determined by the mechanism step size of the PCA pump.

For the Alaris PCA module, the average "set" distance is 2.5 millionths (0.0000025) of an inch. Thinking of it in terms of fluid delivered from an actual syringe gives an idea of the flow continuity level. For example, a BD 60 cc syringe at a rate of 0.1 mL/hr will have 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.

39. **What is the flow uniformity for the Alaris PCA module?**

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, the

better uniformity. For the start-up curve, the steadier the line or the smaller the fluctuations, the better. Trumpet and start-up curves are published in the User Manual.

40. **Does the Alaris PCA module have a separate battery?**

The Alaris PCA module requires an Alaris PC unit for power and operation and does not have a separate battery. The Alaris System, via the PCU, can run on battery power when unplugged.

41. **Can the Alaris PCA module be used during MRI?**

No.

42. **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.

43. **Does the Alaris PCA module offer a keep vein open (KVO) option upon infusion complete?**

As with traditional PCA pumps there is no KVO option upon infusion complete.

44. **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.

45. **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 1 hour, 2 hour, 4 hour, 8 hour, 12 hour and 24 hour intervals. 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

46. **Can the patient history be downloaded to a printer? Can it be sent electronically to a flow sheet or patient record?**

No, not at this time.

47. **What patient and family education materials does BD provide?**

BD provides PCA patient and family education sheets in both English and Spanish. Also, BD can provide a sticker (English/Spanish) to place on the Alaris PCA patient dose request cord alerting the family that the patient dose request cord is for patient use only. To order or ask questions, call BD Customer Support: (888) 876-4287.

Alaris EtCO$_2$ module FAQs

1.   What features and definitions are related to the Alaris EtCO$_2$ module?

Below are 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 near 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

2.   How is the Alaris EtCO$_2$ module used?

The Alaris EtCO$_2$ module is an easy-to-use capnograph that displays respiratory waveforms and numeric values of the patient's exhaled breath. The module incorporates Medtronic patented Microstream™ circuit technology in conjunction with FilterLine™ disposables to offer near real-time ventilatory status of the patient. A breath sample from the patient's nose and/or mouth is captured externally via the nasal cannula and delivered to the EtCO$_2$ device for analysis. The Alaris EtCO$_2$ measures ventilation and is indicated for continuous non-invasive EtCO$_2$ monitoring, FiCO$_2$ monitoring, 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 including patients on supplemental oxygen.

3.   What is the Medtronic FilterLine disposable (*patient sampling cannula*)?

The FilterLine cannula collects the EtCO$_2$ sample during exhalation and conveys it to the Alaris EtCO$_2$ module where it is measured and displayed. The FilterLine cannula is unique as it collects a sample by nose or mouth breathing. Moisture handling is accomplished by Nafion® material, which minimizes the complications caused by clogged sample lines. This will increase the length of time a FilterLine cannula can be used before it displays occluded. The FilterLine can also deliver up to 5L of oxygen. The oxygen is delivered through the small pinholes under the nose prongs instead of through the nasal prongs. **Note:** For more information on FilterLine, contact the manufacturer, Medtronic. Telephone: (888) 674-3466.

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

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

5. **What are the principles of operation for the Alaris EtCO$_2$ module?**

The Alaris EtCO$_2$ module uses Medtronic 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 patient's 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 via the FilterLine cannula 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.

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)

7. **Does the Alaris EtCO$_2$ module have the ability to display the EtCO$_2$ 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 of 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 (R) in RR column to indicate a no breath alarm limit has been triggered

8. **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 a time. The PCA and EtCO$_2$ trend data can be displayed when the two modules are in operation 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 ($\mathbb{R}$)
- Total dose of medication infused through the Alaris PCA module (*includes continuous infusion, loading dose, bolus dose and PCA dose*)

9. **Can the Alaris EtCO$_2$ module EtCO$_2$ waveform display be adjusted?**

Yes. The Alaris EtCO$_2$ module can display a continuous waveform, a waveform range of 1 to 60 mmHg or 0 to 90 mmHg, or a waveform time scale of five or 10 seconds.

10. **Can humidification be used with the oxygen for the patient?**

Yes.

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

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

EtCO$_2$ readings

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

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

Respiratory Rate

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

12. **What are the Alaris EtCO$_2$ module specifications for environmental conditions?**

The specifications are:

|	Operating	Storage/Transport
Altitude	-380–4,570m (-1,250–15,000 ft)	-380–4,570m (-1,250–15,000 ft)
Atmospheric Pressure	525–795 mmHg (700–1060 hPa)	375–760 mmHg (500–1013 hPa)
Relative humidity	20%–90% Noncondensing	5%–85% Noncondensing
Sound Pressure	34.9 db	Not applicable
Temperature Range	41˚F–104˚F (5˚C–40˚C)	-4˚F to 140˚F (-20˚C–60˚C)

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

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

- Desflurane
- Enflurane
- Halothane
- Isoflurane
- Sevoflurane

14. **Does BD 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 respiratory cycle 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.
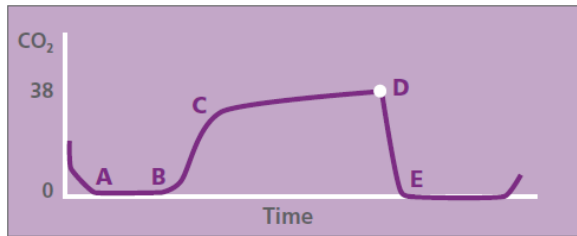
A–B: Baseline period of no CO_2; end of inhalation
B–C: Rapid rise in CO_2
C–D: Alveolar plateau
D: End of expiration; $EtCO_2$
D–E: Inhalation

15. **What type of Alaris $EtCO_2$ module patient and family education does BD provide?**

BD provides patient and family education sheets in both English and Spanish. They can be ordered by calling BD Customer Order Management at 800.482.4822. See the order numbers below:

Patient information guide (English): Order #10273268

Patient information guide (Spanish): Order #10210840

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

SARA is an alarm management technology developed by Medtronic and is embedded in the Alaris $EtCO_2$ module. SARA technology recognizes and reduces respiratory rate nuisance alarms while accurately reflecting the patient's condition and preserving caregiver alarm vigilance.

Alaris SpO$_2$ Module FAQs:

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

The Alaris SpO$_2$ module is an easy-to-use oxygen saturation module which helps continuously, noninvasively monitor oxygen saturation and pulse rates in adult, pediatric and neonatal patients. The Alaris SpO$_2$ Module is available with either Masimo® Signal Extraction Technology (SET®) or Nellcor Pulse Oximetry with OxiMax™ technology.

2. **What unique features are offered by the Alaris SpO$_2$ module?**

The Alaris SpO$_2$ module offers:

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

- **Patient safety:** The Alaris PCA Pause Protocol algorithm using the integrated Alaris SpO$_2$ module promotes early detection of respiratory depression and pauses the PCA infusion when hospital- established oxygen saturation alarm limits are exceeded. This helps provide an added safety net for critical patient risk factors unprotected by programming safety, such as PCA by proxy and undiagnosed clinical conditions

- **Customizable alarm limits** by care area utilizing Guardrails™ Suite MX safety software helps ensure alarms are appropriate for patients

- **Near real-time patient oxygen saturation status** provides an early indication of potentially serious respiratory events throughout the course of infusion therapy

- **Helps clinicians detect and manage** the risk of respiratory depression during complex or high dose PCA therapies

- **PCA Pause Protocol**, when used with the Alaris PCA module, and near real-time SpO$_2$ and PCA dose trend data

3. **What features are available on the Alaris SpO$_2$ module incorporating Masimo® Signal Extraction Technology® (SET®)?**

- Masimo FastSat™ feature offers the ability to detect rapid oxygen saturation changes when it is most needed (*e.g., induction and intubation, apnea, hypopnea*)

- Ability to monitor neonatal through adult applications

- The technology helps eliminate false alarms and assists in providing accurate readings under extreme conditions such as low perfusion, motion and intense ambient light

- Masimo Signal IQ™ technology provides a visual indicator of the arterial oxygen saturation and pulse rate readings during motion and low perfusion

- Perfusion Index (PI) is a numerical value that indicates the pulse strength and can be used to evaluate the appropriateness of a monitoring site

- Adaptive Probe Off Detection (APOD) delivers enhanced protection against erroneous pulse rate and arterial oxygen saturation readings when a sensor becomes detached from the patient

4. **What features are available on the Alaris SpO$_2$ module incorporating Nellcor Pulse Oximetry with OxiMax™ technology?**

- Advanced signal processing algorithms enable reliable operation, even during the most challenging situations

- Ability to monitor neonatal through adult clinical applications

- Nellcor technology provides clinical performance that helps ensure appropriate oxygenation throughout the cardiorespiratory cycle—even in such difficult monitoring conditions as low perfusion and signal interference

- OxiMax technology includes specialty sensors that address specific patient care challenges, so clinicians can effectively monitor a broader range of patients

- SatSeconds alarm management is a clinician-selectable feature that enables clinicians to manage nuisance alarms by differentiating between clinically significant desaturations and minor transient events