URGENT FIELD SAFETY NOTICE

IMPORTANT SAFETY INFORMATION

SAFETY NOTICE (FSN)

CONCERNING

Quality Flowmeter Serie

Lübeck, 20.08.2024

MANUFACTURERER INFORMATION	
Company Name	**DEHAS Medical Systems GmbH**
SRN	**DE-MF-000005328**
Address	**Wesloer Str. 107-109** **D-23568 Lübeck**
Contact person	**Jens Meincke**
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Safety Notice Information	
FSN – Referenznummer	**FSN2024-12/2024-14**
FSCA – Referenznummer	**FSCA2024-12/2024-14**
FSN – Datum	**2024-08-21**
Product / Device Name	**Quality Flowmeter Series**

Dear Customer,

Our company's products are subject to continuous and rigorous monitoring to ensure their safety and reliability during use. As part of our product surveillance, we have identified a potential issue with the following product that may affect the device's performance:

Product / Trade Name: QualityMix Flowmeter / Quality Flowmeter

GMDN Code: 61365

BASIC UDI: 42514117FL65

Flowmeter Polemount		Flowmeter Rail		Flowmeter Gas Mixer		Flowmeter Direct Plug-In	
REF Nr. / Artikelnummer	GTIN	REF Nr. / Artikelnummer	GTIN	REF Nr. / Artikelnummer	GTIN	REF Nr. / Artikelnummer	GTIN
D-FL-O2-3-ST-NIST	4251411706708	D-FL-O2-3-SH	4251411706609	D-B-FL-3	4251411700065	D-FL-O2-3-DIN	4251411701611
D-FL-O2-6-ST-NIST	4251411706715	D-FL-O2-6-SH	4251411706616	D-B-FL-6	4251411700072	D-FL-O2-6-DIN	4251411701628
D-FL-O2-15-ST-NIST	4251411706722	D-FL-O2-15-SH	4251411706623	D-B-FL-15	4251411700089	D-FL-O2-15-DIN	4251411701635
D-FL-O2-32-ST-NIST	4251411703875	D-FL-O2-32-SH	4251411706630	D-B-FL-32	4251411700096	D-FL-O2-32-DIN	4251411701642
D-FL-O2-85-ST-NIST	4251411701666	D-FL-O2-85-SH	4251411706647	D-B-FL-85	4251411700102	D-FL-O2-85-DIN	4251411701659
		D-FL-AIR-3-SH	4251411706654	D-B-FL-3-N2O	4251411701727	D-FL-AIR-3-DIN	4251411701673
		D-FL-AIR-6-SH	4251411706661	D-B-FL-6-N2O	4251411701734	D-FL-AIR-6-DIN	4251411701680
		D-FL-AIR-15-SH	4251411706678	D-B-FL-15-N2O	4251411701741	D-FL-AIR-15-DIN	4251411701697
		D-FL-AIR-32-SH	4251411706685	D-B-FL-32-N2O	4251411701758	D-FL-AIR-32-DIN	4251411701703
		D-FL-AIR-85-SH	4251411706692	D-B-FL-85-N2O	4251411701765	D-FL-AIR-85-DIN	4251411701710
				D-B-FL-15-NO	4251411706739	D-FL-O2-3-BS	4251411706456
						D-FL-O2-6-BS	4251411706463
						D-FL-O2-15-BS	4251411706470
						D-FL-O2-32-BS	4251411706487
						D-FL-O2-85-BS	4251411706494
						D-FL-O2-3-NF	4251411702816
						D-FL-O2-6-NF	4251411702823
						D-FL-O2-15-NF	4251411702830
						D-FL-O2-32-NF	4251411702847
						D-FL-O2-85-NF	4251411702854
						D-FL-O2-3-SS	4251411706500
						D-FL-O2-6- SS	4251411706517

						D-FL-O2-15- SS	4251411706524
						D-FL-O2-32- SS	4251411706531
						D-FL-O2-85- SS	4251411706548
						D-FL-O2-3- CAR	4251411706555
						D-FL-O2-6- CAR	4251411706562
						D-FL-O2-15- CAR	4251411706579
						D-FL-O2-32- CAR	4251411706586
						D-FL-O2-85- CAR	4251411706593
						D-FL-O2-3- UNI	4251411702762
						D-FL-O2-6- UNI	4251411702779
						D-FL-O2-15- UNI	4251411702786
						D-FL-O2-32- UNI	4251411702793
						D-FL-O2-85- UNI	4251411702809

Therefore, we would like to provide you with the following information:

Introduction:

As part of our market surveillance, we have identified a potential issue where the top tube of the flowmeter may become detached if the connection is improperly handled and exposed to excessive pressures. This could lead to leaks and device malfunctions.

Description of the Problem and Root Cause:

Our investigations, along with seven reported field incidents, have revealed that the top tube of the flowmeter may become loose during operation due to improper handling, particularly with repeated disassembly and reassembly. This issue may occur if the top tube is removed, for instance, for cleaning or disinfection purposes, and not correctly reattached. Such handling can cause damage to the thread, increasing the likelihood of leaks. These damages include noticeable wear (cross-threading) and potential cracking of the top tube's thread. In addition to the sudden detachment of the top tube during operation, this can lead to product leaks, as there is an O-ring between the top tube and the flowmeter body that ensures tightness through compression at the connection point. Repeated disassembly and reassembly can cause the O-ring to shift, resulting in leaks.

Background of the Corrective Action:

The product is not intended to be disassembled by the user or third parties. The instructions for use clearly state that the product must not be disassembled, even for cleaning or disinfection. However, investigations and field incidents have shown that the product, when subjected to repeated disassembly/reassembly or excessive operating pressure, can develop leaks or cause the top tube to become detached.

Risk to Patients, Users, or Third Parties with Continued Use of the Product:

Continued use of a flowmeter that has undergone multiple disassembly and reassembly carries the risk of leaks, leading to inaccurate flow measurements. This could result in device malfunctions, and in the worst case, treatment errors or device failure. Improper detachment of the top tube during use can damage the product, which should then be replaced immediately.

Risks to Patients Who Have Already Been Treated with Affected Products:

Patients treated with affected products may have received treatment based on inaccurate flow measurements.

Risk Assessment:

Our investigation results indicate that no damaged or leaking product could have left our manufacturing facility, as all devices are tested for accuracy and tightness after final assembly. Therefore, the described issues could only have arisen from improper handling by the user after delivery. The risk to patients, users, or third parties is considered acceptable. We strongly recommend strictly following the instructions for use and avoiding any disassembly to ensure the product's safety and effectiveness.

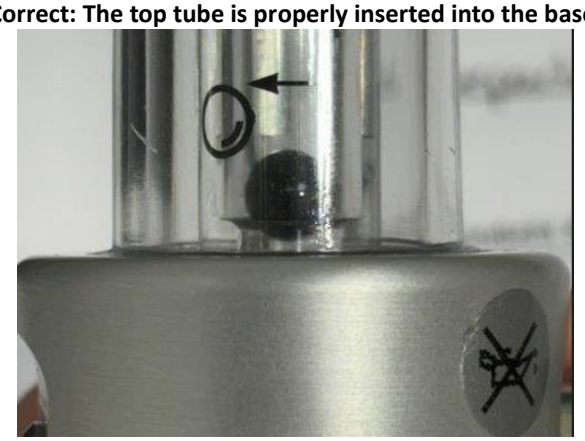
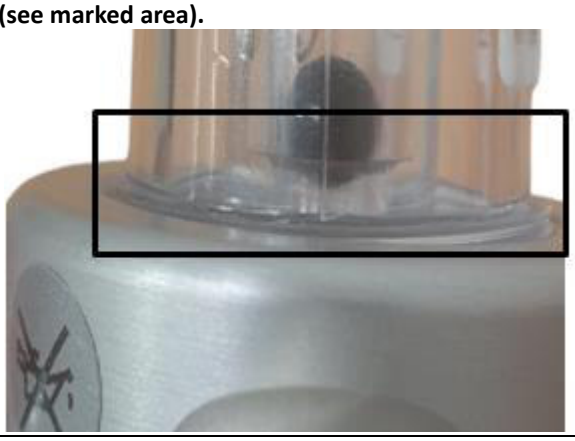
Actions to Be Taken by the Recipient:

Immediate Action by Operators/Users:

Inspect the products for the connection point between the top tube and the flowmeter body. If you detect any leaks, damage to the product, or notice that the top tube is not correctly mounted, immediately contact a technician or service representative. Do not continue to use the affected flowmeter until it has been serviced or repaired by authorized personnel.

Guide for Regular Visual Inspection of the Product before Use:

Step	Action	Description
1	**Visual Inspection Before Use**	Regularly inspect the flowmeter visually for: • Damage to the product due to drops or impacts on the top tube (see Step 3) • Incorrect assembly: top tube improperly inserted into the base; O-ring in the

Step	Action	Description
		base is pinched; missing components (see Step 3). • Contamination
2	**Report Damage**	If the device is damaged due to a drop or impact before or during use, immediately notify the responsible medical engineering department. A drop or impact may cause an O-ring or the top tube of the flowmeter to shift, resulting in unintended leakage.
3	**Visual Inspection of Correct top tube Assembly**	**Correct: The top tube is properly inserted into the base.**  **Incorrect: The top tube is either tilted in the base or dislodged due to a severe impact or fall (see marked area).** 
4	**Warning!**	Do not connect or use the device if there are any doubts about its condition.
5	**Operating pressure**	Always ensure that the operating pressure of the medical gas used to operate the flowmeter is 4.5 bar, as specified by the manufacturer.

Guide for Inspection / Service / Maintenance and Repair

Section	Task	Description
1	**Inspection/Checks**	The flowmeter should be regularly cleaned, inspected for damage (before and after each use), and tested for performance. The frequency of

Section	Task	Description
		inspections and performance tests (leakage test and flow test) depends on usage. With daily use, a full performance check may be required every six months; with infrequent use, an annual check may suffice.
2	**Service/Maintenance and Repair**	Service, maintenance, and repair should only be performed by authorized personnel. Maintenance activities and inspections depend on the type and intensity of use. A maintenance manual with the necessary maintenance kits is available from the manufacturer. All silicone seals (O-rings) in the device should be regularly inspected and replaced if necessary (see Inspection/Checks). A two-year interval is recommended by DEHAS. If any damage to the device is found, repair must be carried out by authorized personnel! A maintenance manual with the necessary maintenance kits is available from the manufacturer. For flowmeters with an indirect connection, the hose should be replaced according to the manufacturer's specified replacement date, which can be found on the hose label.
3	**Caution!** **This step should only be performed by authorized personnel!** **Inspection of the O-ring in the base and the correct fit of the top tube**	**Process Steps** 1. Hold the flowmeter in a vertical position. 2. To check the correct fit of the O-ring in the base, carefully unscrew the top tube from the base. Set the top tube with the large red O-ring aside. Remove the flowmeter tube from the base and take out the ball from the flowmeter tube. Set both aside. 3. Hold the flowmeter in a vertical position and check if the thin O-ring in the base lies flat against the bottom and thread, without being wavy or twisted. If it is, realign it. 4. Take the flowmeter tube and gently rinse it internally with medical compressed air. 5. Before reassembly, ensure that the small O-ring at the bottom end of the flowmeter tube is undamaged and present. 6. Place the ball back into the flowmeter tube. 7. Insert the flowmeter tube firmly into the base until resistance is felt. The scale should be aligned toward the adjustment knob (facing the user). 8. Before mounting the top tube, gently rinse it internally with medical compressed air. 9. Ensure that the black O-ring in the base seals when the top tube is inserted and does not get squeezed out from the sides. If this occurs, reposition the O-ring into its correct position. 10. Slip the top tube over the flowmeter tube and carefully screw it clockwise into the base thread. Tighten by hand, do not overtighten. 11. Ensure that the large red O-ring inside the top tube is correctly seated between the top tube and the flowmeter tube. 12. Clean the product as described in Chapter 10 of the user manual.

Description of Safe Use of the Product:

The product can continue to be used without restriction, provided it is operated and cleaned in accordance with the instructions for use. If visible damage or leaks are detected, the product must be taken out of service immediately until it has been thoroughly inspected and, if necessary, repaired by authorized personnel.

Preventive Measures by the Manufacturer:

The thread and associated connection of the top tube to the flowmeter body will be redesigned. The thread pitch and size will be changed (from fine to coarse thread) to prevent damage due to improper assembly and to ensure any tampering is immediately detectable. Additionally, the flowmeter instructions for use have been updated to revision 2.0, including additional information regarding the intended safe use and inspection of the product.

Please ensure that all users of the above-mentioned products within your organization and any other individuals who need to be informed are aware of this Urgent Safety Information. If you have distributed the products to third parties, please forward a copy of this information or notify the contact person listed below.

Please keep a copy of this notice along with the instructions for use and confirm receipt of this communication by emailing INFO@DEHAS.de. Please retain this information until the corrective action has been completed.

The Federal Institute for Drugs and Medical Devices has received a copy of this "Urgent Safety Information."

We apologize for any inconvenience this may cause. Should you have any further questions or require additional information, please do not hesitate to contact us.

Best regards,

Jens Meincke
PRRC / BDL, Regulatory Affairs Manager
DEHAS Medical Systems GmbH
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