

FSN Referenz QM301 20.01.2026

Gackebach, 20. January 2026

Urgent Field Safety for Breathing Circuits for Ventilators of Fritz Stephan with patient component P7

FSN QM301

Batch recall for heated single use breathing circuits P3/P7 from batches 2025-03, 2025-06, 2025-07, 2025-08

RECIPIENTS:

Specialists and care staff as well as service technicians in medical facilities where ventilators of Fritz Stephan with patient component P7 are used.

AFFECTED PRODUCTS:

| Ref. | Produkt |
|-----------|--|
| 100761300 | Heated single-use breathing tube P3/P7 |

MANUFACTURER:

Fritz Stephan GmbH
Kirchstraße 19
D-56412 Gackebach
Germany



REASON FOR THE SAFETY NOTICE:

Fritz Stephan GmbH has been informed that, in isolated cases in various batches, the temperature sensors in the heated single use patient tube system 100761300 may slip out of their holders. If a temperature sensor slips out of its port, the resulting leak may prevent the desired ventilation pressure from being established in the tube system. The holder for the temperature sensor is too wide if the temperature sensor can be inserted into the port completely without force.



Figure 1)
The port diameter is too large.
The sensor can slip out.



Figure 2)
The port is correctly dimensioned.
The sensor has sufficient grip.
There is a small gap between the sensor head and the top edge of the mount.

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MEASURES BY THE MANUFACTURER

Fritz Stephan GmbH will provide an O-ring for the temperature sensor to prevent it from slipping out of the holders of the heated single use patient tube system 100761300.

MEASURES BY THE USER

Until the above-mentioned O-rings are available, users should check that the temperature sensors are securely seated before using the hose system and only use hose systems in which the temperature sensor is positioned in the holder as shown in Figure 2).

Until the O-rings for securing the temperature sensors are available, the temperature sensors can be secured using adhesive tape, as shown in the adjacent illustration. Ensure that the adhesive tape is applied so that it overlaps. Minor leaks that may occur do not impair ventilation. Please pay attention to hygiene when securing the temperature sensors with adhesive tape.



As soon as the O-rings are available, Fritz Stephan GmbH will make them available to the affected customers. To use the O-ring, remove it from the packaging and place it in the groove of the temperature sensor.

Figure 3) O-ring in the groove of the temperature sensor



Figure 4) The O-ring must be disposed of after each patient change or change of the tube system!
The O-ring can be removed with tweezers.





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CONTACT

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

We will be pleased to answer your questions:

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Sincerely,

Fritz Stephan GmbH

Jan Schliecker (CEO)



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RESPONSE TO SAFETY INFORMATION

FSN QM301

**Batch recall for heated single use breathing circuits P3/P7 100761300 from batches
2025-02, 2025-03, 2025-06, 2025-07, 2025-08**

| 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 Gackebach
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.

QTY of affected breathing circuits: _____

Name (in capital letters): _____

Job title (in capital letters): _____

Date: _____

Signature: _____