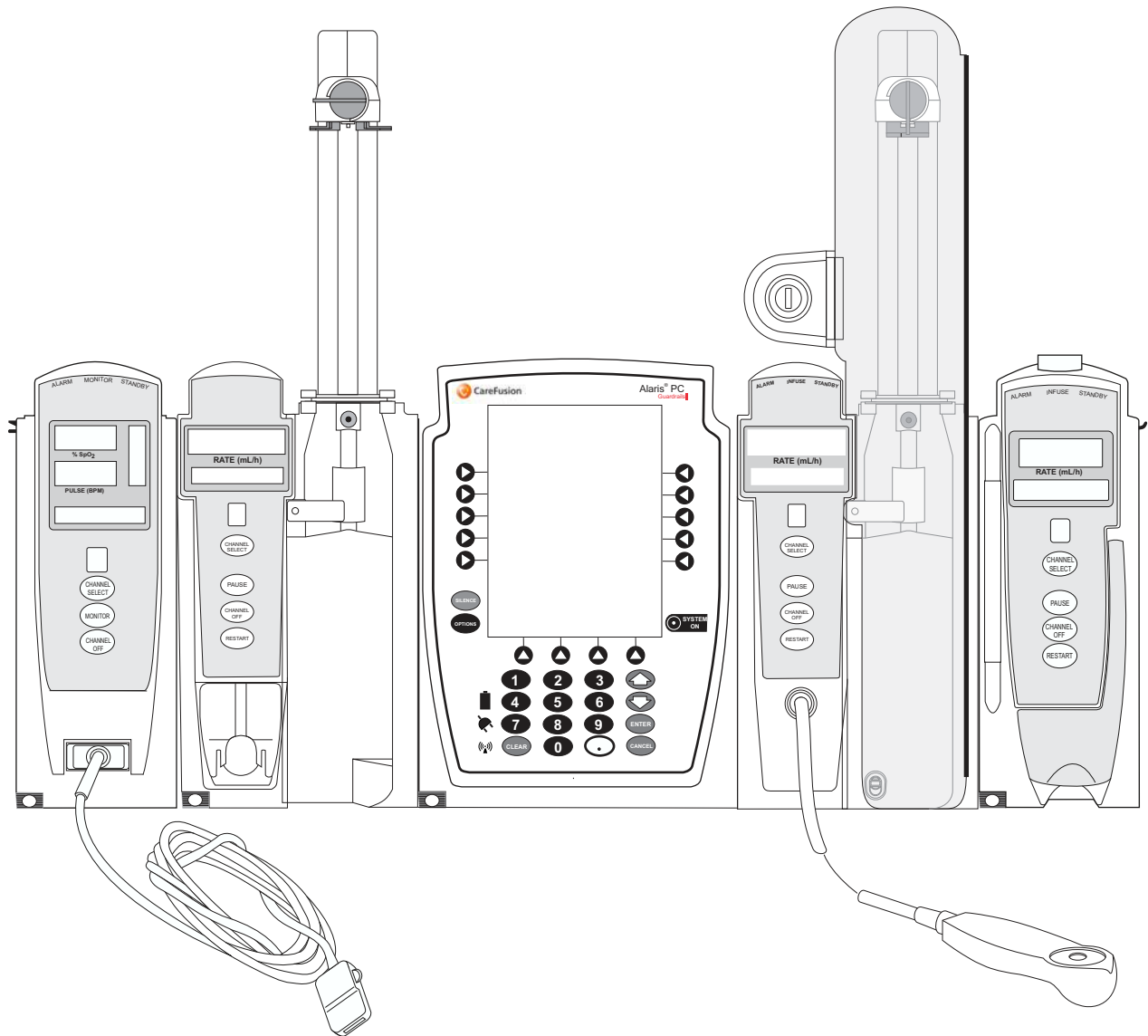


User Manual Addendum

Alaris™ System with Guardrails™ Suite MX

Alaris PC unit, Model 8015, Software Version 9.xx



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Alaris™ Syringe Module, Model 8110

Alaris™ PCA Module, Model 8120

Purpose of Addendum

This addendum replaces the following areas of the Alaris™ System with Guardrails™ Suite MX (with Alaris™ PC Unit, Model 8015, User Manual).

Syringe Module Section:

1. In the Compatible Syringes (Syringe Module) Section, the table has been updated to include compatibility for the BD Plastipak 50 mL syringe.

PCA Module Section:

1. In the PCA Module Compatible Syringes Section, the table has been updated to include compatibility for the BD Plastipak 50 mL syringe.
2. In the PCA Volume Check Section, a note for the BD® 50 mL syringe has been added.

General Information

Products Affected

- Alaris PC Unit Model 8015 with v9.xx Software

References

- Alaris PC Unit, Model 8015, and Alaris Pump Module, Model 8100 Technical Service Manual
- Alaris™ System with Guardrails™ Suite MX (with Alaris™ PC Unit, Model 8015 User Manual)

Accessing Documentation

For North American customers, service manuals, service bulletins, and software upgrade instructions are available through the CareFusion Customer Portal. The link below takes you to the portal's Welcome screen:

<https://cp.carefusion.com/>

1. If you are registered, enter your email and password, and click **LOGIN**. If you are not registered yet, click **SIGN UP**, and follow the prompts.
2. On the CareFusion Customer Portal home page, click **CONTENT LIBRARY**.
3. When the library page appears, select Service bulletins and manuals in the Content Type field to find the information you seek.

For customers outside of North America, contact CareFusion Customer Support with Infusion Technical queries/questions at:

GMB-INTL-TechnicalSupportInfusion@carefusion.com

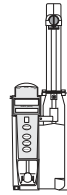
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Syringe Module

Compatible Syringes (Syringe Module)

The syringe module is calibrated and labeled for use with the following single-use disposable luer-lock syringes. Use only the syringe size and type specified on the Main Display. The full list of permitted syringe models is dependent on the software version of the syringe module



CAUTION



When using a **10 mL or smaller syringe**, CareFusion strongly recommends using an extension set with a pressure disc, for improved pressure monitoring and shorter times to occlusion alarm.

Compatible syringe availability and model numbers vary from country to country. The syringes listed in the table below may not be available in all countries, including the US and Canada. See the *Alaris Syringe module compatible syringes and flow rate ranges specification* for the country-specific syringe model numbers supported.

Manufacturer	1 mL	3 mL	5 mL	6 mL	10 mL	12 mL	20 mL	30 mL	35 mL	50 mL	60 mL
BD Plastipak	x	x	x		x		x	x		x	x
Monoject		x ^①		x		x	x		x		x
Terumo		x	x ^②		x ^②		x	x ^②			x

NOTES:

- ① The Monoject SoftPack Luer-Lock Syringe (blister pack) is the only currently supported Monoject 3 mL.
- ② The Terumo 5 mL can also be used as a 6 mL, the 10 mL as a 12 mL, and the 30 mL as a 35 mL.

Compatible Syringes (PCA Module)

Compatible Syringes (PCA Module)

The PCA module is calibrated and labeled for use with the following single-use disposable luer-lock syringes. Use only the syringe size and type specified on the Main Display. The full list of permitted syringe models is dependent on the PCA module's software version.

Syringe variability can impact occlusion pressure sensing. The variability can reduce the device's time to alarm and/or might require that a higher alarm pressure limit be programmed.

Manufacturer	20 mL	30 mL	35 mL	50mL	60 mL
BD Plastipak	x	x		x	x
IMS Pump Jet		x ^①			
Monoject	x		x		x
Terumo	x	x			x

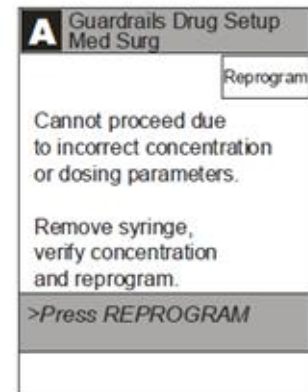
NOTE:

① Prefilled Morphine Sulfate 1 mg/mL.

PCA Volume Check

To reduce the instances of programming errors, the PCA checks the total volume of all programmed PCA parameters against a percentage (35%) of the capacity of the installed syringe. A PCA infusion can only be started when the total programmed volume is less than 35% of the syringe capacity.

The PCA volume check includes one hour of Continuous Dose, PCA Dose, Bolus Dose or Loading Dose. If the programmed volume is 35% or more of the capacity of the installed syringe during initial or subsequent programming, the clinician is presented with an alert which requires a reprogram.



PCA syringe sizes and the correlating 35% of the syringe capacity

Syringe Size	35% of Syringe Capacity
60 mL ^①	21 mL
35 mL	12.25 mL
30 mL	10.5 mL
25 mL	8.75 mL
20 mL	7 mL

NOTE:

① BD[®] 50 mL Syringe model 309653 (formerly BD[®] 60 mL Syringe model 309653) markings no longer extend beyond 50 mL, but the syringe dimensions remain the same and continue to be compatible with both the Alaris[™] Syringe and Alaris[™] PCA modules. Clinicians will continue to choose “BD Plastipak 50/60 mL” on the Alaris[™] PC Unit display. The PCA volume check for the BD[®] 50 mL Syringe is based on a 60 mL capacity, therefore a 21 mL threshold applies.



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