

Service Life of Valves with Integrated Pressure Regulator (VIPRs) Fitted to Medical Gas Cylinders

What is the issue?

The new revision of the standard for medical Valves with Integrated Pressure Regulator (VIPRs), ISO 10524-3 :2019 *Pressure regulators for use with medical gases — Part 3: Pressure regulators integrated with cylinder valves (VIPRs)*, introduces the term *service life*, which is defined as the “*time period during which a VIPR can be used to refill a cylinder*”.

It is the first time that this term and concept has been defined in the standards covering this kind of equipment. The aim of this technical bulletin is to clarify the requirement and to share with the manufacturers of VIPRs some inputs for the justification of the intended lifetime in the VIPR technical file.

Recommendations

Service life of the VIPR is the period between the time when the VIPR is fitted to the cylinder and up to the time when the cylinder fitted with this VIPR may no longer be filled.

The filled cylinder can be used by the user after the service life has been exceeded, up to the time when medical gas has reached its expiry date.

The VIPR shall therefore be removed from service when it next comes back from the user after its last fill.

The service life of the VIPR should ideally correspond to the test period of the cylinder, for example, 10 years.

The maximum period during which the VIPR can be used consists of the sum of the following periods:

- shelf life of the VIPR
the maximum period between the VIPR manufacturing date and when it is first fitted to a cylinder (information to be provided by the VIPR manufacturer);
- service life of the VIPR
as defined in the standard: time period during which a VIPR can be used to refill a cylinder; and
- shelf life of the medical gas.
the period between the last filling date up to the expiry date for the medical gas.

Unless stated otherwise by the manufacturer of the VIPR, a reasonable VIPR shelf life should at minimum be one year.

Medical gas shelf life is generally from 2 to 5 years as defined in the Marketing Authorisation.

The life time information given in the user manual of the VIPR is considered to be the service life as defined in this Technical bulletin.

DISCLAIMER

All technical publications of EIGA or under EIGA's name, including Codes of practice, Safety procedures and any other technical information contained in such publications were obtained from sources believed to be reliable and are based on technical information and experience currently available from members of EIGA and others at the date of their issuance.

While EIGA recommends reference to or use of its publications by its members, such reference to or use of EIGA's publications by its members or third parties are purely voluntary and not binding. Therefore, EIGA or its members make no guarantee of the results and assume no liability or responsibility in connection with the reference to or use of information or suggestions contained in EIGA's publications.

EIGA has no control whatsoever as regards, performance or non performance, misinterpretation, proper or improper use of any information or suggestions contained in EIGA's publications by any person or entity (including EIGA members) and EIGA expressly disclaims any liability in connection thereto.

EIGA's publications are subject to periodic review and users are cautioned to obtain the latest edition.