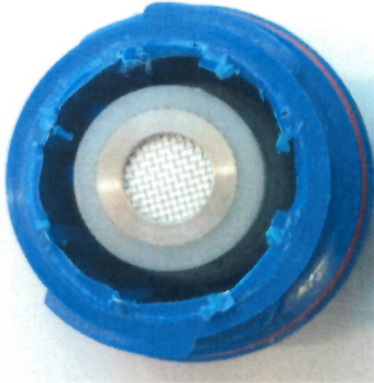


I. PRODUKTINFORMATION PRODUCT INFORMATION		VORGANGSDATEN (KUNDE, EINGANGSDATUM USW.) SIEHE TRANSACTION DETAILS (CUSTOMER, INHOUSE DATE ETC.) SEE		RMA	17/5169																								
TYP / AUSFÜHRUNG / SERIENNUMMER / REVISION / SOFTWARESTAND – TYPE / MODEL / SERIAL NO. / REVISION / SOFTWARE 5 x OOM110 SN:V103005; V103329; V103330; V103471; V103760 Viamed																													
REKLAMATIONSBECHREIBUNG 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																													
<table border="1"> <thead> <tr> <th>Serial no. - Seriennr.</th> <th>Artikel Description - Artikel Beschreibung</th> <th>Warranty - Garantie</th> <th>Problem Code - Problemcode</th> </tr> </thead> <tbody> <tr> <td>V103329</td> <td>OOM110</td> <td>ESCAPE</td> <td>O2-S005</td> </tr> <tr> <td>V103330</td> <td>OOM110</td> <td>ESCAPE</td> <td>O2-S005</td> </tr> <tr> <td>V103005</td> <td>OOM110</td> <td>OPERATOR</td> <td>O2-S005</td> </tr> <tr> <td>V103471</td> <td>OOM110</td> <td>ESCAPE</td> <td>O2-S005</td> </tr> <tr> <td>V103760</td> <td>OOM110</td> <td>ESCAPE</td> <td>O2-S005</td> </tr> </tbody> </table>						Serial no. - Seriennr.	Artikel Description - Artikel Beschreibung	Warranty - Garantie	Problem Code - Problemcode	V103329	OOM110	ESCAPE	O2-S005	V103330	OOM110	ESCAPE	O2-S005	V103005	OOM110	OPERATOR	O2-S005	V103471	OOM110	ESCAPE	O2-S005	V103760	OOM110	ESCAPE	O2-S005
Serial no. - Seriennr.	Artikel Description - Artikel Beschreibung	Warranty - Garantie	Problem Code - Problemcode																										
V103329	OOM110	ESCAPE	O2-S005																										
V103330	OOM110	ESCAPE	O2-S005																										
V103005	OOM110	OPERATOR	O2-S005																										
V103471	OOM110	ESCAPE	O2-S005																										
V103760	OOM110	ESCAPE	O2-S005																										
<table border="1"> <thead> <tr> <th>Problem Code - Problemcode</th> <th>Problem Description - Problembeschreibung</th> </tr> </thead> <tbody> <tr> <td>O2-S005</td> <td>Housing Defective - Gehäuse Defekt</td> </tr> </tbody> </table>						Problem Code - Problemcode	Problem Description - Problembeschreibung	O2-S005	Housing Defective - Gehäuse Defekt																				
Problem Code - Problemcode	Problem Description - Problembeschreibung																												
O2-S005	Housing Defective - Gehäuse Defekt																												
<table border="1"> <thead> <tr> <th>Problem Area Code - Problembereichcode</th> <th>Problem Description - Problembeschreibung</th> </tr> </thead> <tbody> <tr> <td>ESCAPE</td> <td>Warranty accepted - Produktfehler anerkannt</td> </tr> <tr> <td>OPERATOR</td> <td>Warranty expired - Garantie abgelaufen</td> </tr> </tbody> </table>						Problem Area Code - Problembereichcode	Problem Description - Problembeschreibung	ESCAPE	Warranty accepted - Produktfehler anerkannt	OPERATOR	Warranty expired - Garantie abgelaufen																		
Problem Area Code - Problembereichcode	Problem Description - Problembeschreibung																												
ESCAPE	Warranty accepted - Produktfehler anerkannt																												
OPERATOR	Warranty expired - Garantie abgelaufen																												
					Page – Seite:																								
Q:\RMA\2017\In Bearbeitung\RMA17_5169_Viamed\CR17_5169.doc					1																								

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
 Sensor with big inner Cell	... to Nov.2015	
 Sensor with small inner Cell without O-Ring	From Nov.2015 to End of July.2016	Implementation of product change to inner standard cell to improve product quality, life time and lead time.
 Sensor with small inner Cell with O-Ring	From End of July.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.

The cell with the big O-Ring starts with the serial number V103371.

		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 correktive 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 Alter Holzhafen 13 D-23966 Wismar Tel.: +49(0)3841 / 360 - 423 Fax: +49(0)3841 / 360 - 222			
UNTERSCHRIFT BEARBEITER/ SIGNATURE PROCESSED BY: <i>M. A. D.</i>			

> REKLAMATIONSBEARBEITUNG – COMPLAINT PROCESSING