

Urgent - Field Safety Notice

CPX Medical Gas Manifold for breathing gases.

07/10/2015

Dear Customer,

Precision UK Ltd has initiated a mandatory field action for its CPX manifolds for breathing gases. You are receiving this notification because our records indicate that you have one or more of the devices affected by this action. Please reference the "Affected Products" list below.

This Field Safety Notice is intended to inform you about:

- The problem, and under which circumstances it can occur.
- The actions that should be taken by the customer / user in order to prevent risks for patients or users
- The actions planned by Precision UK Ltd to correct the problem.

This document contains important information for the continued safe and proper use of your equipment

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain a copy with the equipment Instruction for Use.

This field action is being conducted to correct a problem with CPX manifolds. In the very rare event that the regulator may ignite, toxic halogenated fumes may be dispensed to the patient down the pipeline. There is very small possibility the regulator will ignite as the regulators are tested for resistance to ignition as outlined in BS EN ISO 10524-2.

Patient safety, product quality and customer satisfaction is our ultimate priority. Precision UK Ltd. continuously monitor our manufacturing and field performance data to proactively identify any potential issues that could manifest as a reliability, quality, or safety concern and work to address them immediately.

This notice has been reported to the appropriate regulatory agencies.

Precision UK Ltd apologises for any inconveniences caused by this problem.

Sincerely

Robert Parry
Managing Director.

www.precisionuk.co.uk



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AFFECTED PRODUCTS	Precision UK Ltd Medical Gas Manifolds for breathing gases i.e. Oxygen, Nitrous Oxide, Oxygen/Nitrous Oxide Mixture (50/50%), Medical Air and Helium.
PROBLEM DESCRIPTION	There are halogenated polymers contained within the regulator which if ignited could potentially release some toxic fumes into the pipeline. This is very unlikely as the position of the halogenated polymers if ignited would cause the pressure in the system to rise substantially therefore lifting the in line pressure safety valve and venting any toxic fumes to atmosphere.
HAZARD INVOLVED	Toxic fumes delivered to the patient in the unlikely event of the ignition of the halogenated polymers within the regulator and safety relief valve failure.
HOW TO IDENTIFY AFFECTED PRODUCTS	All CPX manifolds for breathing gases within the European Union are affected.
ACTION TO BE TAKEN BY CUSTOMER / USER	The affected manifolds shall be retrofitted with new regulators which fully comply with BS EN ISO 10524-2, Precision UK Ltd will contact each customer affected to agree a suitable time for the retrofit of the device(s). Ensure that devices are inspected and serviced regularly intervals. Particular attention should be paid to the proper operation of the safety relief valve.
ACTIONS PLANNED BY PRECISION UK	<ol style="list-style-type: none">1. Precision UK Ltd are working with a regulator supplier who can produce a regulator to BS EN ISO 10524-2 to achieve the earliest delivery date with the changes required by Precision UK Ltd. for retrofitting the existing manifolds.2. Precision UK Ltd Intend to retrofit all manifolds within the EU to replace the existing regulators with regulators which fully comply with BS EN ISO 10524-2.3. Precision UK Ltd shall contact all customers within the EU who have purchased manifolds and issue them with a "Field Service Notice" to inform them of the changes required to the manifolds.4. Working with customers and Healthcare Facilities, Precision UK shall establish a timescale convenient to all parties for the retrofit of the regulators to take place.5. Precision UK Ltd shall inform their notified body and the MRHA of the field safety notice. Precision UK Ltd. shall keep records of all the retrofitted manifolds.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact +44 (0)161 487 2822 Please quote ref: OP20-06 -001 Manifolds

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