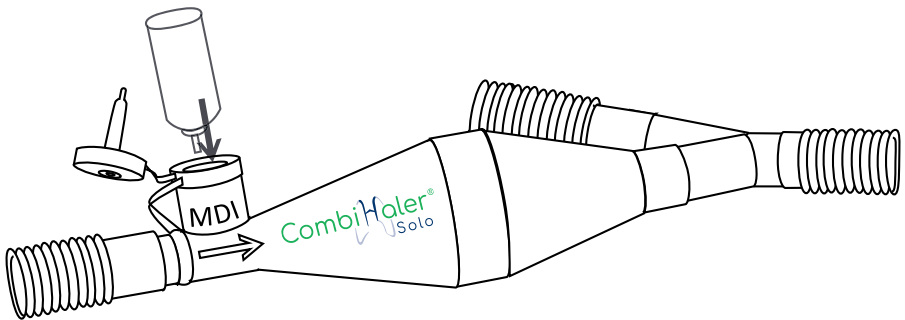


CombiHaler® Solo



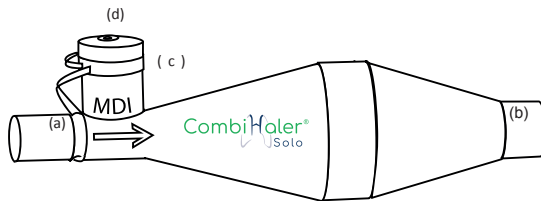
Operating Manual

Manual of CombiHaler® solo to mechanically ventilated patients.

1) **Description:** CombiHaler® solo is a spacer designed for mechanical ventilation systems invasive and noninvasive. It allows the simultaneous use of a pressurized metered dose inhaler.

It consists of :

- a. An entry
- b. An output
- c. An opening for MDI
- d. Sealing cap



2) **Special precautions :**

a. CombiHaler® solo comes assembled. It should never be opened before use. Any CombiHaler® solo 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 is positioned correctly when no MDI 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 is positioned correctly when no MDI is used.
- ii. The nozzle for MDI ensures its proper function (visual inspection during each puff of product release.)

3) **Duration of use :**

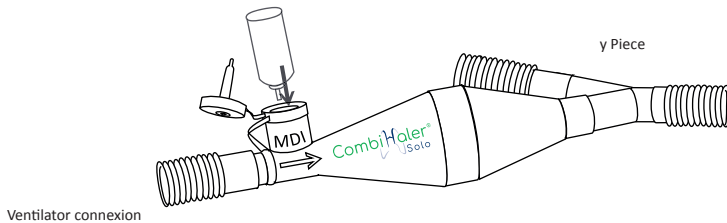
a. CombiHaler® solo non-sterilized single patient use device.

b. CombiHaler® solo can be used during the life of the ventilating circuit for not more than seven consecutive days.

c. CombiHaler® solo 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 CombiHaler® solo.

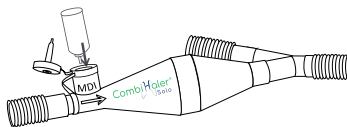
4) Mounting the circuit and use :



a. Insert the CombiHaler® solo 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® solo.

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.

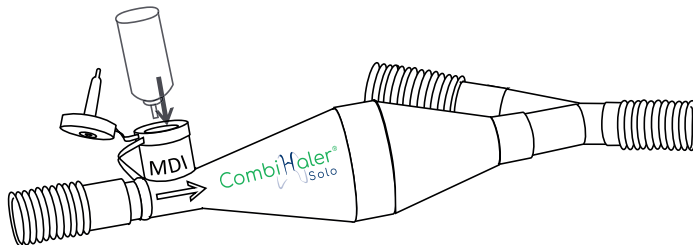
b. Using an MDI with CombiHaler® solo :



- 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. CombiHaler® solo can be used with an MDI.

CombiHaler® Solo



CombiHaler® solo is manufactured in France by :

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The trademark CombiHaler® solo belongs to Laboratoire ProtecSom OptimHal.

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

