

To whom it may concern

Date: 22-08-2018

Ambu SPUR II Infant with open oxygen reservoir tube

Ambu GmbH received a complaint from CIRS Bayern concerning the Ambu SPUR II resuscitator. The resuscitator was delivered to customer with an oxygen reservoir tube and O₂ supply tube pre-attached.

According to complaint customer had dis-assembled the resuscitator. When customer re-assembled the resuscitator the connector for the O₂ wall connection was placed in the connector for the O₂ reservoir tube.

The SPUR II resuscitator is a single-use resuscitator. It comes with one or more special accessories such as oxygen reservoir tube and O₂ supply tube pre-attached.

The oxygen inlet and the placement of the oxygen reservoir tube are shown in the illustrations within the IFU.

Preparation of the resuscitator before use is described in the IFU and includes the following step:

- If the resuscitator is packed in a compressed state, unfold by pulling on the patient valve and the inlet valve.
- If the facemask supplied with the resuscitator is wrapped in a protective pouch, the pouch should be removed before use.
- Fit the facemask and place all items in the plastic bag supplied with the resuscitator.
- The integrity of the kits issued for storage ready for use should be inspected at the interval established in the local protocol.
- Before use on the patient make a brief functional test as described in section 7.

The IFU does not prescribe dis-assembling of the resuscitator.

To ensure correct use it is stated as a caution in the IFU that the resuscitator is for use by trained personnel only and it shall be ensured that personnel are made familiar with the content of the IFU. A professional user would recognize the fault and remove the O₂ supply tube from the oxygen reservoir tube connection before use.

The connectors of the O₂ supply tube are in compliance with the specification of EN 13544-2: 2002+A1: 2009 Respiratory Therapy equipment – Part2: Tubing and connectors.

Best regards,



Kristine Rasmussen
Senior Regulatory Affairs Professional