Complaint Summary # SUMM-12626 Created by Elisabetta Esposto on 07-Jan-2020 17:51

Basic

SUMMARY NUMBER
SUMM-12626

SITE
Mirandola

COMPLAINT INFORMATION

COMPLAINT NUMBER
2019-05610

EXT REFERENCE

HOSPITAL/CLINIC
[redacted]

RGA / RMA #

DATE OF SUBMISSION
16-Aug-2019

EVENT DETAILED DESCRIPTION
High gas line pressure of 50mmhg. Customer would normally expect to see 10-15 mmhg

PRODUCT INFORMATION

PRODUCT PART NUMBER
08049

PRODUCT DESCRIPTION
CP8049 IT MIRANDOLA

PRODUCT LOT
1906210121

PRODUCT SN

INVESTIGATION

INVESTIGATION SUMMARY

The complained failure is an high resistance experienced on gas line equipped with 0,2 um membrane gas filter. Three filters complained as for this case and case 2019-05609 have been returned overall, without being identified if related to this complaint or the other. All of these filters have been tested with other filters returned for the same issue occurred in the same center. Results of the performed tests have been reported in our CP_MIR_MIS_001421/000.
Returned gas filters have been at first visually inspected without finding any defect or damage.

Pressure drop test:

Two tests have been performed applying a flow of Oxygen at three different values 2, 3, 5 and 10lpm and measuring pressure across the device:
- First test has been performed on returned units without any additional conditioning (identified as PRE);
- Second test has been performed on same units after drying them in oven for 72 hours at 50°C and tested again with the same values of gas flow applied during the previous test (identified as POST).

According technical specification for the device, prescribed pressure drop is:
?P ? 120 mmHg @ 10lpm

All of the units have been found not aligned to technical specification at the first pressure drop test (without conditioning).

The pressure drops values measured in second test (after the drying conditioning phase) have been found decreased for all of the units and for cases 2019-5609/10 (A. B) and 2019-06392 the values have been found to have recovered and to be conform to the expected specifications.

Microscopic Inspection:

SEM (Scanning Electron Microscopy) analysis at 100x, 500x and 2000x has been performed comparing the morphology of the complained membrane (following referred as 2019-05320) with the not assembled membrane of a different lot taken from our inventory (following referred as lot 1909030125). Based on this microscopic analysis results, morphological comparison between the membrane of complained gas filter and a brand-new membrane taken from the inventory (and not assembled) did not highlight any structural difference.

The DHR review has been performed: the lot has been released as conform according to the specifications.
Further complaints from the same center has been received in the last 12 months.
No further complaint for the same issue occurred in the last 12 months from other centers.
The issue has been detected at the beginning of the procedure, prior to any patient involvement.

No modification of the initial reportability assessment
The present report has been reviewed as per reportability criteria described in current revision of CS_BU_GP_0023 and the review does not modify the initial reportability assessment for all applicable regulations.

ROOT CAUSES

[redacted]

January 13, 2020 12:57 PM GMT+0

Based on the resistance to Oxygen flow offered by the filters once returned in LivaNova and after they have been dried in oven, it is possible to suppose that the filters may have come in contact with moisture due to water-vapor deposition (derived from humidity of the gas supply) on the filter mesh and reducing the effective area of the filter.
This effective area reduction subsequently caused the increase flow resistance through the filter membrane.
Furthermore, the morphological comparison between the membrane in the complained gas filter and a new membrane taken from the inventory did not unveil any difference on the base structure.
As per received information and performed analysis, it is not possible to confirm a device malfunction.

CORRECTIVE ACTIONS
Since no device malfunction has been identified, no corrective action has been identified for the time being.
Anyway we confirm our full availability and support to solve any possible discomfort and dissatisfaction experienced by the Customer.
LivaNova will keep monitor feedback from customers to check if similar events will reoccur, and evaluate if more specific technical actions are needed.

INVESTIGATION INFORMATION

INVESTIGATION NUMBER
INV-009454

CONFIRMATION OF REPORTED FAILURE
Not confirmed

CONCLUSION

CONCLUSION
Thank you for contacting Sorin Group about the issue you experienced. We have completed our investigation and this report provides the root causes and the corrective actions we have taken. By partnering with us to provide the information about the event, together we can achieve improved product quality for patients around the world. If you have any questions, please contact your sales person.

MAIL ACTIVITY

SEND MAIL TO

SEND MAIL TO EMAILS
[redacted]

Send Mail

Elisabetta Esposto, Email: Investigation complete for Complaint 2019-05610, 07-Jan-2020 17:52

SUMMARY ATTACHMENTS

OI ATTACHMENTS

FINAL SUMMARY ATTACHMENTS

Access Control

Additional Document Security

Managers	Editors	Readers
Complaint Summary Form Default Managers	Complaint Summary Form Default Editors	Complaint Summary Form Default Readers

Last Edited by Elisabetta Esposto on 07-Jan-2020 17:52

Comments

Last Comment

Elisabetta Esposto [1648]: 07-Jan-2020 17:52

All Comments

Elisabetta Esposto [1648]: 07-Jan-2020 17:52

[redacted]