

INSTRUCTIONS FOR THE USE AND SERVICING OF THE **easy-resp™** THE ORAL VENTILATION MASK AND ITS HARNESS

INTENDED USE : **easy-resp™** buccal mask is delivered with two joins : a blue one without deliberate leaks for non-invasive ventilation (NIV) with expiratory circuit. The transparent join with deliberate leaks for CPAP or BIPAP with single circuit.

Easy-resp masks and harnesses are available for hospital use or at home and should be used by appropriate people in order to connect and put the mask.

Easy-resp masks, joins and harnesses are unique for each patient and have a lifespan of one year after the first usage.

This mask is sold in a kit with different sized harnesses suitable for adults and children more than 4 years old.

Harness could be sold separately but should be used with easy-resp mask

The two joins with the mask :

- Blue join applied for ventilation without leaks (on the side of the mask, the male extremity of 22mm of diameter, non conical, and on the side of the ventilation equipment, the female extremity with a 22mm diameter, conical)
- Transparent join applied for ventilation with deliberate leaks (extremities of 22mm of diameter, male, non conical)

WARNINGS :

- This mask is not equipped with an anti-suffocation valve and must be used with ventilators equipped with the appropriate alarms and a back-up system allowing the patient to breath in the case of ventilator failure.
- The blue join without deliberate leaks should not be used with CPAP or BIPAP ventilators which require deliberate leaks mask
- This mask should not be used in patients who could not remove the mask for physical or psychological reasons
- Do not use the mask when there is a risk of vomiting or nausea
- In case of allergic lesions or oral pain during mask ventilation, call the physician
- Do not use cleaning products or cleaning procedures not available or non advised
- Avoid the obstruction of air leaks

SET UP AND ADJUSTMENT OF THE MASK DURING FIRST USAGE **easy-resp™**

The first non-invasive ventilation setup with an easy-resp mask and harness **easy-resp™** should be prescribed by a physician. It must be carried out by specialized medical or paramedical staff, who must then train the patient. Only the physician should set the type mask and join corresponding to the ventilation mode prescribed and the patient could not put the other join. The mask must be used only with a self-monitored device and must be connected as close as possible to the valve in order to limit dead space.

STEP 1

- Pass the adjustable belts in buckles for fastening harness.
- Open the harness with the white rapid attach.
- Connect the correct join on the mask as prescribed.

STEP 2

- Place you in front of a mirror to facilitate the first implementation.
- Place the mask in front of the mouth and close the harness with in the fast white belt.
- Place the lower belt behind mask. Surround the head with the superior belt.
- Place the skull apex with the upper belt behind the head, and pass it though the free ring and attach it on itself
- Adjust the tensions of both belts on buckles without excessive tightening.

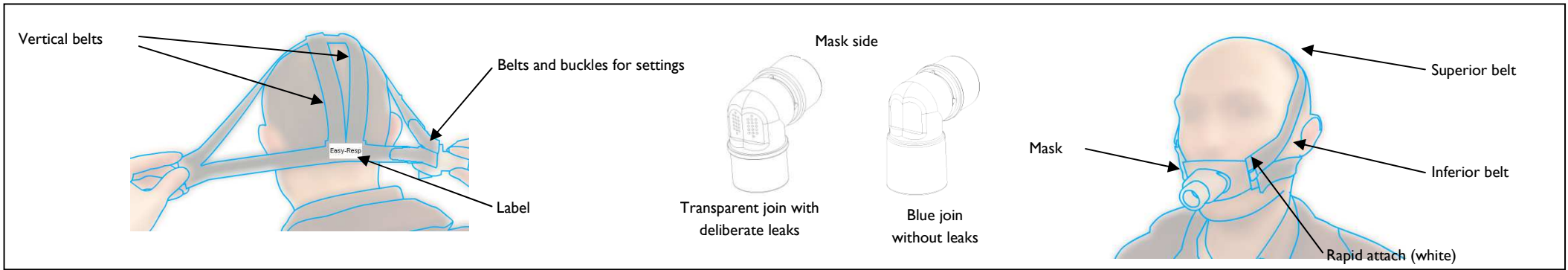
STEP 3

- If necessary, adjust the position of vertical belts vertical of the harness.
- Centre the bottom where's the label by sliding it laterally.
- Spread tops by sliding them in the direction of ears.

STEP 4

- Then re-apply on the face in order to be comfortable and well-balanced. Connect the device of ventilation.
- Plug in the ventilation device
- Adapt belts to avoid any leaks.
- Do not tighten too much for avoiding any hurt on the face.

When these settings are good, do not modify them.



MAKE SET UP FOR EACH SESSION

Check the mask before every use. Change the product : if the mask is torn, if the joint is damaged, if the Velcro areas are dirty or in case of loss of elasticity of the harness.

STEP 1

The fastening of the harness is made with the help of a quick attachment using the white belt. Attach the blue part of the belt over the corresponding Velcro® area.

STEP 2

It is also possible to use all of the Velcro® attachments on the harness and slip it on just like a hood.

IN CASE OF EMERGENCY OR NECESSITY,

By simply pulling the white belt, one can rapidly release the mask from the patient face.

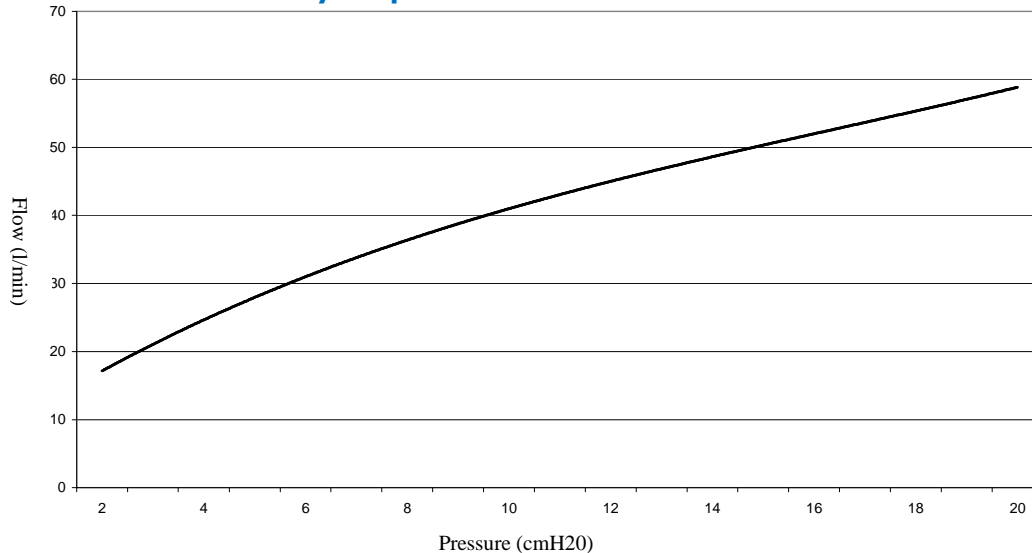
If non deliberate leaks happen during the use, put the mask another time and adjust the belt without excessive tightening.

INFORMATION ON FLOW OF THE DELIBERATE LEAKS

- Curve of the relationship between measured leaks flow and the work pressure driven by the patient

Dead space of the mask (measured on model) = 35 cm³

easy-resp™ with deliberate air leaks



Pressure (cmH2O)	2	4	6	8	10	12	14	16	18	20
Flow (l/min)	17	25	31	36	41	45	49	52	55	59

MAINTENANCE OF THE MASK AND THE HARNESS **easy-resp™**

Mask storage : Between each use, the mask and harness must be stored in clean space without moisture for preventing contamination or damage of the material.

Cleaning the device at home :

Wash the mask and joins regularly with a light detergent (soap for exemple) rinse it thoroughly and let it dry before using it to avoid the risk of maceration. Mask and joins could be put both in washing machine.
Wash the harness each week as indicated on tag, by hand with water and light detergent (soap for exemple), rinse it thoroughly and let it dry on a cooling bed. Do not fold the transparent foreside.

Warm disinfection :


Soak the mask and joins in hot water at 70 °C during 30 mns or 80 °C during 10 mns.
Mask could support sterilization in autoclave at 121 °C during 30 mns or 134 °C during 18 mns.
Masks and joins **easy-resp™** could support 50 washes cycle in normal conditions.

For more information : www.easy-resp.com

The mask is made in pure silicone without latex as joins. At end of life, mask joins and harness have to be eliminated in accordance with laws.

For all claims, keep the packaging where the batch number is written.



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