

Handout GEMÜ Code 54

EN

Validation Guide

General Information Document



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1 Background

Due to the discontinuation of polymers used in the construction of the single piece PTFE laminated code 52 and code 5A diaphragms, GEMÜ have released a replacement code 54 diaphragm.

2 Details of Code 54 diaphragms

1. PTFE material in contact with process media unchanged (same as Code 52/5A).
2. Design and dimensions unchanged from those of Code 52/5A diaphragm.
3. Diaphragm backing (not in product contact) made of the new code 19 elastomer material developed and optimized by GEMÜ.

3 Advantages/Innovation of Code 54 diaphragms

1. Improved long-term tightness values as result of new optimized diaphragm backing material.
2. Requirement for retightening valves reduced due to the improved compression set of the backing material.

4 Comparison of material for Code 54 and 52/5A diaphragms

The following Table 1 shows the Values for the compression set, hardness, tensile strength and elongation at break for both Code 54 and 52/5A elastomeric diaphragm raw material. The Code 54 material shows a better compression set behavior which is an indication of a tighter sealing behavior. In addition, the Code 54 material shows a higher tensile strength and higher elongation at break compared to the material of the Code 52/5A diaphragms. The hardness of both materials is nearly identical.

Test:	Code 54	Code 52/5A
Compression set	++	+
Hardness	+	+
Tensile strength	++	+
Elongation at break	++	+
"+" = good		

Table 1 Comparison of material test results Code 54 and 52/5A diaphragms

5 Endurance testing for Code 5M diaphragms

The service life of Code 54 diaphragms has been validated and compared to that of the Code 52 and Code 5A diaphragms using endurance tests. The Code 54 test diaphragms are assembled on valves by trained personnel. Leak testing in accordance with DIN EN 12266 is carried out before, after and during endurance tests. These tests are used to determine whether, and to what extent, the leak-tightness characteristics of the diaphragms are reduced by the stresses of the endurance tests. The endurance tests result in artificial ageing due to the effects of mechanical and thermal stress as well as direct contact with corrosive media. Once the test valve has completed the specified test program, it is removed and a final leak test is carried out. Following this, the test valve is disassembled and the diaphragm is analyzed for faults by diaphragm experts.

The sterility endurance test is run in cycles. During a sterility cycle, the test valve is exposed to steam, vacuum and cold water. From our analysis of the results of our testing, GEMÜ can state the Code 54 diaphragm has equal or better performance than the Code 52/5A diaphragms that it is replacing.

Additional performed tests passed successfully

1. Steam endurance test
2. Vacuum endurance test
3. Determining the pin pull-out forces
4. Determining the pin over torque

6 Batch testing for Code 54 diaphragms

Every new diaphragm batch is tested by GEMÜ's quality assurance department. The diaphragm surface, dimensional tolerances, the hardness is audited by quality assurance personal. For every diaphragm batch a steam endurance test with leak measurements in accordance with DIN EN 12266 is done. Only if the diaphragm batch passes all quality tests within the tolerances it will be released for use.



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