

Urgent Medical Device Recall - Update

MP05785 Filter SafeStar 90 Plus - All Lot Numbers

MP05790 Filter SafeStar 55 Plus - All Lot Numbers

MP05795 Filter SafeStar 60A Plus - All Lot Numbers

MP05801 Filter/HME TwinStar HEPA Plus - All Lot Numbers

Slow Increase of CO₂ Curve When Using the Sampling Port of the Filter

July 2025

**Risk Manager
Purchasing/Materials Manager**

Dear Madam/Sir,

In June 2025, we informed you of a voluntary recall on the Dräger filters referenced above with an Urgent Medical Device Recall Notice. While the information regarding the issue and potential health risk remains unchanged, we are updating the necessary action:

Necessary Action:

Draeger recommends that any unused filters in your stock not be used. Unused stock should be removed.

Please contact your local Draeger Consumables Representative who will be able to provide you with information regarding alternative filter solutions.

To replace/return unused products, please contact Draeger Customer Success via phone between the hours of 8:00 AM – 6:00 PM EST Monday thru Friday at 1-800-437-2437 (press 2 at the prompt, then 1) or via email at US-Medical@draeger.com. You will also be provided with a Return Material Authorization and pre-paid shipping document to return the unused product to Draeger.

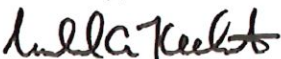
Please ensure that all potential users in your facility are made aware of this Urgent Medical Device Recall Update Notice and the information contained herein. If you have forwarded affected products to third parties, please also forward this Urgent Medical Device Recall Update notification. Although you may have already completed the Medical Device Recall Return Response Acknowledgment and Receipt Form from the June 2025 notice, we ask that you complete the enclosed Medical Device Recall Return Response Acknowledgment and Receipt Form again to confirm that you have received this updated information and have acted accordingly.

Adverse events or quality problems experienced with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program either online or by phone at 1-800-FDA-1088.

We apologize for any inconvenience resulting from this action. If you have any questions regarding this letter, please contact Michael Kelhart between the hours of 8:00 AM – 4:30 PM EST at 267-664-1131 or via email at mike.kelhart@draeger.com.

The US Food and Drug Administration has been advised of this updated action.

Sincerely,



Michael A. Kelhart
Director, Quality
Draeger, Inc.

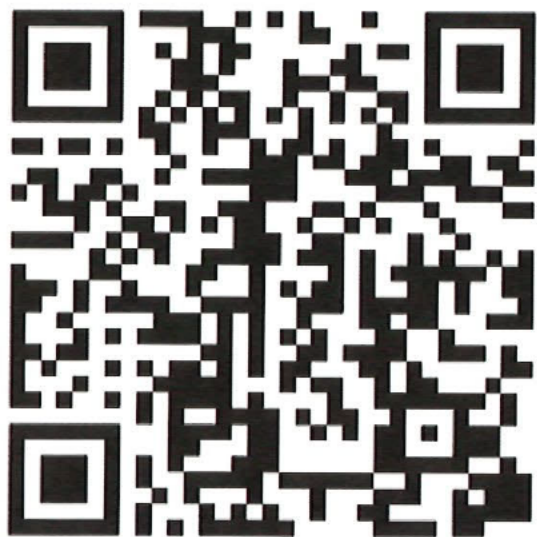
Attachments – Urgent Medical Device Recall notice dated June 2025
– Medical Device Recall Return Response Acknowledgment and Receipt Form



**Medical Device Recall Return Response
Acknowledgment and Receipt Form - Update**
Response is Required

MP05785 Filter SafeStar 90 Plus - All Lot Numbers
MP05790 Filter SafeStar 55 Plus - All Lot Numbers
MP05795 Filter SafeStar 60A Plus – All Lot Numbers
MP05801 Filter/HME TwinStar HEPA Plus - All Lot Numbers
Slow Increase of CO2 Curve When Using the Sampling Port of the Filter
Customer Acknowledgement and Receipt Form Instructions

Please complete the Customer Acknowledgment Form *Online* within three (3) business days upon receipt of this notification.



STEP 1 - Scan the QR Code or visit the link below to access the response form.

<https://iqvia-response.my.site.com/mt/fca?cid=draegertsb316-v2>

STEP 2 – Enter your unique Account Number

Your Unique Number -

STEP 3 – Acknowledge the receipt of this notice & complete the form online.

Call IQVIA for any questions/concerns with response form.

Ph: (855) 210-6559 | Email: draeger-tsb316@iqvia.com

Draeger, Inc. has partnered with IQVIA MedTech to assist in this device correction.
For any assistance regarding online response processing please contact IQVIA using the information above.

Phone: (855) 210-6559

Email: draeger-tsb316@iqvia.com

Thank you.

Urgent Medical Device Recall

MP05785 Filter SafeStar 90 Plus - All Lot Numbers

MP05790 Filter SafeStar 55 Plus - All Lot Numbers

MP05795 Filter SafeStar 60A Plus - All Lot Numbers

MP05801 Filter/HME TwinStar HEPA Plus - All Lot Numbers

Slow Increase of CO₂ Curve When Using the Sampling Port of the Filter

June 2025

Risk Manager

Purchasing/Materials Manager

Dear Madam/Sir,

As part of our global post market monitoring, we have become aware of cases in which users have reported a slow increase of the CO₂-curve when the gas sample line of the gas measurement of a Dräger anesthesia machine is connected to the gas sampling port of the filters/HME shown in the below table. It has been reported that the CO₂-curve rises more slowly (Fig. 1) compared to the measurement at the Y-piece (Fig. 2). We are aware of two cases, in which this was assessed as a sign of obstruction and appropriate medication was administered. No further negative effects on the health of the affected patients were reported.

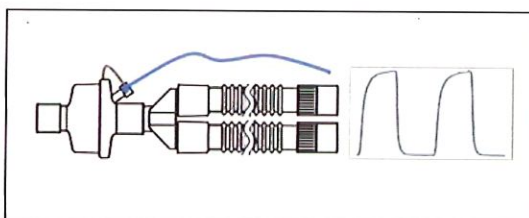


Fig.: 1 One of the possible CO₂-curves when the gas sample line is connected to the gas sampling port of an affected filter/HME

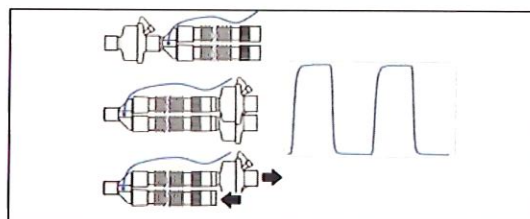


Fig.: 2 CO₂-curve with alternative connection of the gas sample line, e.g. at the Y-piece

Our investigation has shown that the changes in the CO₂ waveforms (Fig. 1) only occurs when the gas sample line is connected to the gas sampling port of a filter/HME shown in the below table. Other setups, as shown in Fig. 2, are not affected.

Part no.	Designation	UDI
MP05785	Filter SafeStar 90 Plus	04048675665762
MP05790	Filter SafeStar 55 Plus	04048675558736
MP05795	Filter SafeStar 60A Plus	04048675665786
MP05801	Filter/HME TwinStar HEPA Plus	04048675665823