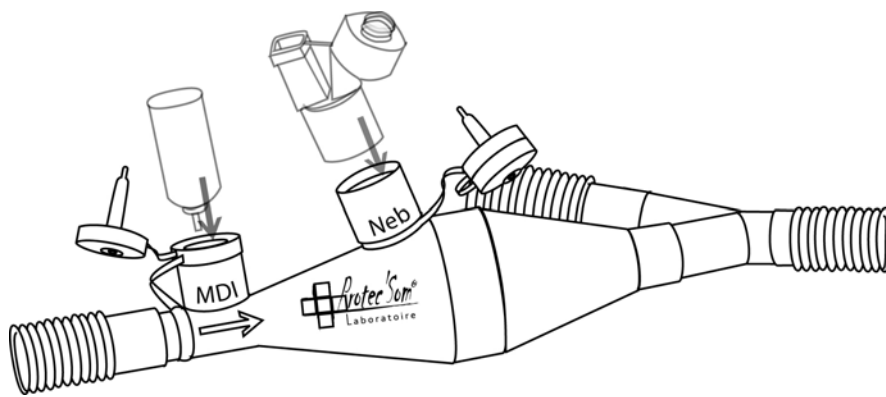


# combiHaler®



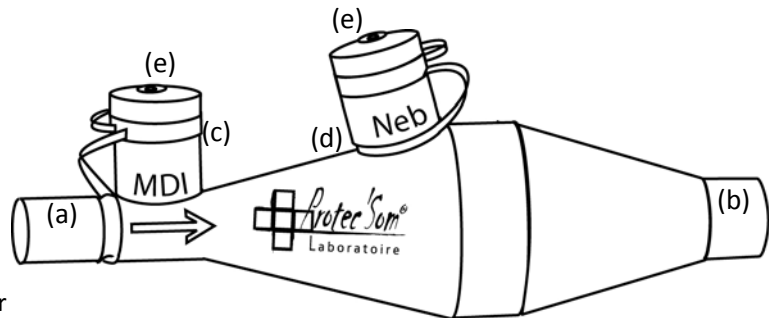
## Operating Manual

## Manual of Combi-Haler™ to mechanically ventilated patients.

- 1) Description: Combihaler® is a spacer designed for mechanical ventilation systems invasive and noninvasive. It allows the simultaneous use of a pressurized metered dose inhaler and a vibrating mesh nebulizer.

It consists of:

- a. An entry
- b. An output
- c. An opening for MDI
- d. An opening for Nebulizer
- e. Two sealing caps



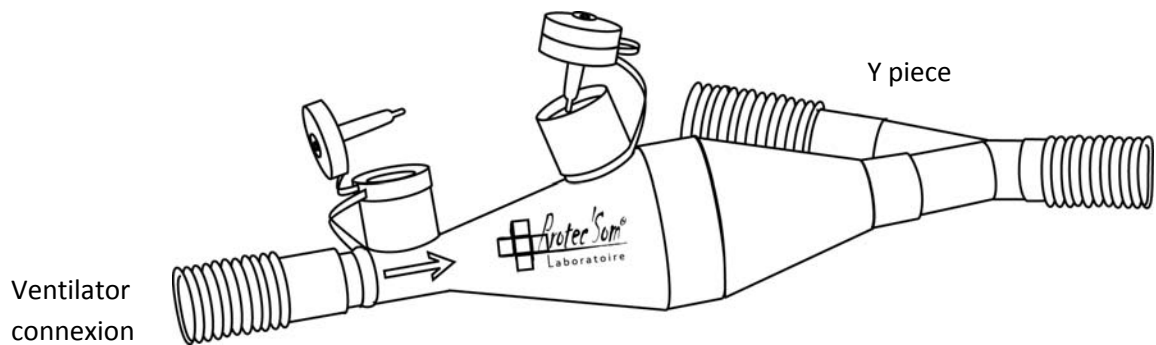
### 2) Special precautions :

- a. Combi-Haler™ comes assembled. It should never be opened before use. Any Combi -Haler® which has been opened should be discarded and replaced.
- b. When commissioning, it is necessary to ensure that:
  - i. The device does not contain any foreign body.
  - ii. The caps are positioned correctly when no MDI and / or nebulizer is used.
  - iii. The nozzle for MDI ensures its proper function (tested visually with a puff of product.)
- c. During use it is necessary to ensure that:
  - i. The caps are positioned correctly when no MDI and / or nebulizer is used.
  - ii. The nozzle for MDI ensures its proper function (visual inspection during each puff of product release.)

### 3) Duration of use :

- a. Combi-Haler™ non sterilized single patient use device.
- b. Combi-Haler™ can be used during the life of the ventilating circuit for not more than thirty consecutive days.
- c. Combi-Haler™ should never be used on more than one circuit and must be destroyed under the same conditions as the circuit on which it was mounted.
- d. Any total or partial replacement of the circuit should result in the replacement of Combi-Haler™.

4) Mounting the circuit and use:



- a. Insert the Combi-Haler™ into the circuit of mechanical ventilation between the inspiratory limb and the Y-piece, following the direction of the arrow as indicated on the device Combihaler.

The end of the cartridge of the MDI attaches to the orifice annotated MDI. For proper operation of the inhaler, refer to the manufacturer indications. The end of the nebulizer screen attaches to the orifice annotated Neb. For proper operation of the mesh nebulizer, refer to the manufacturer indications.

- b. Using an MDI with Combi-Haler™ :

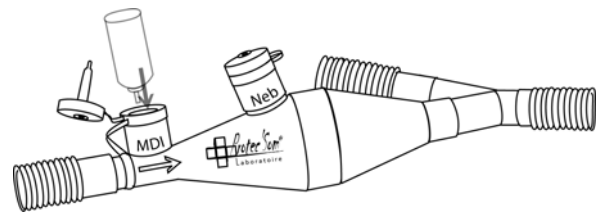
- i. Shake the MDI canister according to the manufacturer's instructions.

- ii. Open the cap of the hole and insert the canister in the hole.

- iii. Operate the MDI from the beginning of the respiratory cycle.

- iv. Let the inspiration from the ventilator administer the drug dose to the patient. Remove the canister of the MDI and replace the cap orifice in place.

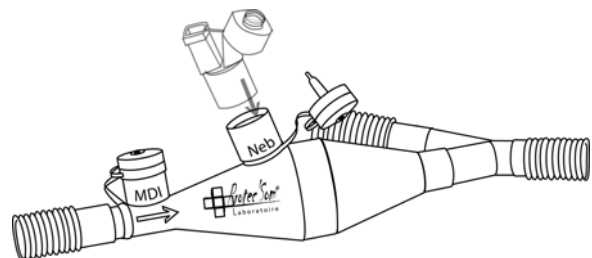
- v. Repeat steps iii to v according to the number of doses needed.



- c. Using a vibrating mesh nebulizer with Combi-Haler™

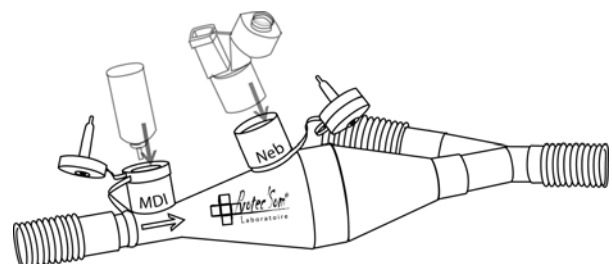
- i. Insert the nebulizer into the Neb entry.

- ii. Place the drug solution in the reservoir of the nebulizer



- d. For proper operation of the nebulizer, follow the instructions provided by the manufacturer.

- e. Combi-Haler™ can be used simultaneously with both an MDI and a vibrating mesh nebulizer.



Combi-Haler is manufactured in France by :

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The trademark Combi-Haler® belongs to Laboratoire ProtecSom SAS.

The patents pending belong to Tours University, INSERM and Laboratoire ProtecSom together.



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