

I. PRODUKTINFORMATION PRODUCT INFORMATION		VORGANGSDATEN (KUNDE, EINGANGSDATUM USW.) SIEHE TRANSACTION DETAILS (CUSTOMER, INHOUSE DATE ETC.) SEE		RMA	17/5169																								
TYP / AUSFÜHRUNG / SERIENNUMMER / REVISION / SOFTWARESTAND – TYPE / MODEL / SERIAL NO. / REVISION / SOFTWARE 5 x OOM110 SN:V103005; V103329; V103330; V103471; V103760 Viamed																													
REKLAMATIONSDESCHEIBUNG INKL. ANWENDUNGSUMGEBUNG – COMPLAINT DESCRIPTION INCL. CONFIGURATION OF APPLICATION - Gas leaking through the sensor internally																													
				SIEHE ANLAGE NR. SEE ENCLOSURE NO.																									
II. URSACHENANALYSE REASON ANALYSIS				BEARBEITER - PROCESSED BY Schliemann	DATUM – DATE 26.09.2017																								
MASSNAHMENPLAN – INVESTIGATION PLAN - measurement tests, visual inspection																													
ERGEBNISSE – INVESTIGATION RESULTS																													
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Complaint Sensors

SN	Build Date	Found Error
V103005	2015-12	was open (out of warranty)
V103471	2016-10	was open
V103760	2017-06	was open
V103330	2016-07	was open
V103329	2016-07	has leakage

Build type	Build Time	Reason for Change
 V103005 (2017-06) Sensor with big inner Cell	... to 20.11.2015	
 V103330 (2016-07) Sensor with small inner Cell without O-Ring	From 20.11.2015 to 12.07.2016	Implementation of product change to inner standard cell to improve product quality, life time and lead time.
 V103760 (2017-06) Sensor with small inner Cell with O-Ring	From 12.07.2016 to now	Implementation of a centering ring as CAPA resulting from a customer complaint. The centering ring stabilizes the position of the inner standard cell and prevents the occurrence of leakages after mechanical shock or fall.

Auswertung – Evaluation

All product changes have been thoroughly tested, validated and approved. The design without O-Ring have passed the shock test at CE-Cert and a freefall test at EnviteC. The design change got the approval by Viamed at. 11.01.2016. On the basis of further experiences we implemented a corrective and preventive action to stabilize the position of the inner cell with a O-Ring. In accordance to our testing and product monitoring no leakage was observed since implementation of the CAPA.

I assume that we had communicated this change at a meeting at EnviteC.

A risk of the installed base in use was not evaluated as the equipment would detect a gas leakage during their pre-use checks.

		SIEHE ANLAGE NR. SEE ENCLOSURE NO.	
REKLAMATIONSTYP TYPE OF COMPLAINT	ENTWICKLUNGSFEHLER / DESIGN PROBLEM	☐	FERTIGUNGSFEHLER / MANUFACTURING DEFECT
	DOKUMENTAT. /KENNZEICHNUNG / DOCUMENTATION / LABELLING	☐	TRANSPORTSCHADEN / DAMAGE IN TRANSPORT
	ANDERE / OTHERS		RÜCKWEISUNG WG. ANWENDERFEHLER / REJECTED BEC. OF OPERATOR'S FAILURE
-			
Korrekturmaßnahmen – corrective actions			
- No korrektive action needed - Designchange is done before we get a complaint.			
REPARATUR REPAIR	GUTSCHRIFT CREDIT	KUNDENINFO CUSTOMER INFO	AUSTAUSCH REPLACEMENT
☐	☐	☐	☒
DOK.-NR. – DOC. NO.	DOK.-NR. – DOC. NO.	DOK.-NR. – DOC. NO.	DOK.-NR. – DOC. NO.
			VB128829
EnviteC-Wismar GmbH			
UNTERSCHRIFT BEARBEITER/ SIGNATURE PROCESSED BY:		Alter Holzhafen 18 D-23966 Wismar Tel.: +49(0)3841 / 360 - 423 Fax: +49(0)3841 / 360 - 222	

> REKLAMATIONSBEARBEITUNG – COMPLAINT PROCESSING