



CERTADOSE®



PALS SYRINGE HOLDER KIT

FOR USE WITH PEDIATRIC ADVANCED LIFE SUPPORT GUIDELINES

Indications For Use

The Certa Dose® PALS Syringe Holder Kit is intended for use by PALS-certified health care professionals to provide visual indication of maximum dose limits during pediatric cardiac arrest, as defined by PALS guidelines.

Certa Dose® PALS Syringe Holder Kit Contents

- 3 x Epinephrine Syringe Holders, size 10 mL
- 1 x Atropine Sulfate Syringe Holder, size 10 mL
- 1 x Lidocaine HCl Syringe Holder, size 5 mL
- Baseline Reference Labels
- Length-Based Resuscitation Tape
- Instructions For Use



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Certa Dose® PALS Syringe Holder Kit Contents

1 x Atropine Sulfate Syringe Holder, size 10 mL



1 x Lidocaine HCl Syringe Holder, size 5 mL



Instructions For Use



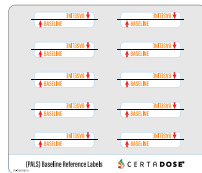
3 x Epinephrine Syringe Holders, size 10 mL



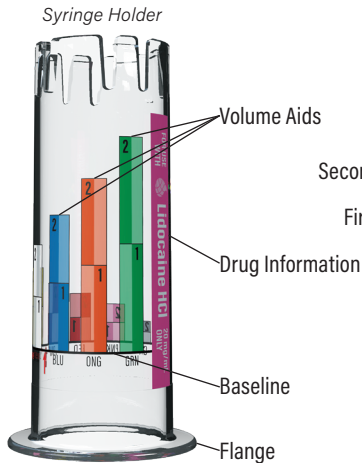
Length-Based Resuscitation Tape



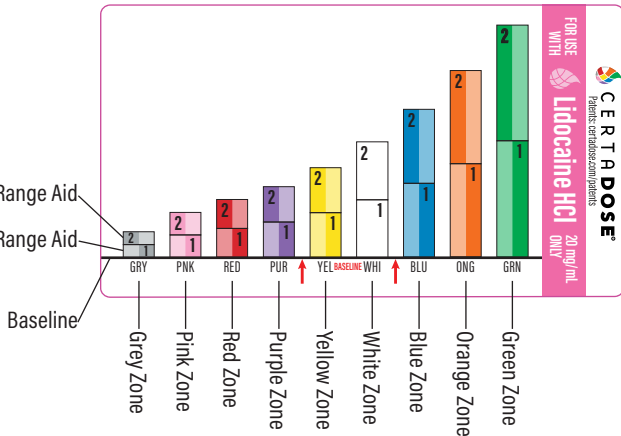
Baseline Reference Labels



Syringe Holder Diagram



Syringe Holder Label Example



Note: Each Syringe Holder has nine (9) distinct color zones matching those of the Standard Pediatric Color Coding System for Weight: grey, pink, red, purple, yellow, white, blue, orange and green.

Approximate Maximum Volume Limits as per PALS Dosing Guidelines

Note: Values in the table provided are approximate maximum volumes as per PALS dosing protocols by patient weight for each respective drug and do not represent dosing recommendations.

Health care providers should rely on clinical judgment and use these values as a general aid. Health care providers should always use the scale on the Bristoject-style syringe to confirm desired dosing volume.

Standard Pediatric Color Coding System for Weight		Approximate Maximum Volumes Per Range		
Color	Weight Range	Atropine Sulfate Dose (0.1 mg/mL)	Epinephrine Dose (0.1 mg/mL)	Lidocaine HCl Dose (20 mg/mL)
Grey	3-5 kg	1.0 mL	0.4 mL	0.20 mL
Pink	6-7 kg	1.4 mL	0.7 mL	0.35 mL
Red	8-9 kg	1.8 mL	0.9 mL	0.45 mL
Purple	10-11 kg	2.2 mL	1.1 mL	0.55 mL
Yellow	12-14 kg	2.8 mL	1.4 mL	0.70 mL
White	15-18 kg	3.6 mL	1.8 mL	0.90 mL
Blue	19-23 kg	4.6 mL	2.3 mL	1.15 mL
Orange	24-29 kg	5.0 mL	2.9 mL	1.45 mL
Green	30-36 kg	5.0 mL	3.6 mL	1.80 mL

Cautionary Statements

- Administration by health care professionals only
- Non-sterile
- Do not use if package is opened or damaged
- Single use only
- Consult instructions for use
- Keep dry
- Store at -29° to 60° C
- Do not use kit under poor lighting conditions
- Not for use by individuals with color vision deficiency



Do not use if package is opened or damaged



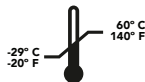
Single use



Consult instructions for use



Keep dry



Store at -29° to 60° C

Product Compatibility Table

IMPORTANT: TO ENSURE PATIENT SAFETY AND PRODUCT COMPATIBILITY, DO NOT USE ANY OF THE CERTA DOSE® SYRINGE HOLDERS WITH A SYRINGE THAT IS NOT SPECIFICALLY INDICATED ON THE PACKAGING OR INSTRUCTIONS FOR USE FOR THE RESPECTIVE SYRINGE HOLDER.

Abboject® is a registered trademark of Abbott Laboratories. LifeShield® is a registered trademark of ICU Medical, Inc. Luer-Jet™ is a trademark of International Medication Systems, Ltd. The Certa Dose® PALS Syringe Holder Kit is not manufactured, endorsed, approved, or associated with the owners of the Abboject®, LifeShield®, or Luer-Jet™ trademarks.

Certa Dose® Atropine Sulfate 10 mL (0.1 mg/mL) Syringe Holder is compatible with:

1. Atropine Sulfate Injection, USP, (0.1 mg/mL), 1 mg/10 mL, LifeShield® Abboject® Syringe. Hospira, Inc. (NDC: 0409-4911-34)
2. Atropine Sulfate Inj., USP, (0.1 mg/mL), 1 mg per 10 mL, Luer-Jet™ Luer-Lock Prefilled Syringe. IMS, Ltd. (NDC: 76329-3339-1)

Certa Dose® Epinephrine 10 mL (0.1 mg/mL) Syringe Holder is compatible with:

1. Epinephrine Injection, USP, 1:10,000, 1 mg (0.1 mg/mL), LifeShield® Abboject® Syringe. Hospira, Inc. (NDC: 0409-4921-20, 0409-4921-34)
2. Epinephrine Inj., USP, (0.1 mg/mL), 1 mg per 10 mL, Luer-Jet™ Luer-Lock Prefilled Syringe. IMS, Ltd. (NDC: 76329-3316-1)

Certa Dose® Lidocaine HCl 5 mL (20 mg/mL) Syringe Holder is compatible with:

1. Lidocaine HCl Injection, USP, 2%, 100 mg/5 mL, LifeShield® Abboject® Syringe. Hospira, Inc. (NDC: 0409-4903-34)
2. Lidocaine HCl Inj., USP, 2%, 100 mg per 5 mL, Luer-Jet™ Luer-Lock Prefilled Syringe. IMS, Ltd. (NDC: 76329-3390-1)



Abboject® Syringe



Luer-Jet™ Syringe

Table 1

How the Certa Dose® PALS Syringe Holder Kit Works

The PALS Syringe Holder Kit provides a visual aid to help medical professionals follow PALS guidelines when working with pediatric patients in cardiac arrest. The included Syringe Holders can be affixed to the Bristoject-style syringes commonly used during a pediatric cardiac arrest. The Syringe Holders have color zones that align with standard color coding for pediatric weight ranges; these color zones serve as a visual aid to indicate the approximate maximum volume of atropine sulfate, epinephrine, or lidocaine HCl, as per PALS guidelines.

Note: The PALS Syringe Holder Kit does not include Bristoject-style syringes (Abboject® or Luer-Jet™) as outlined in Table 1 on page 8.

Important: Prior knowledge of operating an Abboject® or Luer-Jet™ syringe is needed.

The components of the PALS Syringe Holder Kit include:

- Syringe Holders with color zones that correspond to standard color coding for pediatric weight ranges.
- The Syringe Holders can be used as a visual aid for up to three doses of the selected medication; the number of doses may vary by medication and patient color zone.
- Baseline Reference Labels (to be applied to medication vials to allow the Syringe Holders to act as a visual aid).
- A Length-Based Resuscitation Tape that can be used to estimate the weight and the corresponding color zone for a pediatric patient by measuring the child's length.

Note: If patient weight is unknown, a Length-Based Resuscitation Tape may be used to estimate the weight and the corresponding color zone for a pediatric patient by measuring the child's length. Please see page 10 for instructions.



Instructions For Use

Important: If you already have the patient's weight, go to step 5 (Select Bristoject Syringe) on page 12.

Estimate Patient Weight

The Length-Based Resuscitation Tape included in the PALS Syringe Holder Kit can be used to quickly estimate the weight and the corresponding color zone for a pediatric patient by measuring the child's length.

1. The pediatric patient must be on their back, legs fully extended. See Figure 1 below.
2. Place the end of the Length-Based Resuscitation Tape, labeled "Measure From This End", next to the top of the patient's head.
3. Fully extend the Length-Based Resuscitation Tape beyond the heels of the patient.

Important: Maintain placement of the retractable tape at the head of the patient during extension. Do not measure a seated patient.



Measure from this end

Pull Length-Based Resuscitation Tape

4. The color zone adjacent to the heels of the patient indicates the estimated weight. See Figure 2.

Note: The color zone of the patient as identified using the provided Length-Based Resuscitation Tape or Standard Pediatric Color Coding System corresponds to the color zone on Certa Dose® Syringe Holders. Use clinical judgment to estimate patient weight.



Select Bristoject Syringe

5. Select the drug to be administered along with the appropriate Bristoject-style syringe for use in IV administration of the intended drug for dosing.

Refer to compatibility information on page 8.

Note: If a difference in drug name, concentration, or medication color is observed, do not use the Certa Dose® Syringe Holder.

Important: Note that Certa Dose® does not make any recommendations regarding patient care, including drug selection, dosing, and administration.



Abboject® Syringe



Luer-Jet™ Syringe

Choose Syringe Holder

6. Select the Syringe Holder that matches the drug selected.
See Figure 3.



Figure 3

7. Remove Drug Confirmation Label from the end of the Syringe Holder by pulling on the Drug Confirmation Label. See Figure 4.



Figure 4

Attach Syringe Holder

8. Slide the Syringe Holder on the injector until it snaps to the base of the injector. See Figure 5a. Pinch flange of Syringe Holder and injector flange together. See Figure 5b. The Syringe Holder is properly attached when the flanges on the Syringe Holder and the injector are in direct contact without any gap, as shown in Figure 5c.

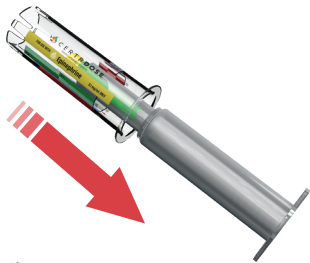


Figure 5a

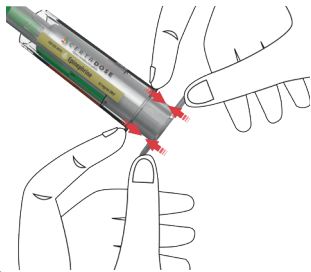


Figure 5b

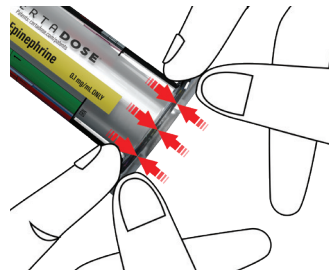
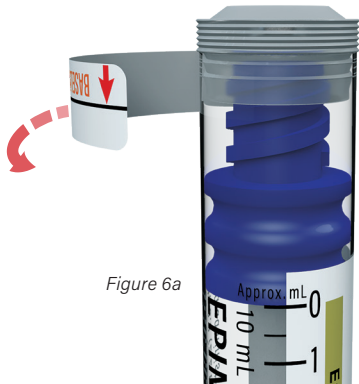


Figure 5c

Caution: Confirm that there is no gap between the flanges of the Syringe Holder and injector. If a gap exists, push the Syringe Holder fully on the injector as shown in Figure 5c.

Place Baseline Reference Label on Drug Vial

9. Apply Baseline Reference Label to the top of the drug vial just below the vial cap. See Figure 6a (label application in process) and Figure 6b (label application complete).



Apply Baseline Reference Label to top of drug vial



Assemble Vial and Syringe

10. Remove protective caps from drug vial and base of injector. See Figures 7a and 7b.



Figure 7a



Figure 7b

Note: Please reference the syringe manufacturer's instructions for use regarding product handling.

11. Thread vial into injector to assemble syringe. See Figure 8.



Figure 8

Note: Do not push vial into injector as this may cause misalignment.

12. Confirm the syringe is assembled according to the manufacturer's instructions for use. See Figure 9.



Figure 9

13. Reconfirm that attached Syringe Holder matches the drug to be administered. See Figure 10.

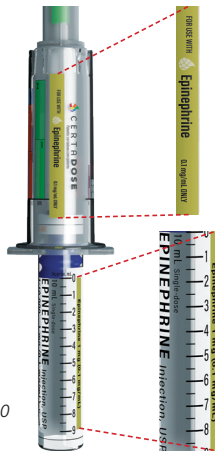


Figure 10

14. Remove Luer cap. See Figure 11.

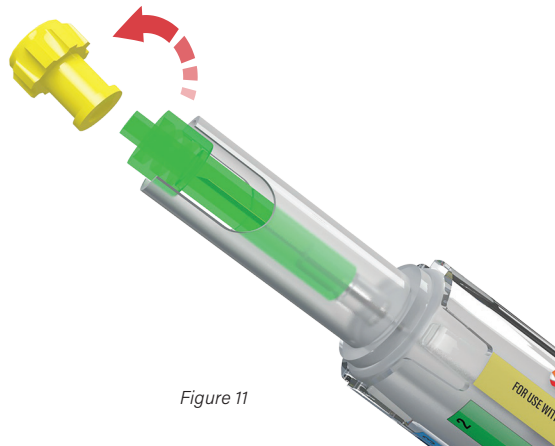


Figure 11

Align Syringe Holder and Drug Vial

15. Expel air; depress vial until stopper aligns with the zero line on vial. See Figure 12.

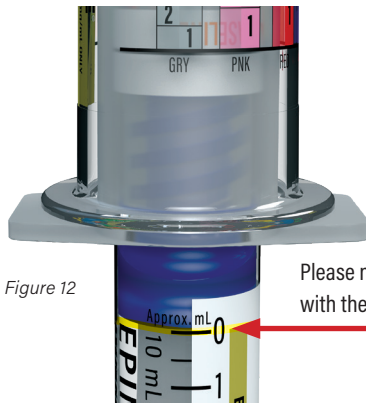
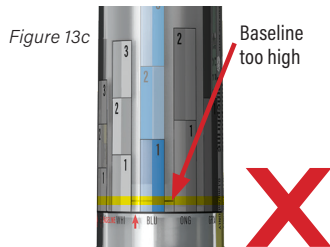
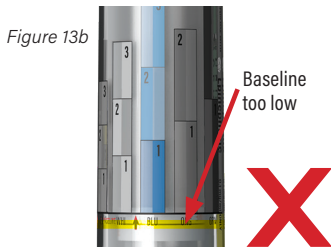
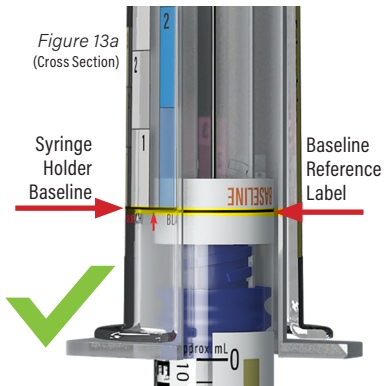


Figure 12

Please note that the stopper aligns with the zero line (highlighted)

16. Confirm Baseline Reference Label is aligned with baseline on the Syringe Holder. See Figure 13a; please note the highlighting showing alignment. **Caution:** If the Baseline Reference Label is not aligned with the baseline on the Syringe Holder, determine whether the Baseline Reference Label is above or below the baseline on the Syringe Holder. See Figure 13b and Figure 13c.



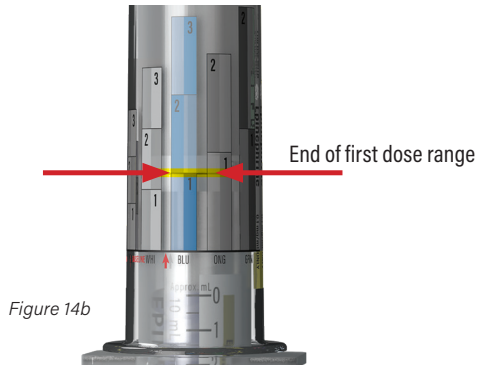
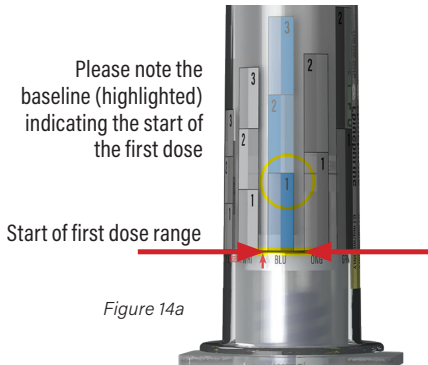
Note: If the Baseline Reference Label is **below** the baseline on the Syringe Holder as indicated in **Figure 13b**, **expel medication prior to connecting the syringe to patient IV line** by pushing the vial gently into the syringe until the Baseline Reference Label is aligned with the baseline on the Syringe Holder as shown in **Figure 14a**.

Caution: If the Baseline Reference Label is **above** the baseline on the Syringe Holder as indicated in **Figure 13c**, **do not use the Syringe Holder as a visual aid for following PALS guidelines**. Please use the syringe as per the manufacturer's instructions and clinician judgment.

Deliver First Dose

17. Find the patient's color zone on the Syringe Holder.

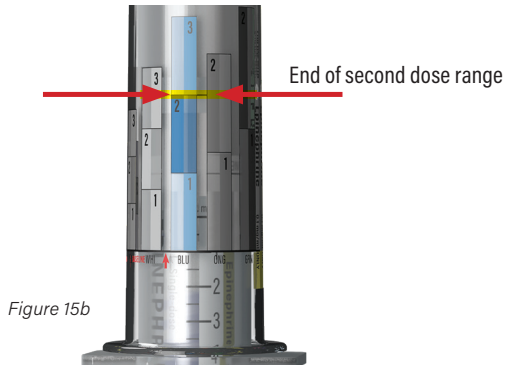
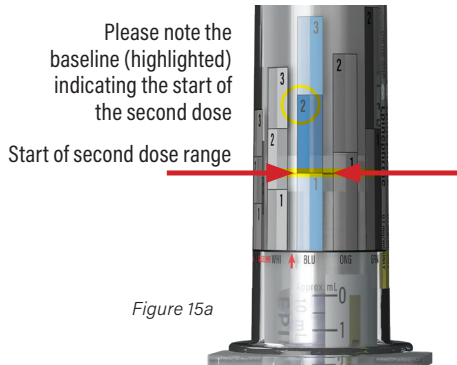
18. Deliver first dose using the first dose range (labeled with the number 1) as a visual aid. See Figure 14a and 14b.



Note: Use clinician judgment and health care protocols to determine if additional doses are appropriate.

Deliver Additional Dose(s)

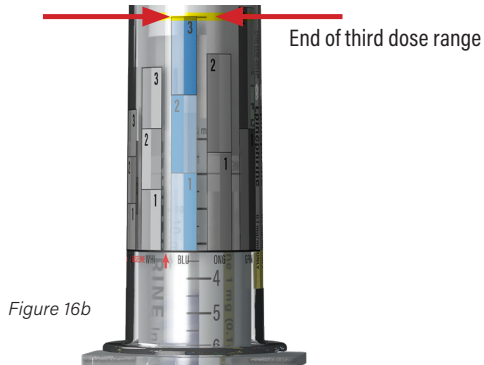
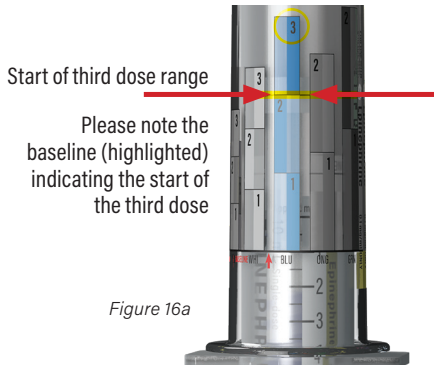
19. Deliver second dose using the second dose range (labeled with the number 2) as a visual aid. See Figure 15a and 15b.



Important: Prior to delivering the second dose, reconfirm that the Syringe Holder is aligned with the patient's color zone. Also confirm that the Baseline Reference Label is at the start of the second dose range (labeled with the number 2).

20. Deliver third dose using the third dose range (labeled with the number 3) as a visual aid. See Figure 16a and 16b.

21. After use, safely dispose of all medical waste. If additional doses of epinephrine are needed as per patient's color zone, select a new Syringe Holder and place it on a new Bristoject syringe. Repeat process starting with step 5, as seen on page 12.



Important: Prior to delivering the third dose, reconfirm that the Syringe Holder is aligned with the patient's color zone. Also confirm that the Baseline Reference Label is at the start of the third dose range (labeled with the number 3).



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Questions or comments?

Call 1-844-477-8607

Email info@certadose.com

Certa Dose, Inc.

7351 E Lowry Blvd #400

Denver, CO, 80230

Visit us at www.certadose.com