

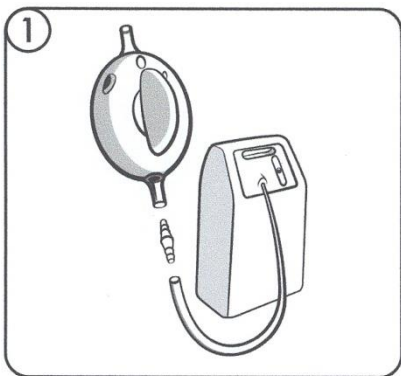
Information for healthcare professionals.

FLEX 02

Patient-controlled flow restriction of oxygen supply from oxygen concentrators.

Connecting FlexO2

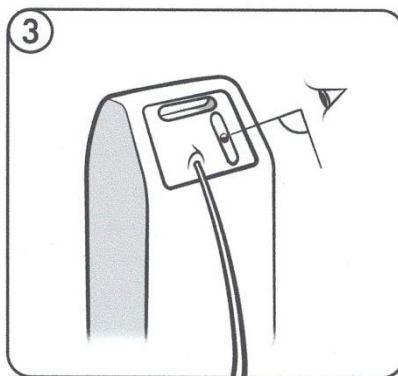
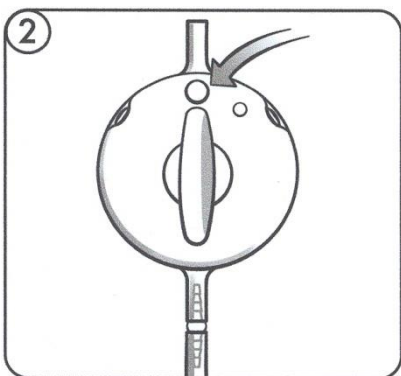
Connect FlexO2 with the nipple to the tube and oxygen concentrator as shown in image 1. Use a flexible strong tube intended for long-term oxygen treatment. The tube must not be too soft so that the flow of oxygen can be interrupted.



Setting up FlexO2

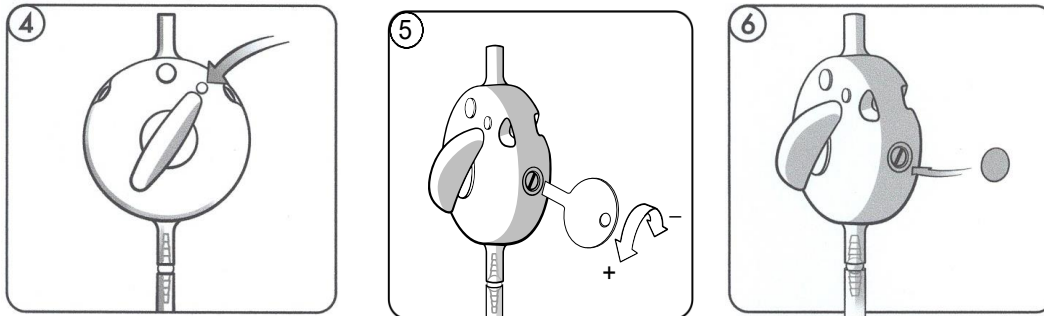
Start by setting prescribed activity dose. To set prescribed activity dose the FlexO2 is connected as shown in image 1. Set the handle as shown in image 2.

Start the oxygen concentrator and set it to prescribed activity dose. The dose is shown on the concentrator's flow meter. See image 3. Always check as per the instruction for the oxygen concentrator being used. Check that the tube connections are securely fastened and that the tube is not twisted. There must always be an obstacle-free passage through the tube for the oxygen to flow.



Next set the prescribed resting dose

Set the handle on FlexO2 so that it points to the smaller round symbol. FlexO2 is now in resting setting. See image 4.



To set the prescribed resting dose adjust the screw on the right side of FlexO2. The flow is adjusted with a normal screwdriver. See image 5.

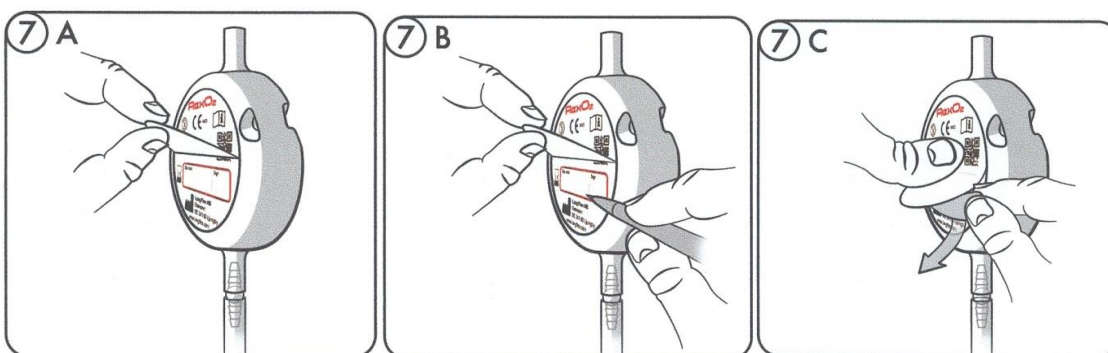
Turn clockwise to reduce the flow and anticlockwise to increase it. Adjust until the prescribed resting dose is achieved. The dose can be read on the concentrator's flow meter.

Toggle between activity and rest a few times, ensuring that the dose is still correct. If not, adjust again as above, until it is achieved. Seal the right-side screw hole with the enclosed cover label. See image 6.

Last permitted date of use

Note the last permitted date of use on the label located on the back of FlexO2. The maximum period of usage is two (2) months after the user has started to use the device.

Turn up the label's lower edge (image 7A) and enter the date when the device must be swapped (image 7B). Remove the label's protective paper and reseal (image 7C).



IMPORTANT The manufacturer guarantees the device for a maximum period of two (2) months after first use. After this time the device may not be used and the product is no longer approved for use.

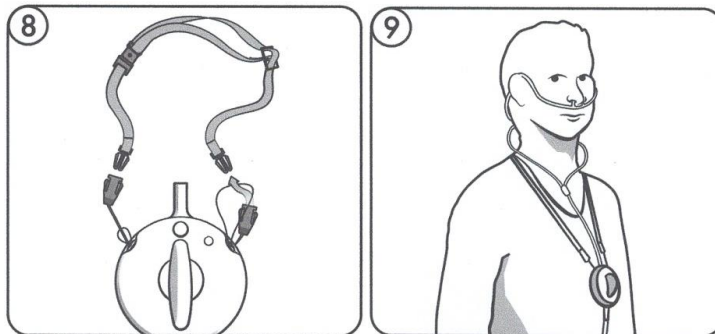
The device must be disposed of after two months' use and discarded as combustible waste.

Neck strap

The device comes with a neck strap which is attached to the two upper attachment points on FlexO2. To attach a neck strap to FlexO2, the fittings at each end of the strap separate into two parts. Take the loose part, thread the loop through the hole in FlexO2. Then push the fitting through the loop and tighten so the fittings are joined together. Repeat with the other fitting. See image 8.

The strap allows the load to be moved from the ears to neck and to be balanced over a larger area.

The strap is adjustable and has an added safety mechanism which separates the strap if the user gets caught in something.

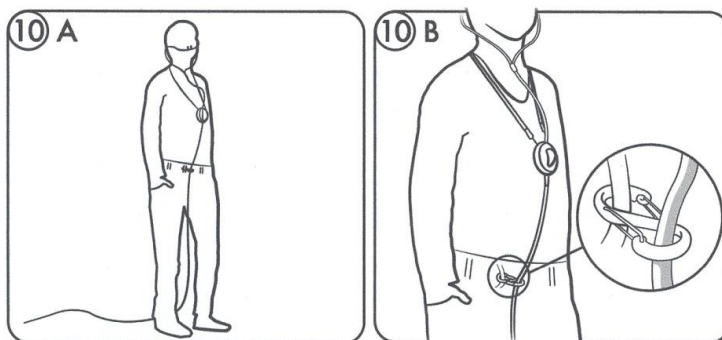


Nasal cannula / mask

Connect FlexO2 to the tube of the cannula/mask using a nipple. See image 9.

S-hook

An S-hook can be used (not included) where one half is fastened to a hole in the patient's trousers, belt or button hole as close as possible to the midpoint vertically under FlexO2. See image 10A and 10B.



When the user enters their house with the tube attached, problems can often arise with the tube getting caught. To avoid this happening, ensure that the tube from the oxygen concentrator to FlexO2 is allowed to hang vertically, guided by the S-hook and hanging down between the patient's legs and backwards. See image 10A. When the user changes direction, their legs steer the tube up and direct it backwards so that it follows their body. This way the tube does not get caught up as easily and thereby the risk of falling is reduced. The risk of the tube getting bent out of shape or twisted is also minimal. The tube is loosely coupled in its part of the S-hook and cannot get caught. This facilitates visits to the bathroom, for example.

Showering

FlexO2 must not be exposed to moisture. When showering, the nasal cannula with a short tube should be changed to a nasal cannula with a longer tube. This allows the device to be hung at the side of the shower and thereby protected from moisture whilst remaining easily accessible if the user needs to change the dose.

Cleaning

Wipe clean using a damp cloth. The device can withstand normal medical disinfectants.

Service.

Contains no user-serviceable part.

Operating time

When two (2) months of use have passed, the unit should be replaced. Date of last use can be viewed at the back of the unit.

In the event of damage or suspected damage, the unit must be replaced.

Disposal

The device should be discarded as combustible waste.

Information for the user

The user must have a cognitive ability and understand the function.

Inform and instruct the user on handling, usage, safety precautions and the importance of changing the device in time.

Product information

FlexO2

Article number: LF 100 100.

Made of ABS, phthalate-free PVC and stainless steel. Materials are medically approved.

Weight: 45 gram.

Measure: diameter 60 mm, height 39 mm.

Class: MDD class IIa 93/42/EEG, LVFS 2003:11.

CE marking: CE 0402.

Neck strapRem

Article number: LF 100 118.

Made of tube-woven PE. The fittings and safety mechanism are made of phthalate-free PVC. The neck-strap is eco-friendly.

The strap is adjustable and has an added safety mechanism which separates the strap if the user gets caught in something.

Nipple

Article number: LF 100 120.

Made of PP, non sterile product, MDD class 1.

Length: 48 mm, outer diameter conical 4,3 - 6,2 mm.

S-hook

Article number: LF 100 121.

Made of glass filled PA and stainless steel powder coated.

Used near the patients body to steer up the tube and reduce the risk of falling.

The tube must be loosely coupled in the S-hook.



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Rev. 2022-09-04