

Drägerwerk AG & Co. KGaA, 23542 Lübeck, Germany

To our customers of
Filter/HME TwinStar® Plus

July 2023

Important Safety Notice!

**Possible desaturation due to late replacement of Filter/HME
Only the products listed in Annex I are affected**

Dear Madam/Sir,

Our market surveillance activities regarding Filter/HME TwinStar® Plus revealed cases of increased inspiratory resistance resulting in insufficient ventilation, which may be related to formation of condensate in the filter housing.

Filter/HME TwinStar® Plus products are intended exclusively for single patient use no longer than 24 hours. Excessive condensation can significantly shorten the period of use of the Filter/HME TwinStar® Plus and require the product to be replaced latest after 24 hours.

Increased resistance carries the risk of desaturation for the patient. Should this hazardous situation encounter, please consider the possibility that it may be related to the occlusion of the filter due to condensate.

The current Filter/HME TwinStar® Plus Instructions for Use contain warnings related to condensate. However, we determined that the instructions can be further improved. We are currently working on an update with highest priority.

Until the revised Instructions for Use are available you may continue using the Filter/HME TwinStar® Plus as long as both airway pressure and volume are permanently monitored and alarm limits for each patient are suitably selected. Change the filter in the case of resistance increase.

Please add a copy of this Important Safety Notice to every box of Filter/HME TwinStar® Plus you have in your facility and ensure that all users of the above-mentioned products and other persons within your organization are made aware of it.

If you have provided the products to third parties, please forward a copy of this information.

Dräger will be updating the Filter/HME TwinStar® Plus Instructions for Use accordingly. Until the updated version of the Instructions for Use is available, we will be adding this Important Safety Notice to each box of Filter/HME TwinStar® Plus.

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Chairman of the Supervisory Board
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and Drägerwerk Verwaltungs AG:
Stefan Lauer
Executive Board:
Stefan Dräger (chairman)
Rainer Klug
Gert-Hartwig Lescow
Dr. Reiner Piske
Anton Schrofner

Please keep this information at least until the measure has been completed.

The responsible authorities have been notified of this action.

Identification of the affected medical devices:

According to our records, you have received Filter/HME TwinStar® Plus manufactured by Drägerwerk AG & Co. KGaA, (SRN: DE-M F-000005329, see part numbers in Annex I) that are affected by this issue.

Contact:

If you have any questions, please do not hesitate to contact your local Dräger representative.
We apologize for any inconvenience caused by this measure.

With kind regards



Sebastian Henning
Product Management
Business Unit Hospital Consumables & Accessories



Oliver Möller
Post Market Surveillance
Quality and Regulatory Affairs

Attachments

- Annex I - List of affected products
- Annex II - Key abstract in multiple languages

Annex I – List of affected products

Part No. From RI	Part Name UDI	Part No. From RI	Part Name UDI	Part No. From RI	Part Name UDI
MP05800 00	Filter/HME TwinStar® 90 Plus 04048675665809	MP07225 01	Set2go Ventilation 85 (A) 04048675694205	MP07938 01	Set2Go Ventilation 26 (A) 04048675559436
MP05805 00	Filter/HME TwinStar® 55 Plus 04048675665847	MP07238 00	Set2Go Ventilation 95(A) 04048675744115	MP07950 06	Set2Go Ventilation 1 (A) 04048675420033
MP05810 00	Filter/HME TwinStar® 60A Plus 04048675665861	MP07243 00	Set2go Ventilation 92 (A) 04048675732600	MP07951 04	Set2Go Ventilation 2 (A) 04048675437123
MP05815 00	Filter/HME TwinStar® 25 Plus 04048675665885	MP07902 01	Set2Go Ventilation 74 (A) 04048675609902	MP07952 04	Set2Go Ventilation 3 (A) 04048675443650
MP05820 00	Filter/HME TwinStar® 9 Plus 04048675665908	MP07905 01	Set2Go Ventilation 72 (A) 04048675633068	MP07954 04	Set2Go Ventilation 5 (A) 04048675446811
MP12060 00	CombiStar Plus Filter + HME straight 04048675713685	MP07909 01	Set2Go Ventilation 69(A) 04048675596554	MP07968 02	Set2Go Ventilation 12 (A) 04048675544739
MP12061 00	CombiStar Plus Filter + HME flex 04048675714408	MP07912 01	Set2Go Ventilation 66 (A) 04048675595632	MP07972 02	Set2Go Ventilation 14(A) 04048675544364
MP20370 00	Pack2Go Evita invasive Vpack CO2 Cuvette 04048675714521	MP07914 01	Set2go Ventilation 64 (A) 04048675595670	MP07981 01	Set2Go Ventilation 27 (A) 04048675552734
MP20371 00	Pack2Go Evita invasive Vpack 04048675714545	MP07917 02	Set2go Ventilation 62 (A) 04048675569879	MP07984 02	Set2Go Ventilation 22 (A) 04048675547488
MP20375 00	Pack2Go invasive Vpack Coax 04048675714620	MP07919 01	Set2Go Ventilation 58(A) 04048675653103	MP07988 02	Set2Go Anesthesia 15(A) 04048675555124
MP20376 00	Pack2Go invasive Vpack Basic 04048675714644	MP07920 01	Set2Go Ventilation 57(A) 04048675652984	MP07991 01	Set2Go Ventilation 30(A) 04048675555148
MP20377 00	Pack2Go Evita inv. Vpack Coax/CO2 Cuv. 04048675714668	MP07921 01	Set2Go Ventilation 56(A) 04048675652960	MP07992 01	Set2Go Ventilation 31(A) 04048675555162
MP20378 00	Pack2Go Evita invasive Vpack Coax 04048675714682	MP07922 01	Set2Go Ventilation 53 (A) 04048675635611	MP07994 01	Set2Go Ventilation 33 (A) 04048675557333
MP07209 01	Set2go Ventilation 77 (A) 04048675666844	MP07924 01	Set2Go Ventilation 76 (A) 04048675633709	MP07998 01	Set2Go Ventilation 37 (A) 04048675558507
MP07213 01	Set2go Anesthesia 31 (A) 04048675674047	MP07926 01	Set2go Ventilation 54 (A) 04048675569084	MP07999 01	Set2Go Ventilation 38 (A) 04048675558521
MP07214 03	Set2go Ventilation 79 (A) 04048675674061	MP07927 01	Set2go Ventilation 55 (A) 04048675569305	MP07232 01	Set2go Ventilation 85 (A) 04048675716426
MP07218 02	Set2go Ventilation 82 (A) 04048675677123	MP07936 02	Set2Go Ventilation 45 (A) 04048675559566		
MP07224 01	Set2go Ventilation 84 (A) 04048675692638	MP07937 02	Set2Go Ventilation 44 (A) 04048675559580		

Annex II – Key abstract in multiple languages

<p>EN/ENUS – Risk of patient injury If liquid appears on the device-side of the product or in case of resistance increase, the product must be replaced. Permanently monitor airway pressure and volume and set suitable alarm limits for each patient.</p>	<p>DE – Patientengefährdung Wenn Flüssigkeit auf der Geräteseite des Produktes auftritt oder der Luftwiderstand ansteigt, muss das Produkt ausgetauscht werden. Atemwegsdrücke und Atemvolumen müssen kontinuierlich überwacht und Alarmgrenzen dem Patienten entsprechend gewählt werden.</p>
<p>FR – Risque de blessure du patient Si du liquide apparaît sur le côté appareil du produit ou en cas de résistance accrue, le produit doit être remplacé. Surveillez de manière continue la pression et le volume des voies aériennes et définissez des seuils d'alarme adaptés pour chaque patient.</p>	<p>ES – Riesgo de lesiones para el paciente Será preciso sustituir el producto si observa líquido en el lado del dispositivo o ante un aumento de la resistencia. Supervise permanentemente la presión y el volumen de las vías respiratorias y establezca límites de alarma adecuados para cada paciente.</p>
<p>IT – Rischio di lesioni al paziente Se compare del liquido sul lato dispositivo del prodotto o nel caso in cui aumenti la resistenza, il prodotto deve essere sostituito. Monitorare costantemente la pressione e il volume delle vie aeree e impostare limiti di allarme adeguati per ciascun paziente.</p>	<p>PTBR – Risco de lesão no paciente Se aparecer líquido na lateral do equipamento ou em caso de aumento da resistência, o produto deve ser substituído. Monitore permanentemente a pressão e o volume das vias aéreas e defina limites de alarme adequados para cada paciente.</p>
<p>NL – Risico op letsel bij de patiënt Als er vloeistof aan de apparaatzijde van het product verschijnt of als de weerstand toeneemt, moet het product worden vervangen. Bewaak permanent de luchtdruk en het luchtwegvolume en stel geschikte alarmlimieten in voor elke patiënt.</p>	<p>DA – Risiko for skade på patienten Hvis der opstår væske på apparatsiden af produktet, eller hvis modstanden øges, skal produktet udskiftes. Luftvejstryk og -volumen skal hele tiden overvåges, og egnede alarmgrænser skal sættes for hver patient.</p>
<p>NO – Fare for pasientskade Dersom det kommer ut væske på apparatsiden av produktet eller motstanden øker, må produktet skiftes ut. Overvåk kontinuerlig luftveistrykk og volum og definer passende alarmgrenser for hver enkelt pasient.</p>	<p>SV – Risk för patientskador Om vätska uppstår på produktens enhetsida eller om motståndet ökar måste produkten bytas ut. Övervaka hela tiden luftvägstrycket och luftvägsvolymen och ställ in lämpliga larmgränser för varje patient.</p>
<p>FI – Potilasvahingon vaara Tuote on vaihdettava, jos nestettä on havaittavissa laitteen puolella tuotetta tai jos vastus kasvaa. Tarkkaile jatkuvasti hengitystiepainetta ja -tilavuutta ja säädä hälytysrajat kulloisellekin potilaalle sopiviksi.</p>	<p>LT – Paciento sužalojimo rizika Jei ant gaminio prietaiso pusės atsiranda skysčio arba padidėja atsparumas, gaminį reikia pakeisti. Nuolat stebėkite kvėpavimo takų slėgį ir tūrį bei nustatykite tinkamas aliarmo ribas kiekvienam pacientui.</p>
<p>LV – Traumu risks pacientam Ja uz izstrādājuma ierīces sāniem parādās šķidrums vai ja palielinās pretestība, izstrādājums jānomaina. Pastāvīgi uzraugiet elpceļu spiedienu un tilpumu un katram pacientam iestatiet piemērotas trauksmes robežas.</p>	<p>ET – Patsiendi vigastuse oht Kui vedelik ilmub toote küljele või takistuse suurenemise korral tuleb toode välja vahetada. Jälgige pidevalt hingamisteede rõhku ja mahtu ning seadistage sobivad häirelimiidid iga patsiendi jaoks</p>
<p>RU – Риск травмирования пациента Если на изделии со стороны устройства появилась жидкость или увеличилось сопротивление, изделие необходимо заменить. Постоянно следите за давлением и объемом в дыхательных путях и устанавливайте для каждого пациента соответствующие пределы тревоги.</p>	<p>KK – Emdeluşınıñ jaraqat alu qaupı Önimniñ qurylğy jağynda süyqytyq paıda bolsa nemese qarsylyq küşeise, önimdi auystyru kerek. Tynys alu joldarynyñ qysymy men kölemin tūraqty baqylap, är emdeluşı üşin säikes dabyl şekteulerin ornatyñyz.</p>
<p>PL – Ryzyko wystąpienia urazu u pacjenta Jeżeli po stronie urządzenia na produkcie pojawi się ciecz lub w przypadku wzrostu oporu, wtedy produkt należy wymienić. Należy stale monitorować ciśnienie w drogach oddechowych i objętość oraz ustawić odpowiednie granice alarmów dla każdego pacjenta.</p>	<p>CS – Nebezpečí poškození zdraví pacienta Pokud se na straně přístroje v produktu objeví nějaká kapalina nebo v případě nárůstu rezistance, musí být produkt vyměněn. Neustále monitorujte tlak v dýchacích cestách a objem a pro každého pacienta nastavte vhodné mezní hodnoty alarmů.</p>

<p>SK – Riziko poranenia pacienta</p> <p>Výrobok sa musí vymeniť, ak sa na strane zariadenia výrobku objaví tekutina alebo v prípade zvýšenia odporu. Nepretržite sleduje tlak v dýchacích cestách a objem a pre každého pacienta nastavte vhodné limity poplachu.</p>	<p>SL – Nevarnost poškodbe pacienta</p> <p>Če se na strani pacienta na izdelku pojavi tekočina ali povečanje upora, je treba izdelek zamenjati. Stalno nadzirajte tlak in volumen v dihalnih poteh in za vsakega pacienta nastavite ustrezne alarmne meje.</p>
<p>HU – A páciens sérülésének veszélye</p> <p>Ha az eszköz felőli oldalon folyadék jelenik meg, illetve az ellenállás megnövekedése esetén le kell cserélni az eszközt. Folyamatosan monitorozza a légúti nyomást és a térfogatot, továbbá állítson be megfelelő riasztási határértékeket minden páciens számára.</p>	<p>HR – Opasnost od ozljede pacijenta</p> <p>Ako se tekućina pojavi na strani proizvoda ili u slučaju povećanja otpora, proizvod se mora zamijeniti. Stalno nadzirite tlak i volumen u dišnim putovima i postavite odgovarajuće granice alarma za svakog pacijenta.</p>
<p>RO – Risc de rănire a pacientului</p> <p>Dacă apare lichid pe partea de dispozitiv a produsului sau în caz de creștere a rezistenței, produsul trebuie înlocuit. Monitorizați în permanență presiunea și volumul căilor respiratorii și stabiliți limite de alarmă adecvate pentru fiecare pacient.</p>	<p>SR – Rizik od povrede pacijenta</p> <p>Ako se na strani uređaja proizvoda pojavi tečnost ili u slučaju povećanja otpora, proizvod se mora zamijeniti. Trajno nadgledajte pritisak i zapreminu u disajnim putevima i podesite odgovarajuća ograničenja alarma za svakog pacijenta.</p>
<p>BG – Опасност от увреждане на пациента</p> <p>Ако се появи течност по продукта на страната откъм уреда или в случай на увеличаване на съпротивлението, продуктът трябва да се смени. Постоянно следете налягането и обема на дихателните пътища и задайте подходящи граници на алармата за всеки пациент.</p>	<p>EL – Κίνδυνος τραυματισμού ασθενούς</p> <p>Εάν εμφανιστεί υγρό στην πλευρά της συσκευής του προϊόντος ή σε περίπτωση αύξησης της αντίστασης, το προϊόν πρέπει να αντικατασταθεί. Παρακολουθήστε συνεχώς την πίεση και τον όγκο του αεραγωγού και ορίστε κατάλληλα όρια συναγερμού για κάθε ασθενή.</p>
<p>TR – Hasta yaralanma riski</p> <p>Ürünün cihaz tarafında sıvı görünürse veya direncin artması durumunda ürün değiştirilmelidir. Hava yolu basıncını ve hacmini sürekli olarak izleyin ve her hasta için uygun alarm limitlerini ayarlayın.</p>	<p>ID – Risiko cedera pada pasien</p> <p>Produk harus diganti jika cairan muncul di sisi perangkat produk atau jika resistansi naik. Secara permanen, pantau tekanan jalan napas dan volume dan tetapkan batas alarm untuk setiap pasien.</p>
<p>VI – Nguy cơ tổn thương bệnh nhân</p> <p>Nếu có chất lỏng xuất hiện trên mặt thiết bị sản phẩm hoặc trong trường hợp điện trở tăng, cần phải thay thế sản phẩm. Thường xuyên theo dõi áp suất và thể tích đường thở, và đặt giới hạn báo động phù hợp với từng bệnh nhân.</p>	<p>ZH – 患者受伤的危險</p> <p>如果在产品设备侧出现液体或空气阻力增加，这时必须替换产品。为每一位患者持续监控导气管气体压力和容量以及设置合适的警报限值。</p>
<p>KO – 환자 부상 위험</p> <p>제품의 장치 측에 액체가 생기거나 저항이 상승하는 경우 제품을 교체해야 합니다. 기도압 및 유량을 항상 모니터링하며 각 환자마다 적절한 알람 한도를 설정하십시오.</p>	<p>JA – 患者負傷の危険性</p> <p>本製品の装置側内部に液体が浸入している場合、または抵抗が増大した場合は、本製品を交換する必要があります。気道内圧と換気量を常にモニタリングし、各患者に対して適切なアラームリミットを設定して下さい。</p>
<p>UK – Ризик травмування пацієнта</p> <p>При появі рідини з боку виробу або у разі збільшення опору виріб необхідно замінити. Постійно контролюйте тиск і об'єм дихальних шляхів та встановлюйте відповідні межі сигналів тривоги для кожного пацієнта.</p>	