Fritz Stephan GmbH
Medizintechnik
Kirchstr. 19
56412 Gackenbach
Germany
Fon +49 6439-91 25-0
Fax +49 6439-91 25-111
info@stephan-gmbh.com
www.stephan-gmbh.com

FSN Reference QM329 24.06.2026

Gackenbach, June, 2026

Important safety information

for ventilators of the EVE family and Oxylog 600

FSN QM329

Possible delivery of a lower oxygen concentration than set

RECIPIENTS:

Specialist and nursing staff as well as service technicians in medical facilities where EVE IN, EVE NEO, Oxylog 600 (NIST), Oxylog 600 (NIST/CO2) devices with Blower SW V2.17.1 or V2.17.0 are in operation.

AFFECTED PRODUCTS:

Ref.	Product	UDI-DI / GTIN
107061410	EVE IN	04064428000482
107061411	EVE IN mit Masimo	04064428000499
107061420	EVE NEO	04064428000505
107061401	EVE NEO mit Masimo	04064428000512
107161400	Oxylog 600 (NIST)	04064428001243
107161401	Oxylog 600 (NIST/CO2)	04064428001250

MANUFACTURER:
Fritz Stephan GmbH
Kirchstraße 19
D-56412 Gackenbach

REASON FOR THE SAFETY NOTICE:
Fritz Stephan GmbH has been informed that, when using the EVE ventilator, an insufficient dosage of oxygen in the patient's breathing gas may occur. This deviation of the delivered oxygen concentration may lead to hypoxia in the patient and requires intervention by the user.
The issue occurred in spontaneously breathing patients in CPAP mode. No patients were harmed.

The cause was identified as a software error in the function responsible for mixing the input gases. Due to differing calibration values of a system component, the effect varies between devices.

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MEASURES BY THE RECIEPIENTS

By observing the following instructions, devices of the EVE/EVA/Oxylog600 family may continue to be used.

- Please forward this safety notice to all users and other persons within your organization who need to be informed.
- Devices with software versions other than Blower SW V2.17.1 or V2.17.0 can be used without restriction. The software version can be viewed in the menu "System Settings", submenu "System", menu item "Info".
- Ensure that the alarm limits for the delivered oxygen concentration (FiO2) are set appropriately.
- Ensure that patients are connected to an oxygen saturation monitor.
- If clinically possible, set FiO2 to 100% temporary when the issue occurs.
- If clinically possible, select a ventilation mode with pressure variation (e.g., PC-ACV+, DUOPAP) when the issue occurs, a change in FiO_2 then is not needed.

MEASURES BY THE MANUFACTURER

Fritz Stephan GmbH will provide new software for the EVE and Oxylog 600 device families as soon as possible and will contact affected customers regarding the software replacement.

CONTACT

If you have any questions, please contact your local medical product advisor or us directly.

We will be pleased to answer your questions:
Tel: +49 (0) 64399125-0
Email: info@stephan-gmbh.com

Sincerely,

Fritz Stephan GmbH

[redacted]

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RESPONSE TO SAFETY INFORMATION

Title

Customer information	
Name of health facility:	
Street, no.:	
Postal code/city:	
Country:	

Please complete this response form using capital letters and return it by fax, email or post to:

Fritz Stephan GmbH
Kirchstraße 19
56412 Gackenbach
GERMANY

Fax 🖷: +49 (0) 6439 9125 – 111
Email ✉: vigilance@stephan-gmbh.com

☐ I have read and understood the safety information and confirm this with my signature. All users and other people who must be informed in my facility are aware of this letter.

Name (in capital letters): _____

Job title (in capital letters): _____

Date: _____

Signature: _____