Application Note

FESTO

Using oxygen as a medium with piezo valves and the proportional flow control valve VEMD

Technical documentation for the implementation of IEC 60601

This application note contains information on the use of piezo valves and the proportional flow control valve VEMD with oxygen as the medium or in oxygen-enriched environments in medical devices.

VEMD
VEMR
VEMC
VEMP
VEAE
VAVE-P-TP

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1 Valid for the following components

Type/Name	Version Software/Firmware	Date of manufacture
VEMD 8086472-475	n.a.	
Piezoventile VEMR, VEMC, VEMP, VEAE	n.a.	
Piezo Elektronikmodul VAVE-T-TP	n.a.	

Table 1.1: 1 Components/Software used

1.1 Summary

Piezo valves from Festo and the proportional flow control valve VEMD are suitable for use in medical devices in line with the specified technical characteristics.

The IEC 60601-1 standard, among others, applies to medical devices. Chapter 11.2 “Fire prevention” and its subchapter 11.2.2.1 “Risk of fire in oxygen-enriched environments” explicitly address fire prevention in oxygen-enriched environments.

The wetted materials of the piezo valves and the proportional flow control valve VEMD are tested for oxygen compatibility according to EN 1797.

Although possible in principle due to the design, no sparking can be triggered and observed with the piezoelectric driver electronics under standard conditions according to the datasheet ($U_{max} < 310$ V and $I_{max} < 11$ mA). This also applies to operation in a pure oxygen atmosphere up to 10 bar. In damaged piezo benders, sparking could be triggered at currents >20 mA, which, however, could never be converted into independent combustion even in an oxygen atmosphere.

Caution

To ensure safe operation, we therefore recommend that Festo piezo valves in medical devices be operated exclusively with current limitation to a maximum of 8 mA, taking a safety reserve into consideration.

In the flow control valve VEMD-... and the piezo E-box VAVE-P..., the charging current of the piezo valves is limited to typically 5 mA, which reliably prevents sparking in the piezo valve even in the first fault case.

For the flow control valve VEMD, current limiting is also used for the thermal flow rate sensor in order to prevent the heating element of the sensor from heating up excessively and igniting. The general rule for the electronics used to generate voltage for piezo valves is to avoid oxygen-enriched environments, e.g. by providing adequate ventilation.

This application note contains information from test results and recommendations for the use of piezo valves and the proportional flow control valve VEMD with oxygen as a medium for use in medical devices in compliance with the standard IEC 60601-1.

It thus serves as a basis for medical device manufacturers who want to use Festo piezo valves to perform a risk assessment for the risk of fire in oxygen-enriched environments according to IEC 60601-1.

2 Introduction

2.1 Use of Festo components in medical devices, IEC 60601-1

Festo piezo valves and the proportional flow control valve VEMD are components that are intended to be installed in an end product. The valves are suitable for applications in medical technology in line with the specified technical key features.

For use in medical devices, the standard IEC 60601-1 can be used, among others.

Chapter 11.2 “Fire prevention” and its subchapter 11.2.2.1 “Risk of fire in an oxygen-enriched environment” explicitly address fire prevention in an oxygen-enriched environment. When using a piezo valve, the defined limits according to Figure 2 (IEC 60601-1 Fig. 36) cannot be observed. The voltage on Festo piezo valves are in the range of up to 310 V.

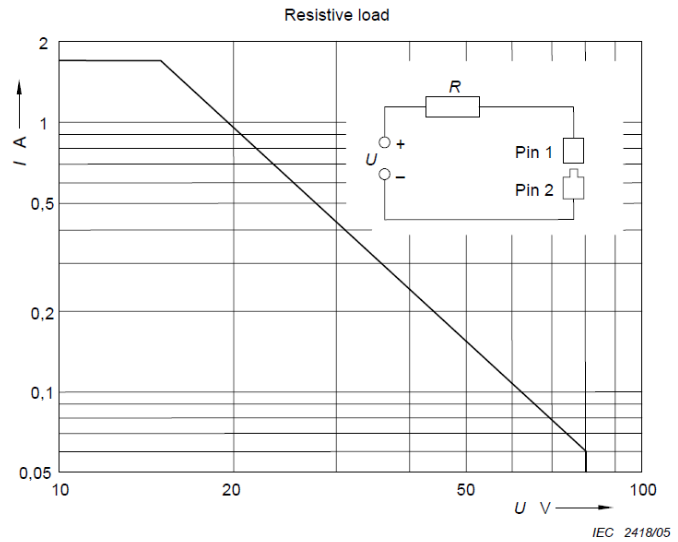


Figure 35 – Maximum allowable current *I* as a function of the maximum allowable voltage *U* measured in a purely resistive circuit in an OXYGEN RICH ENVIRONMENT
(see 11.2.2.1)

Figure 1 Excerpt from IEC 60601-1 – resistive (ohmic) load

– 160 – 60601-1 © IEC:2005

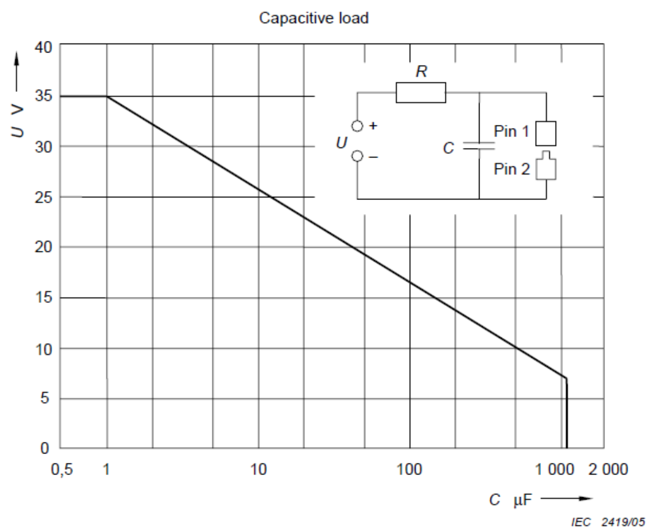


Figure 36 – Maximum allowable voltage *U* as a function of the capacitance *C* measured in a capacitive circuit used in an OXYGEN RICH ENVIRONMENT
(see 11.2.2.1)

Figure 2 Excerpt from IEC 60601-1 – capacitive load

The test mentioned in chapter 11.2.2.1 IEC 60601-1 cannot be performed on the piezo bender from a technical point of view. In principle, a spark with sufficient energy can be generated in the piezo valve due to its design, but the materials in the piezo valve cannot be ignited.

2.2 Terms

- Oxygen-enriched environment:

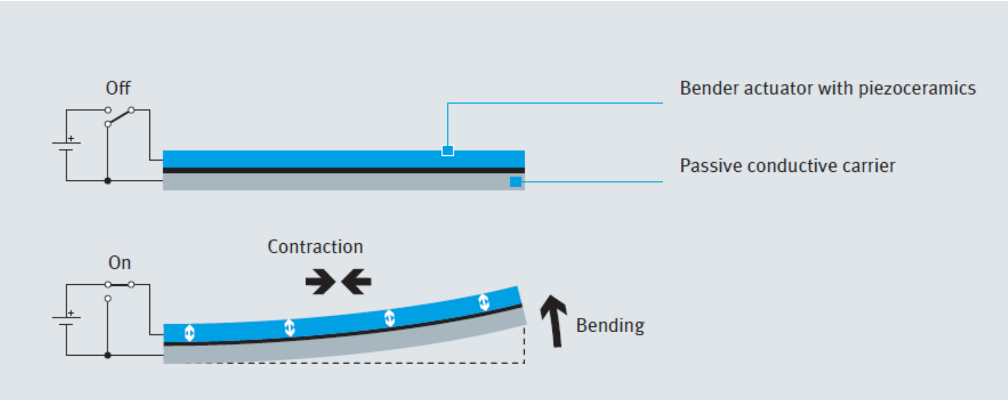
  Environment in which the concentration of oxygen

  a) amounts to more than 25% at environmental pressures up to 110 kPa or

  b) has an oxygen particle pressure greater than 27.5 kPa at environmental pressures over 110 kPa.

2.3 Design of the Festo piezo valves

Festo piezo valves use a piezoresistive ceramic that deforms when a voltage is applied, allowing the flow of the medium in the valve to change. The deformation is proportional to the applied voltage, thus allowing proportional flow rate control.

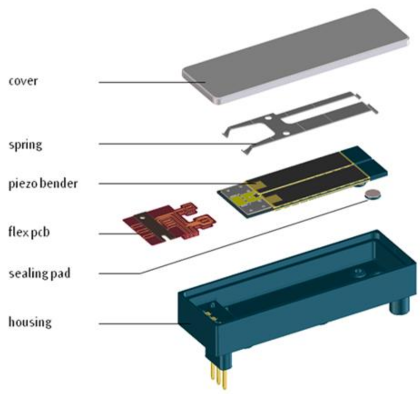


Function of the bender actuator in piezo valves

The piezo ceramic has a high resistance (> 10 Mohm) and a capacitive character. Capacitances range from 20 nF (VEMR) to 70 nF (VEAE) per piezo ceramic, depending on the piezo valve. The piezo valves are operated with voltages of 0-310 V, which are applied directly between the two sides of the piezo ceramic.

Festo piezo valves are all similar in design.
They consist of:

- the piezo bender actuator (with the piezo ceramic layer). This is also where the elastomer sealing pads, which seal against the nozzle(s) in the housing, are located.
- a metal spring for resetting
- the plastic housing with the injected nozzles
- the electrical contacts with a flex conductor, (contacting to the outside either directly via flex conductor or via pins, depending on the type)
- the plastic cover (laser-welded to seal the housing)

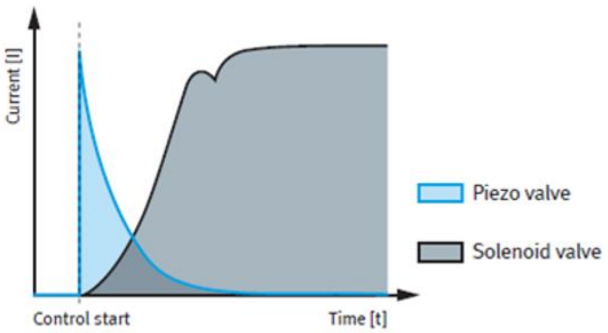


VEMC/VEMP

VEMR

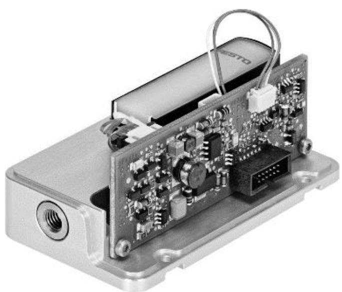
VEAE

Due to the capacitive character of the ceramic, the current curve looks different from that of solenoid valves. With piezo valves, a short current pulse is required at the beginning to charge the piezo ceramic and to achieve the deformation of the piezo ceramic. Only a very small current ‹ 0.1 mA is required to hold the current position. As there is no ohmic or inductive heating, piezo valves do not get hot.



The proportional flow control valve VEMD has a Festo piezo valve type VEMR on the inside and is therefore included here because it can be used to control the flow of oxygen.

VEMD



3 Test procedure and results

3.1 Test procedure

Due to the lack of heating, the fire hazard consists mainly in the generation of sparks on or in the piezo ceramic, which is surrounded by the medium (including oxygen), and these sparks potentially generate an ignition in the piezo valve.

Self-ignition caused by excessive temperature is ruled out in piezo valves by their very nature – the materials in contact with the medium can only be ignited by an external energy supply, such as a spark.

Spark generation is therefore considered during the test procedure to see if it can ignite the wetted materials in the vicinity of the piezo ceramics.

The test mentioned in chapter 11.2.2.1 IEC 60601-1 cannot be performed on the piezo bender from a technical point of view. According to the standard, the test must be performed with cotton. However, there is no cotton in the valve, otherwise the function of the valve is not guaranteed. According to the data sheet specifications for piezo valves, they must be operated with a filter. The filter must correspond to a filter fineness of at least 5 µm. Cotton fibres have a typical length of 15 - 56 mm and a typical diameter of 12 - 35 µm. Cotton fibres can therefore not get into the piezo valve. Instead of cotton, the materials used in the piezo valves are considered to see if a fire can be generated. Tests were carried out on the generation of sparks and on ignition/fire of the materials of the piezo valves:

1. Tests with non-defective piezo valves with air and pure oxygen environment
2. Experiments with manipulated piezo valves to generate sparks (first fault case), with air and a pure oxygen environment

The tests were carried out on series-produced parts. The bender of the piezo valve VEAE is used for testing. This has the largest capacity; there is no difference between the design and the moisture-proof coating of the benders of the various Festo piezo valves. The VEAE bender therefore acts as a "worst case" model for the other piezo valve types (VEMR, VEMP, VEMC).

All tests used a power supply (0-500 V, 0-0.5 A) that is powerful enough to produce sparks with sufficient energy for a fire and to maintain flashover over time.

The voltage is increased with a ramp function up to the permitted maximum voltage of 310 V and then held, while the current curve is continuously recorded. In case of a spark or fire, the voltage drops and the current increases abruptly. A spark/flashover can also be perceived acoustically.

These voltage/current curves were recorded for different scenarios (in air, oxygen 4 bar and oxygen 8 bar).

3.2 Voltage and current curve on a piezo valve

The following diagrams show the voltage (grey) and current (blue) curve on the piezo bender.

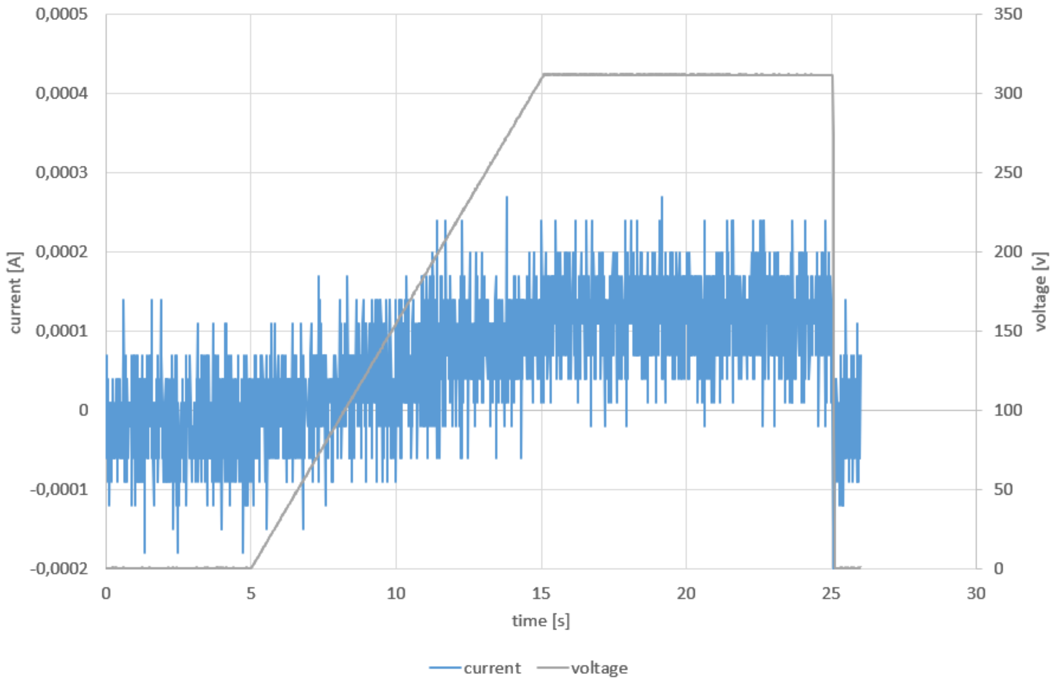


Figure 3 Voltage / current curve on a piezo bender

The voltage and current curve at a piezo valve is shown in Figure 3. The voltage increases from 0 V to 310 V from 5 s to 15 s and remains constant at 310 V until 25 s. The voltage is then switched back to 0 V. The current is ‹ 0.2m A and therefore very small.

No spark can be generated. This also applies when the voltage is increased to 500 V.

3.3 Result of the test series

Sparking was never observed under the operating conditions permitted in the datasheet (Umax ‹ 310 V and Imax ‹ 11 mA). The tests were also carried out in a pure oxygen atmosphere at 10 bar without sparking.

Only at currents › 20 mA could sparks be generated on manipulated piezo benders. In the tests, however, it was not possible to initiate independent combustion that lasted beyond the duration of the energy supply, even under an oxygen atmosphere of up to 10 bar.

⚠ **Warning**

Taking into account a safety reserve (factor 2.5), this leads to the recommendation that Festo piezo valves in medical devices should only be operated with a current limitation of max. 8 mA. (20 mA / 2.5 = 8 mA)

The Festo products VEMD and the piezo E-box VAVE-T-TP contain an active current limitation to a maximum of 5 mA and therefore comply with this recommendation.

This also applies in the first error case.