

F.No. 18-04/2021-DC
Central Drugs Standard Control Organization
Government of India
Ministry of Health and Family welfare

FDA Bhawan, New Delhi
Dated the 16th May, 2021

ADVISORY NOTICE

Advisory regarding Oxygen Concentrators suitable for COVID-19 case management in Home settings

- Oxygen concentrator is an electrically powered medical device designed to concentrate oxygen from ambient air. These devices deliver oxygen at the bedside, typically through an attached nasal cannula (or prongs), to a patient requiring oxygen therapy. The intended use or clinical purpose of oxygen concentrators is the delivery of low-flow, continuous, clean and concentrated oxygen, preferably with concentration of 90% or more, from room air (which usually contains only 21% oxygen).
- At present various models of oxygen concentrators, having different capacities of continuous flow(1 to 10 Liters/Min) and widely varying concentration of oxygen, are being marketed.
- The Ministry has from time to time advised that oxygen concentrators with flow capacity of 5 litre per minute or more and delivering oxygen with concentration of 90% or more are suitable for management of COVID-19 patients at the COVID Care Centers, the Dedicated COVID Health Centers and in home settings. The World Health Organisation has also prescribed these norms for oxygen concentrators.
- Many people are not aware about these minimum parameters of Oxygen Concentrators and therefore may be using the concentrators that are not suitable for COVID-19 case management. This advisory is issued to inform people about minimum standards of Oxygen Concentrators for COVID-19 case management, for use especially in home settings.
- It is advised that Oxygen Concentrators having following specifications may be used in home setting:
 - Provides a continuous flow of concentrated oxygen (> 90%) from room air through one oxygen outlet.

- Minimum Continuous flow of up to 5 L/min or more.
- Contains oxygen monitor to verify concentration.
- Digital or analogue meter that displays cumulative hours of device operation.
- It is advised that Oxygen Concentrators of less than 5 litres per minute capacity may not be sold under the misleading label of “for home based COVID care.”
- It is further advised that Oxygen Concentrators must be purchased with:
 - Consumables required to operate.
 - User care instructions and protocols, including guidance for replacement of accessories and consumables and safe decontamination of reusable parts, indicating if they are generic or brand related.
 - Technical maintenance protocols.
- It is strongly advised that all sellers must prominently display the following information, for each model of Oxygen Concentrator for sale -
 - Continuous flow capacity in litre per minute.
 - Percentage of Oxygen that a concentrator generates; and
 - The Maximum Retail Price.

The aim of this advisory is to provide minimum parameters, that must be verified by people before using a Oxygen Concentrator for COVID-19 case management in Home settings.



(Dr. V.G. Somani)
Drugs Controller General (I)

To
All State/UT Drugs Controllers