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Service Life of Valves With Integrated Pressure Regulators (VIPRs) Fitted to Medical Gas Cylinders

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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 as mentioned in country regulatory standards, or any global best practice in absence of a country regulation

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 up to 5 years, as may be defined by the country regulations.

The life time information given in the user manual of the VIPR is considered to be the service life as defined in this Safety Bulletin

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