

## A Indications for Use:

The **RTC 26-C Inline Aerosol Adapter** is designed to assist in the delivery of *Combivent*<sup>®</sup> (*ipratropium bromide and albuterol*) medication from a *Respimat*<sup>®</sup> Inhaler as prescribed to an adult, mechanically-ventilated patient.

The **RTC 26-C Inline Aerosol Adapter** is intended for use only when connected to ventilator tubing.

The **RTC 26-C Inline Aerosol Adapter** is intended for single patient reuse.

This device is intended for sale by or on the order of a physician.

## C Intended Use:

The **RTC 26-C Inline Aerosol Adapter** is intended to be prescribed for any adult patient who is ventilator-dependent and for whom a *Combivent*<sup>®</sup> *Respimat*<sup>®</sup> Inhaler has been prescribed.

The expected clinical environment for the **RTC 26-C Inline Aerosol Adapter** is Critical Care and/or long term or short term ventilator care facilities.

## D Notes:

- *Combivent*<sup>®</sup> is a registered trademark of Boehringer Ingelheim Pharmaceuticals, Inc. Copyright © 2016 Boehringer Ingelheim International GmbH.
- *Respimat*<sup>®</sup> is a registered trademark and used under license from Boehringer Ingelheim International GmbH.
- The **RTC 26-C Inline Aerosol Adapter** is not affiliated with, or endorsed by, Boehringer Ingelheim Pharmaceuticals, Inc. or Boehringer Ingelheim International GmbH in any way.
- All illustrations are examples.
- The **RTC 26-C Inline Aerosol Adapter** must be placed inline exactly as shown in **Panel G (figure 1)**.
- The **RTC 26-C Inline Aerosol Adapter's Medication Port** fits inside the "Mouthpiece" on the *Combivent*<sup>®</sup> *Respimat*<sup>®</sup> Inhaler.
- The **RTC 26-C Inline Aerosol Adapter DOES NOT** actuate the *Combivent*<sup>®</sup> *Respimat*<sup>®</sup> Inhaler.
- The *Combivent*<sup>®</sup> *Respimat*<sup>®</sup> Inhaler may be inserted into the **RTC 26-C Inline Aerosol Adapter's Medication Port** in either orientation, i.e., with the cap resting on top of the *Combivent*<sup>®</sup> *Respimat*<sup>®</sup>, or dangling beneath it. Either orientation is acceptable.
- Once the **RTC 26-C Inline Aerosol Adapter** is placed into the **Inspiratory Limb** of the ventilator circuit it **SHOULD NOT** be disconnected. (*Use for a period of time not to exceed 14 days.*)

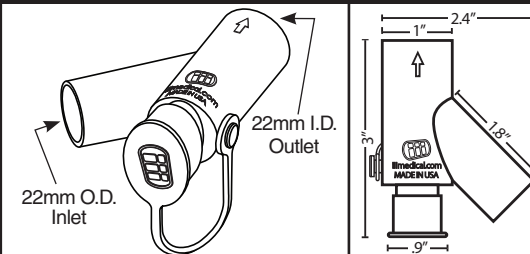
## E Cautions:

- Before use, ensure that the instructions for the *Combivent*<sup>®</sup> (*ipratropium bromide and albuterol*) *Respimat*<sup>®</sup> Inhaler have been reviewed and are kept available.
- Prepare the *Combivent*<sup>®</sup> *Respimat*<sup>®</sup> Inhaler as per medication manufacturer's instructions prior to placing it onto the **RTC 26-C Inline Aerosol Adapter's Medication Port**. Ensure that the *Combivent*<sup>®</sup> *Respimat*<sup>®</sup> Inhaler is primed per the medication manufacturer's instructions.
- The *Combivent*<sup>®</sup> *Respimat*<sup>®</sup> Inhaler must be pressed onto the **Medication Port** of the **RTC 26-C Inline Aerosol Adapter** tightly to completely block air vents on the *Combivent*<sup>®</sup> *Respimat*<sup>®</sup> Inhaler mouthpiece as shown in **Panel H (figure 3)**.
- Grasp the **RTC 26-C Inline Aerosol Adapter** firmly while performing all medication delivery steps.
- A temporary reduction in tidal volume and Positive End Expiratory Pressure (PEEP) may be encountered when the cap is removed from the **RTC 26-C Inline Aerosol Adapter's Medication Port**.
- If medication is not visible immediately after dosing, ensure that the *Combivent*<sup>®</sup> *Respimat*<sup>®</sup> Inhaler is properly primed and fully seated on the **RTC 26-C Inline Aerosol Adapter's Medication Port**.
- To assure proper patient ventilation, be certain that the cap is **firmly re-attached** to the **RTC 26-C Inline Aerosol Adapter's Medication Port** after use.
- To help prevent the risk of cross-contamination, **DO NOT** use the *Combivent*<sup>®</sup> *Respimat*<sup>®</sup> Inhaler on multiple patients. **Use on a Single Patient only.**
- The **RTC 26-C Inline Aerosol Adapter** should be discarded when replacing the circuit according to CDC and facility guidelines. *Use for a period of time not to exceed 14 days.*
- **DO NOT** attempt to use the **RTC 26-C Inline Aerosol Adapter** with a standard MDI canister or any medication delivery system that does not fit properly.

## B Contraindications:

None known.

## F Product Specifications:



<b>Model #</b>	<b>RTC 26-C</b>	
<b>Type</b>	<b>Inline Aerosol Adapter</b>	
<b>Use</b>	<b>Single Patient Reuse</b> (Intended to be used to deliver <i>Combivent</i> <sup>®</sup> ( <i>ipratropium bromide and albuterol</i> ) <i>Respimat</i> <sup>®</sup> medication multiple times to a single patient while installed in a breathing circuit.)	
<b>Port Sizes</b>	<b>Inlet</b>	22mm O.D.
	<b>Outlet</b>	22mm I.D.
<b>Dimensions</b>	<b>Length</b>	3 in.
	<b>Height</b>	2.4 in.
	<b>Body Width</b>	1 in.
	<b>Wye Angle</b>	45°
	<b>Cap Width</b>	1.3 in. (at widest point)
<b>Materials</b>	<b>Tee</b>	Polystyrene-Butadiene
	<b>Cap</b>	Thermoplastic Rubber
<b>Color</b>	<b>Tee</b>	Clear
	<b>Cap</b>	Clear

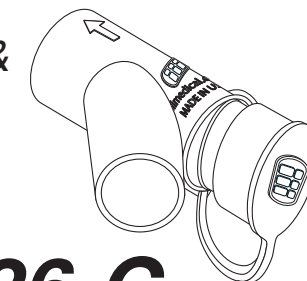


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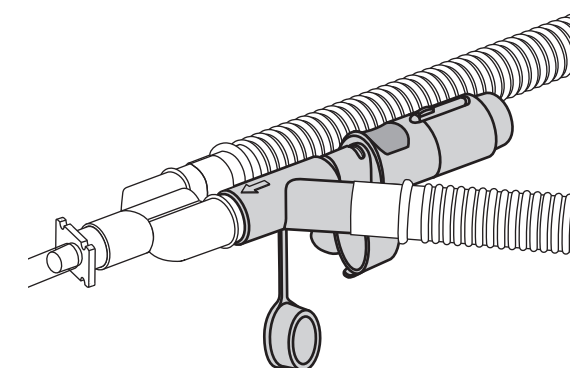
# Inline Aerosol Adapter

Installation & Usage Directions



## RTC 26-C

For use with *Combivent*<sup>®</sup> *Respimat*<sup>®</sup> Inhaler



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## Single Patient Reuse

(Intended to be used to deliver *Combivent*<sup>®</sup> (*ipratropium bromide and albuterol*) *Respimat*<sup>®</sup> medication multiple times to a single patient while installed in a breathing circuit.)

- Not made with Natural Rubber Latex
- Not made with Di(2-ethylhexyl) phthalate (DEHP)
- Not made with Bisphenol A (BPA)

Made in USA!

1-17



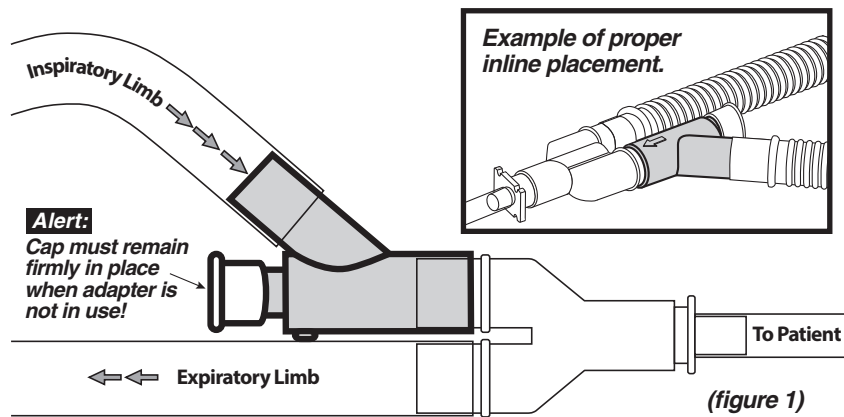
ECO 2411 Rev. 0

## G RTC 26-C Inline Aerosol Adapter Inline Placement Instructions:

1. Place the **RTC 26-C Inline Aerosol Adapter** in the **Inspiratory Limb** at the **Patient Wye**. (figure 1)
2. Ensure that the **Cap** is firmly attached to the **RTC 26-C Inline Aerosol Adapter's Medication Port** when not in use.

### Alert:

**RTC 26-C Inline Aerosol Adapter must be placed in the inspiratory limb of circuit exactly as shown.**



(figure 1)

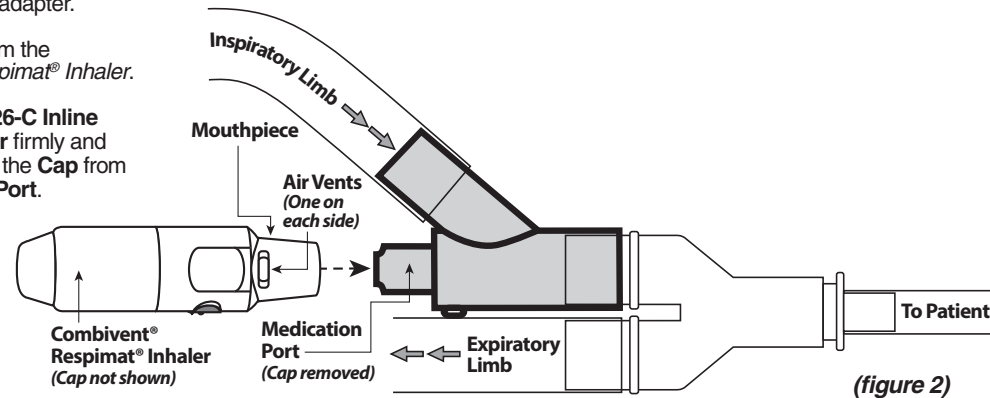
## H Combivent® Respimat® Inhaler Placement:

1. Follow medication manufacturer's instructions to prepare the **Combivent® Respimat® Inhaler** for use. The **Combivent® Respimat® Inhaler** must be primed in an upright position (with mouthpiece pointing upwards, per instructions supplied with the inhaler) before being inserted into the adapter.

2. Remove **Cap** from the **Combivent® Respimat® Inhaler**.

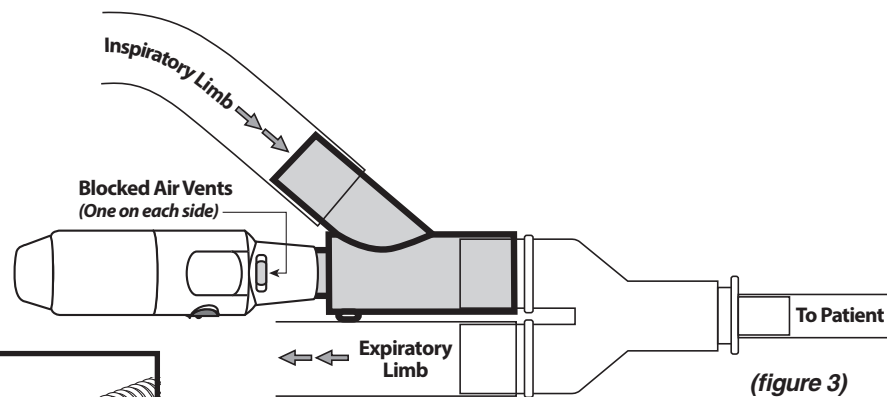
3. Grasp the **RTC 26-C Inline Aerosol Adapter** firmly and carefully remove the **Cap** from the **Medication Port**.

4. Press the **Combivent® Respimat® Inhaler** tightly onto the **Medication Port** of the **RTC 26-C Inline Aerosol Adapter**. (figure 2)



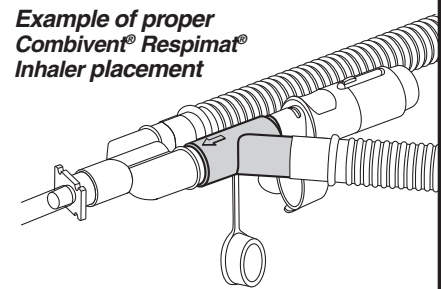
(figure 2)

5. Make sure that the **Air Vents** are completely blocked by the **Medication Port** of the **RTC 26-C Inline Aerosol Adapter**. (figure 3)



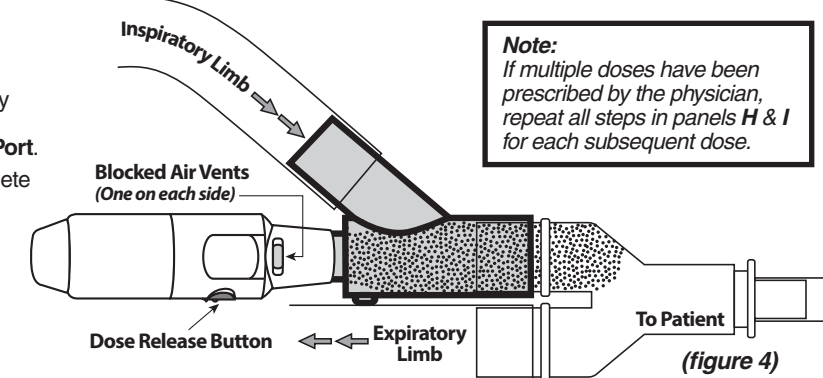
(figure 3)

**Example of proper Combivent® Respimat® Inhaler placement**



## I Combivent® Respimat® Inhaler Activation:

1. Grasp the **RTC 26-C Inline Aerosol Adapter** firmly while performing all medication delivery steps.
2. At the onset of inspiration, activate the primed **Combivent® Respimat® Inhaler** by pressing the **Dose Release Button**. Medication remains suspended inside of the **RTC 26-C Inline Aerosol Adapter** until the ventilator cycle carries it to the patient. (figure 4)
3. If medication is not visible immediately after dosing, ensure that the **Combivent® Respimat® Inhaler** is properly primed and fully seated on the **RTC 26-C Inline Aerosol Adapter's Medication Port**.
4. After medication delivery is complete (see note at right), remove the **Combivent® Respimat® Inhaler** from the **RTC 26-C Inline Aerosol Adapter**.
5. Firmly re-attach the cap on the **RTC 26-C Inline Aerosol Adapter**.



(figure 4)

## J Sterilization/Disinfection:

— This product is designed for **Single Patient Reuse**. (Intended to be used to deliver **Combivent® (ipratropium bromide and albuterol) Respimat®** medication multiple times to a single patient while installed in a breathing circuit for a period of time not to exceed 14 days.) This product is packaged as **non-sterile**.

— **Instrumentation Industries, Inc.** recommends processing before use. After installation into a breathing circuit, cleaning is not recommended. Discard when replacing the circuit according to CDC and facility guidelines. Use for a period of time not to exceed 14 days.

### RTC 26-C Inline Aerosol Adapter Sterilization/Disinfection Recommendations:

Carefully follow facility guidelines for preparing products and solutions for the sterilizing and disinfecting methods and equipment being used.

#### Sterilization

##### STERRAD 100S

Full short sterilization cycle (Hydrogen peroxide gas plasma, 55 minutes, 45°C - 55°C (113°F - 131°F)).

#### High Level Disinfection

##### PASTEURIZATION

Pasteurize at 70°C +/- 3°C (153° - 163°F) for a minimum of 30 minutes.

— **Always carefully examine the physical integrity of this product after processing. Do not use if cracking or crazing is seen, or if parts fit together improperly after processing.**

## K Performance of the RTC 26-C Inline Aerosol Adapter:

	Albuterol	Ipratropium Bromide
Total Delivered Dose from RTC 26-C Adapter (µg) <sup>1</sup>	58.1 - 67.2	11.4 - 13.9
% Reduction in Total Delivered Dose compared to Combivent® Respimat® SMI alone	27.8%	34.0%
Respirable Particle Mass from RTC 26-C (µg, 0.5-5µm) <sup>1</sup>	24.7 - 28.5	5.0 - 5.9
Respirable Fraction (0.5-5µm)	42.4%	43.7%
% Reduction in Respirable Dose compared to Combivent® Respimat® SMI alone	47.5%	50.4%
Coarse Particle Dose (µg, >4.7µm) <sup>1</sup>	22.3 - 28.8	4.0 - 6.3
Particle Fraction > 4.7µm	40.8%	40.5%
Fine Particle Dose (µg, <4.7µm) <sup>1</sup>	35.1 - 39.1	6.8 - 8.1
Particle Fraction < 4.7µm	59.2%	59.5%
Extra-Fine Particle Dose (µg, <1.0µm) <sup>1</sup>	17.7 - 20.6	3.5 - 4.2
Particle Fraction <1.0µm	30.5%	30.2%
Mass-Median Aerosol Diameter (MMAD) (µm) <sup>1</sup>	1.4 - 1.7	1.4 - 1.7
Geometric Standard Deviation (GSD) <sup>1</sup>	3.8 - 4.6	3.9 - 4.6

<sup>1</sup> 95% confidence intervals. Testing done with one Combivent® Respimat® SMI, three samples of RTC 26-C, three tests per sample, for a total of nine measurements per medication and output variable. Cascade impactor testing conducted at 28.3 lpm.