DRAFT

Antony, on 28/06/2024

Reference: R2415683

Subject: Important Safety Information concerning SELECTAFLO BP Range - First Generation calibrated-orifice flow meters (marketed from 1999 to 2012)

Dear Customer,

As part of its monitoring of customer feedback (incidents or near-incidents), Air Liquide Medical Systems wishes to share the safety information hereafter with all customers liable to still have SELECTAFLO BP "first generation" calibrated-orifice flow meters .

These products, which were placed on the market by Air Liquide Medical Systems between 1999 and 2012, met the standards in effect at that time. As these devices have exceeded their lifespan, there are likely very few of them on the market. Nevertheless, some of them are still in use..

For information, a second similar range, "SELECTAFLO ARPEGE", which meets the standard currently in effect was released to the market from 2011.

If you still have "first generation" SELECTAFLO BP devices, we ask that you read the information contained in this document and share it with all user departments at your establishment.

The relevant health authorities have been informed of this voluntary safety information.

For any additional questions, please feel free to contact our hotline or your usual contact.

Air Liquide Medical Systems
HIGH TECHNOLOGY PARK
6 RUE GEORGES BESSE - 92182 ANTONY CEDEX– France
LIMITED COMPANY WITH CAPITAL OF €4,240,800 – R.C.S NANTERRE B 348 921 735 – SIRET 348 921 735 00026

www.device.airliquidehealthcare.com

1. Identifying affected products

The products to which this safety information applies are very easily identifiable by their design.

a. What products ARE affected?

Visual Identification

Device to which this safety information applies

b. What products ARE NOT affected?

Visual Identification

Device to which this safety information does NOT apply information

2. Description of risk

These first-generation products (see §1.a - Identifying affected products) comply with the standard in effect at the time of their release. The flow selector can be mechanically placed between 2 positions.

In this situation:

- **No flow rate display will be found in the orifices provided for this purpose.**
- **No flow will be delivered by the device.**

Flow selector positioned between 2 positions.

<u>=> No display and no flow</u>

Properly-positioned flow selector.

***<u>=> Display and delivery of flow</u>*.**

Air Liquide Medical Systems marketed more than 12,000 units of so-called "first generation" products between 1999 and 2012. To date, only one incident has been reported to us relating to the non-delivery of the desired oxygen flow following an adjustment between 2 positions and having had an impact on the patient.

Important note: Products from the SELECTAFLO ARPEGE range, <u>not affected by this safety information</u> (see §1.b - Identifying affected products) have a design that mechanically makes it impossible to position itself between 2 positions.

3. Corrective Action

If you are concerned that devices from this first generation are still in use at your establishment, we ask that you:

- Remind any potential users of the operating mode for these phased-out products.
- Contact Air Liquide Medical Systems to receive a warning label, which you will be responsible for affixing to the devices still in use.

This warning label contains the following information: ***"Between 2 positions, no flow"***

4. Operating mode

a. Identification of needs

If you are aware that these first generation SELECTAFLOs are still used in your establishment, in order to receive warning labels, we ask you to complete appendix 1 and send it by email to the following address:

almedicalsystems.services@airliquide.com

Once validated by our services, we will send you the labels you will need to affix to your devices as soon as possible.

Important note: Warning labels will only be sent for a period of 6 months from the date this safety information is issued.

b. Warning label placement.

Appendix 1 - Warning Label Request

Safety information R2415683 28/06/2024

Please complete and return this form via email: almedicalsystems.services@airliquide.com

Name and address of establishment	
Contact Name:	
Title:	
Email and telephone number:	

	We acknowledge receipt of this safety information
	We confirm that we have understood its content and disseminated this information to the persons concerned.

Serial No	Version (Air /O2)	Date of acquisition

Signature and Date:	