Cleaning Methods

Applicable to following sensors
SFM3x00-AW

Key content

- Details on performed cleaning tests
- Cleaning instructions
- Post cleaning recommendations

Summary
The SFM3x00-AW sensors are designed to withstand cleaning and autoclaving procedures. Sensirion SFM3x00-AW sensors show a performance within specifications for up to 30 cycles and more, depending on the cleaning procedure. Qualifications tests and results are described in this application note.

Cleaning conditions, in particular autoclaving, are harsh. Therefore care should be used at all times and according to the handling instructions described in the present document.

1 Introduction

This application note describes the qualification tests applied at Sensirion together with handling instructions for the cleaning procedure. These instructions should be followed in order to avoid damage to the sensor.

Caution: Never attempt to remove the mesh or to remove dirt behind the mesh using a sharp tip. Any mechanical damage of the mesh or the housing may lead to a reduced sensor performance.
Caution: Medical device manufacturers are recommended to self-test their cleaning process on the sensor.

This application note shows for which type of cleaning and autoclave sterilization the sensor may be qualified. All recommendations are intended to be used as guidelines.

2 Cleaning Method Details

Various methods for sterilization and disinfection are present in the market. Sensirion tested three procedures based on autoclaving, CIDEX® and STERRAD respectively. Other procedures are likely to work as well but each individual case should be thoroughly tested and verified.
The following table summarizes the statistical results of the cleaning tests performed. Test criteria to determine functioning of the sensors after cleaning are leakage rate and accuracy of the flow reading. Sensors pass if leakage is <0.01 slm at 250 mbar over-pressure and if flow reading is within specification. Note that CIDEX® and STERRAD cleaning did not produce any failure.

Cleaning Method	Number of cycles	Failure rate
Autoclave	30	< 5 %
CIDEX®	100	None
STERRAD	30	None

Sensirion does not guarantee the stability of the flow sensor using arbitrary methods and/or equipment for cleaning/sterilization. Validation of the flow sensor stability for cleaning procedures and/or equipment is the sole responsibility of the customer. No validation of the cleaning procedure efficacy was performed by Sensirion.

2.1 Autoclave Test

The sensor stability against autoclaving was tested in a Laboklav 80 MSLV by repeatedly cycling through the following autoclave steps:

- 135 °C and -0.8…+2.15 bar gauge pressure for 5 min
- Drying through evacuation for 5 min
- Cool down to 50 °C

Testing was done with various batches. The statistics of 100 samples revealed an overall failure rate below 5%. The figure below shows the exemplary flow-error of 30 units SFM3300-250-AW after autoclaving.

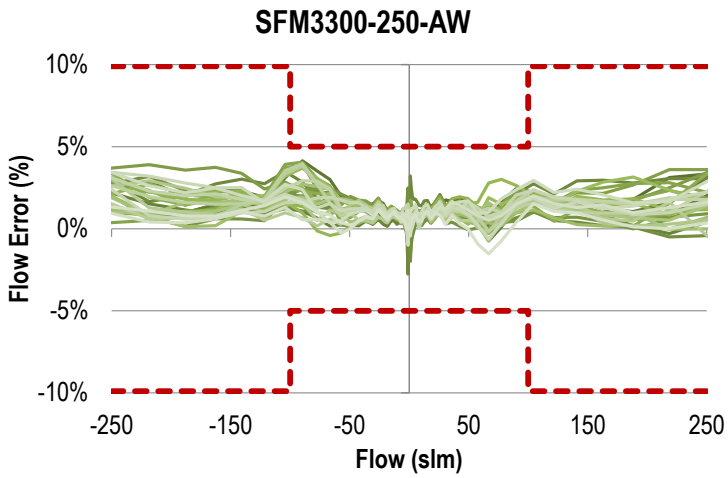

Figure 1. Exemplary flow-error of 30 units SFM3300-250-AW after autoclaving

2.2 CIDEX® Test

The stability of the sensor against cleaning in a liquid solution has been tested by repeatedly cycling the sensors in CIDEX® activated dialdehyde solution for 10 cycles and an extended immersion, using the following steps:

- Complete immersion of clean and dry sensor in CIDEX® for 15 min at ambient temperature (~21 °C)
- All cavities were brought in contact with CIDEX®
- Sensor was removed and thoroughly rinsed with distilled water. This procedure was repeated twice, for a total of three rinses. Each rinse was carried out for approx. 5 minutes in duration and a large volume of fresh distilled water.
- Subsequent rinsing in isopropanol to facilitate the drying process.
- Sensor was entirely dried before re-connection and re-use.

After these 10 cycles, test measurements were performed for each sensor. The sensors were then re-immersed for a prolonged period of >25 hours in CIDEX, which is equivalent to 100 cycles of 15 minutes.

2.3 STERRAD Test

20 Sensirion SFM3300-250-AW sensors were sterilized in a STERRAD 100S machine. 2 samples were used as control samples. Every 5 cycles 3 sensors were removed. A maximum of 30 cycles were tested. Samples were measured back before and after STERRAD procedure. For the entire flow range all samples remained within specifications and no dependency on the number of STERRAD cycles was found. The following figure shows the relative average drift over all 18 samples versus the number of cycles.

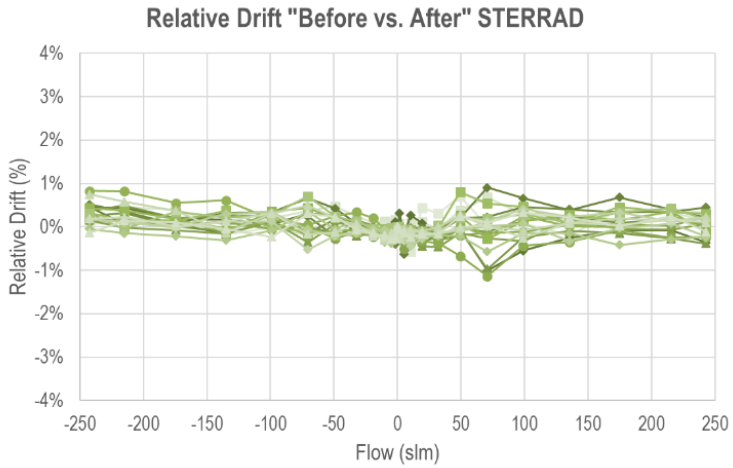

Figure 2. Relative average drift over all 18 samples versus the number of cycles

3 Cleaning Instructions

3.1 Autoclave Sterilization

Step 1: Disconnect all hoses, tubes and electrical connectors before initiating autoclave sterilization.

Step 2: Read and follow the instructions of your autoclave device. Follow all safety precautions.
Caution: As flow sensors are sensitive devices special care should be taken to avoid dirt and residues from entering the sensor.

Step 3: Ensure to place the sensor in a vertical position during autoclaving in order to avoid water from collecting inside the sensor housing.

Step 4: After autoclave allow the flow sensor to cool down and dry entirely before continued usage. We recommend letting the sensor dry in a clean and low-humidity environment. Filtered, oil and contaminant-free pressured air may be used carefully to enhance drying, but may accelerate wear and drift. Drying the sensor in an oven at moderate temperatures (≤50 ° C) is possible.

Step 5: Visually inspect the part after autoclaving. Parts which are mechanically damaged (visible cracks, distorted parts or altered colour) must be replaced.

Caution: Allow any liquid to evaporate entirely before re-connecting and using the sensor again.

3.2 CIDEX® Cleaning

Step 1: Disconnect all hoses, tubes and electrical connectors before beginning with liquid agent cleaning.

Step 2: Read and follow the instructions of how to prepare, activate, use and dispose of the CIDEX® solution. Follow all safety precautions.
Caution: As flow sensors are sensitive devices special care should be taken to avoid dirt and residues from entering the sensor.

Step 3: Entirely submerge clean and dry sensor in CIDEX® solution. Gently move the sensor within the cleaning agent to allow solution to enter all cavities. Soak sensor in CIDEX for 15 min at ambient temperature (~21 °C).

Step 4: Remove sensor from bath and take care to pour excess cleaning agent from sensor housing. Thoroughly rinse with distilled (!) water. Repeat this procedure twice, for a total of three rinses. Each rinse should be carried out for a minimum of one minute in duration, and a large volume of fresh (!) distilled (!) water. Subsequently rinse in isopropanol alcohol in order to facilitate the drying process.

Step 5: Let the sensor dry in a clean and low-humidity environment. Filtered, oil and contaminant-free pressured air may be used carefully to enhance drying speed, but may accelerate wear and drift. Drying the sensor in an oven at moderate temperatures (≤50 °C) is possible.

Step 6: Visually inspect the part after cleaning process. Parts which are mechanically damaged (visible cracks, distorted parts or altered colour) must be replaced.

Caution: Allow any liquid to evaporate entirely before re-connecting and using the sensor again.

Note: Please refer to the CIDEX® solution instructions for more details on how to prepare, activate, use and dispose of the CIDEX® solution.

3.3 STERRAD Cleaning

Carefully follow the handling instructions of your STERRAD device and consider post cleaning test procedures outlined in this application note after each STERRAD cycle and before each use.

3.4 Other methods of sterilization

Other methods of sterilization have not been evaluated by Sensirion. If you are interested in evaluating other methods or substances, please contact Sensirion.

4 Post Autoclave/Cleaning Recommendation

For each flow sensor Sensirion gives a recommended range of autoclaving and cleaning cycles which typically can be performed with the sensor remaining within the specifications. Since the autoclave procedure is harsh and leads to accelerated aging of the sensor it is possible that a single sensor over- or underachieves the typical number of cycles. Residues from the cleaning processes may affect the accuracy of the sensor. Therefore, Sensirion recommends different post cleaning / pre-use tests to ensure correct operation:

a) Offset test with zero flow and sensor in horizontal position. Recommended:
   - SFM3200-AW offset < 0.1 slm
   - SFM3300-AW offset < 0.2 slm
   - SFM3400-AW offset < 0.05 slm

b) Measure a defined flow point with references to other sensors or critical regimes.

c) Leakage test[1]: According to requirements within customer's application.

The highest certainty of detection is reached by performing all three tests. However, it is possible to combine any two or select only one of above tests if a lower certainty is acceptable. The recommendations given are only a guide and should be adapted by the medical device manufacturer according to the use case.

5 Considerations for integrating flow sensors into medical devices

The autoclave and cleaning procedures described above should be used as a guideline for cleaning and disinfection of the sensors as these are verified procedures. Nonetheless it is recommended to carry out own tests to ensure the cleaning procedures and equipment is suitable for using with the flow sensors. Our recommended post cleaning test procedures can help to perform own tests. All other handling instructions and recommendations in the datasheets should be followed as well.

For more details, please contact Sensirion.

[1] If leak tightness is critical in customer application, it remains customer's sole responsibility to leak-test the sensor before usage. It is solely the customer's responsibility to ensure that the sensor does not create a critical situation for a patient or user.

6 Revision history

Date	Author	Version	Changes
Aug 2015	DAT	1.0	Released
Aug 2015	DAT	1.1	Corrected errors
Mar 2017	SAW	2.0	Added STERRAD results, overall update of the application note
July 2017	SAW	2.1	Made application note compatible with SFM3400-AW
Jan 2021	MaKom	2.2	New format

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