

Medical Device Safety

Phone: 02603 9600 4469
Fax: 02603 9600 988
Email: Haendler@loewensteinmedical.com

July 2021**Field Safety Notice for CPAP Phoenix 3(i) and Somnia 3(i)**

Dear Sir or Madam,

Our constantly high standards of customer satisfaction, quality and safety have top priority. This claim requires a high level of transparency in communication. Therefore, we are sending you an urgent safety information with this letter. We ask here for your support for patient safety.

Philips Respironics published a safety notice for the SystemOne (Q-Series). Löwenstein medical is the private label Manufacture (Labeled with Heinen+Löwenstein) Phönix 3(i) and Somnia 3(i).

Reason for the safety information

The affected devices contain a sound-attenuating foam made of polyester-based polyurethane (PE-PUR), which can break down into particles that enter the airway of the device and can be ingested or inhaled by the patient. Additionally, the foam may release certain chemicals.

Potential risks from the release of the chemicals include headache / dizziness, respiratory irritation, hypersensitivity, nausea / vomiting, and toxic and carcinogenic effects. In Germany, there are no known incidents with such damage.

Medical Devices effected:

Item number	Designation	Identical design to Philips Respironics
hl454s		
hl454s/1	Somnia 3	SystemOne 50 Series
hl454s/u		
hl554s		
hl554s/1	Phoenix 3	SystemOne 50 Series
hl554s/u		
hl464s	Somnia 3i	SystemOne 60 Series
hl564s	Phoenix 3i	SystemOne 60 Series

The user must take the following actions:

Please contact your physician before making any changes to your prescribed therapy, in order to determine the most suitable option for further treatment.

Action by the dealer / provider:

Check the attached list of serial numbers. Let us know which serial numbers are in use, have been scrapped or are in your warehouse. This is the only way we can plan a further course of action.

Corrective action by the manufacturer:

We will implement a permanent corrective action to address the issues described. After you report your equipment to us, we will contact you to discuss how to implement the permanent solution for you.

We formally apologize for the inconvenience and thank you for your understanding and support.

If you have any questions, please contact us directly - we will of course be happy to answer your questions: If necessary, please contact your contact person in the dealer team.

With kind regards

