# **Engineering Guidelines for Mass Flow Meters**

#### Applicable to following sensors:

SFM3xxx and SFM4xxx series

#### Key content

- Initial testing and debugging
- Electrical and mechanical integration
- Overview on useful resources, regulatory information, and background on calibration

#### Summary

Sensirion's portfolio of gas-flow sensor modules with our innovative CMOSens® technology enables us to provide OEMs worldwide with a solution that combines the sensor component and signal processing circuitry on a single CMOS silicon chip. The CMOSens® sensor bidirectionally measures gas flow, remains stable over long periods of time and generates very fast, and highly accurate flow readings over the entire flow range. By combining Sensirion's 20-year history in medical and industrial automation, Sensirion's flow meters (SFMs) are the ideal solution to offer highly accurate and repeatable results, free of zero-point offsets or drift over the lifetime of the sensor.

This application note provides engineers integrating our SFMs into their product with an overview of recommended design-in guidelines, with respect to a proper component selection, test procedure, mechanical criteria, electrical configuration, road to regulatory approval, and further background information. While this is a summation of application notes, video tutorials and datasheet references, please always refer to the exact components' datasheet as a key source of comprehensive information and detailed specifications valid for your selected product.

#### Key Benefits of Sensirion's CMOSens® Technology

- Sensing element, amplifier, A-D converter, and calibration data all integrated on a single CMOSens® chip
- Industry-proven technology with a track record of more than 20 years
- Designed for extremely high-volume production
- Individual flow module calibration with integrated temperature compensation

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# 1 Evolution in Flow Sensor Solutions – The SFM Gas Flow Module Series

The SFM gas flow module series offers ideal solutions for:

- dry gases as well as humid conditions
- unidirectional as well as bi-directional flow
- pure gas and gas mixtures
- applications requiring a low pressure drop
- high operating pressures
- digital as well as analog communication interfaces

OEMs globally utilize this turn-key set of solutions to reduce time to market, reduce development risk, and required capital expenses. An example respiratory circuit is shown below to visualize the various locations our sensors are typically used in:

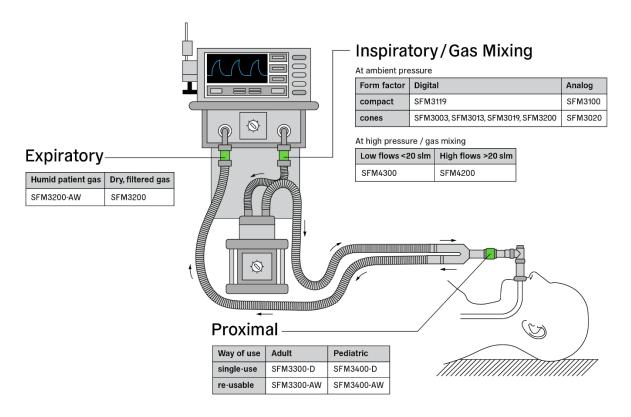


Figure 1. Standard ventilator circuit

Given the wide range of possible applications, below is a high-level breakdown of our flow sensor portfolio along with selected key specifications:



| Part number  | Location                                  | Flow range (slm)   | Interface                                 | Calibration media                                   | Gas conditions   |  |  |  |
|--|---|--|---|---|--|--|--|--|
| <u>SFM3000</u><br>(not recommended<br>for new designs) |   | -200 to +200   | Digital I2C                               | Air, O2   |  |  |  |  |
| <u>SFM3003</u>   | -   | -200 to +200 /<br>-150 to +300 Digital I2C Air, O2, and<br>thereof |   | Air, O2, and mixtures thereof                       |  |  |  |  |
| <u>SFM3013</u>   | -   | -200 to +200   | Digital I2C                               | Air, O2, CO2, HeOx, and mixtures thereof            |  |  |  |  |
| <u>SFM3019</u>   | -   | -10 to +240  | Digital I2C Air, O2, and mixtures thereof |   |  |  |  |  |
| <u>SFM3020</u>   |   | -10 to +160  | Analog 0-5V                               | Air, O2   |  |  |  |  |
| <u>SFM3100</u><br>(not recommended<br>for new designs) | Inspiratory<br>(Expiratory <sup>1</sup> ) | Expiratory <sup>1</sup> )  |   | Air, O2   | Dry or ambient;<br>non-condensing  |  |  |  |
| <u>SFM3119</u>   |   | -10 to +240  | Digital I2C                               | Air, O2, and mixtures thereof                       |  |  |  |  |
| SFM3200-JST <sup>2</sup>                               |   | -100 to +250   | Digital I2C                               | Air, O2   |  |  |  |  |
| SFM3200-AW2  | Expiratory                                | -100 to +250   | Digital I2C                               | Air, O2   | Dry, or ambient;   |  |  |  |
| <u>SFM3300<sup>2,3</sup></u>                           | -   | -250 to +250   | Digital I2C                               | Air, O2   | non-condensing   |  |  |  |
| <u>SFM3400<sup>2.3</sup></u>                           | Proximal                                  | -33 to +33   | Digital I2C                               | Air, O2   | as well as<br>Humidified and<br>condensing when<br>using the on-<br>board heater |  |  |  |
| SFM4100<br>(not recommended<br>for new designs)        | not recommended                           |  | Digital I2C                               | Air, O2, N2O, CO2, Ar                               | Dry, pressurized,  |  |  |  |
| <u>SFM4200</u>   | High-<br>Pressure                         | 0 to +160  | Digital I2C                               | Air, O2   | at ambient   |  |  |  |
| <u>SFM4300</u>   | Side                                      | 0 to +20   | Digital I2C                               | Air, O2, N2O, CO2,<br>HeOx, and mixtures<br>thereof | temperature,<br>non-condensing   |  |  |  |

Table 1. SFM Product Overview

- 1 All inspiratory sensors can also be used in the expiratory limb when combined with an HME filter and a water trap. Inspiratory sensors are not designed to be cleaned or disinfected. They require non-condensing operating conditions.
- 2 SFM modules utilize a bypass, design except the SFM3200, 3300 and 3400 series which have a direct flow channel design to ensure cleanability.
- 3 Available in re-usable/autoclavable-washable (-AW) as well as a single-use/disposable version (-D)



# 2 Initial Testing Recommendations

SFM test setup for initial sensor validation. To allow for straightforward testing and evaluation of our sensor solutions, Flow Meter Kits or Evaluation Kits are readily available in distribution. The kits typically contain a sensor, interface cable(s) and software to get started. The following tips and recommendations allow to validate the correct sensor reading and test-setup successfully, before adding complexity to the setup. The recommended first test is to create the following basic setup below. Our digital sensors can be read out using our <u>Control Center</u> or <u>Viewer Software</u> (for proximal flow sensors). The setup should ideally feature the following:

- 1. Stable, laminar flow source
- 2. Dry air at ambient temperature
- 3. Non-condensing conditions
- 4. Horizontal setup/electrical connectors pointing upwards
- 5. Mesh on the inlet/outlet of the tubing
- 6. >10 cm straight tubing without bends/kinks and an inner diameter like the inner diameter of the sensor.
- 7. 2nd flow meter downstream as a reference meter

This example is represented through the figure below. The reading of both flow sensors should agree within the specified accuracy of the sensors.

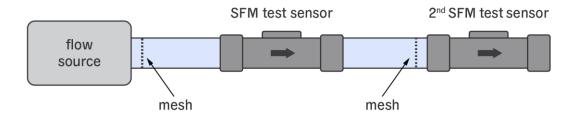


Figure 2. Recommended Initial Test Setup with SFM Modules

Note that this is the recommended first test setup only. After an initial test is performed successfully, we recommend to successively add complexity to the setup (e.g. shorter inlets, variations in gas temperature, gas mixtures, ...) and to quantify the influence. For further details regarding design-in please refer to chapter 3.

#### 2.1.1 Accuracy Troubleshooting

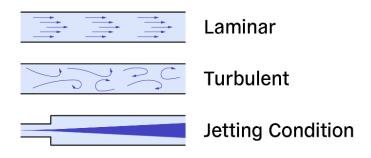


Figure 3. Different flow profiles passing through a tubing set

During the initial testing it is important to avoid turbulence and jetting influences and for the flow source to create laminar flow conditions. These laminar flow conditions will create a stable flow throughout the tubing-set and the sensor flow tube while passing over the sensor chip as pictured in Figure 3.

In the case of turbulent flow, the chaotically varying flow profile over the sensor cross section will not be stable as flow vortices pass over the sensing element causing the readings to continuously change (increased flow noise) or change unsteadily with varying flow. The cause for turbulent flow in the sensor is typically an insufficient design of the flow channel upstream of the flow sensor.

Another effect referred to as "jetting" occurs when the air passes through a narrow diameter before entering the wider diameter of the sensor. Without sufficient tubing space and flow resistance to dissipate the excess flow energy and become laminar, the air will "jet" through the sensor. As the sensor element is located at the top of the flow module, the effect will result in the sensor either over or underestimating the actual flow based on the air-jet directly hitting or missing the sensor element. To understand whether this effect is occurring and how to reduce or avert these effects, you may conduct the simple following two tests and consider the measures explained below (see also section 8.3 Re-Calibration in case you suspect the sensor to be out of specifications).

#### 2.1.2 Identification of Asymmetric Jetting: Rotation of the SFM Module

Rotate the sensor in steps of 90 degrees as shown in Figure 4 (clockwise or counterclockwise). In case the sensor reading is affected by rotation at a constant and unchanged flow, turbulences or jetting are likely occurring. This test can quickly be performed at four different angles for comparison while monitoring the sensor flow readings using the provided Control Center or Sensor Viewer evaluation software. Ensure to repeat the rotation experiment over the applicable flow rate range (for both lower and higher flows).

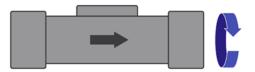


Figure 4. Rotation of the SFM module



#### 2.1.3 Flow Conditioning: Extend the Inlet Tubing Length

a) In this test the length of the tubing connecting to the input of the flow sensor is extended and the two readings with and without the extended tubing are compared at constant flow. In case turbulences or jetting occurs, the two readings between the sensor without and with the additional tubing will significantly deviate at a constant reference flow. For testing, the tubing connected should be extended significantly, by a factor of 5-10 times the sensor length, as it will provide the gas a greater distance to travel and dissipate any excess energy and hence allow the flow to adjust to a more laminar flow profile. Alternatively, when a very constant and stable flow source is not available, 2 flow sensors with the additional tubing placed between the 2 flow sensors can be used and the 2 readings can directly be compared.

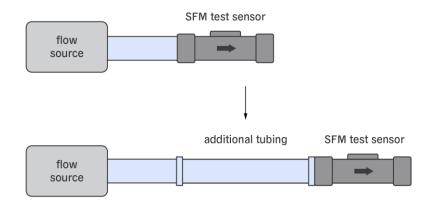


Figure 5. Adding additional tubing or a second reference sensor

b) In case turbulences or jetting occurs, a diffuser (sinter filter or mesh) can be placed on the sensor inlet tubing between the flow source and the sensor. The diffuser will support the dissipation of the turbulent flow energy and the transition to a laminar flow profile as it then passes through the SFM module.

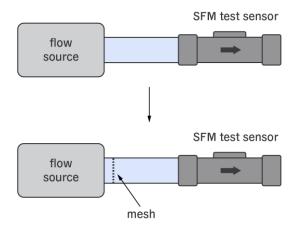


Figure 6. Introducing a mesh structure to mitigate turbulences and jetting effects



# 3 Design-In Recommendations

The previous chapter describes general considerations for initial testing and improving flow conditions. These recommendations remain valid when designing the sensor into a medical device. This chapter addresses additional constraints arising from system level, such as the type of flow source, pressure drop budgets, dimensions, manufacturability etc.

The SFM3xxxx flow meter series is designed with a low pressure drop to enable more design freedom and versatile applications. Turbine-driven devices often have a limited pressure-drop budget and often require minimizing the system flow restrictions. The SFM3xxx series with its low pressure drop and high accuracy is well suited for these applications.

As a result of the sensor's low pressure drop, the flow is not entirely conditioned by the sensor itself. The flow routing of the system leading to the sensor may also have an impact on the flow profile reaching the sensor and can therefore impact the measurement result. For optimal performance, a laminar and rotationally symmetric flow profile entering the sensor is recommended. In the following we provide recommendations on how this can be achieved in typical setups.

### 3.1 Design-In Recommendations

The two main types of flow sources used in medical devices are pressurized gas supplies (wall gas or bottles) and turbines or blowers. The gas flows generated by these sources differ considerably and thus different flow conditioning measures should be considered for optimal flow measurements.

#### 3.1.1 Turbines and blowers

Turbine-driven devices suck in ambient air and transfer it to the patient. The pressure increase by the turbine is limited and thus the tubing diameters are typically kept large while gas velocities are low. The gas flow has little kinetic energy and often a rather laminar and homogeneous flow profile, requiring less flow conditioning. With its low pressure drop the SFM3xxx series is the ideal solution for such applications and setups. Below figure shows such a design example with a SFM3xxx flow sensor.

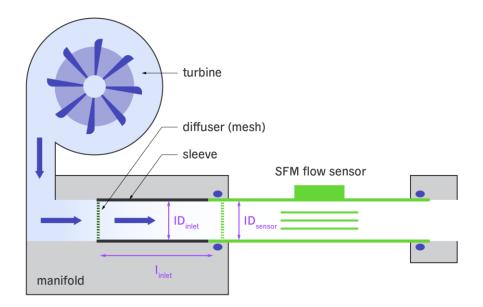


Figure 7. Turbine driven design example of a SFM3xxx flow sensor



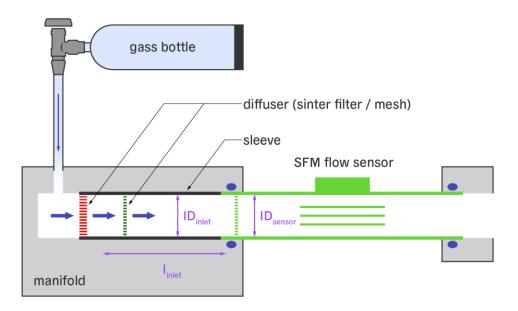
At least 8 cm of straight, rigid tubing upstream of the sensor with the inner diameter of the tubing matching the inner diameter of the flow sensor is recommended. If the pressure budget allows for it, a diffuser such as a mesh placed on the inlet side and far from the sensor will help to condition the flow. The outlet of the sensor is generally less critical. Any flow resistances placed downstream of the flow sensor (e.g. a narrowing or 90° bend) should ideally be placed after a few cm of straight tubing with identical inner diameter. This will suffice in most cases to achieve highest measurement accuracy over the entire flow range.

#### 3.1.2 Pressurized gas supply

Devices running with pressurized, compressed gas from bottles or wall supplies will often deliver flows through a proportional valve which reduces the pressure to ambient levels. The inner diameter at the valve is typically small, leading to flows with high gas velocities and thus jets with a lot of energy and turbulences. This excess kinetic energy of the gas must be dissipated before it reaches the sensor.

One solution is to measure the flow on the high-pressure side of the setup – upstream of the proportional valve – with our SFM4xxx flow meter series. They are designed to withstand several bars of gauge pressure and are thus well suited to be placed upstream of the proportional valve and hence avoiding the jets caused by the valve.

When flow is measured at the low-pressure side – downstream of the proportional valve – special care and considerations should be taken. The figure below shows a drawing of a possible sensor design in for this case.





#### Recommendations

- Feed the gas radially to the sensor inlet path, directed at the opposite wall to dissipate as much kinetic energy as possible.
- Add a sinter filter (indicated in red) or other flow restriction elements to absorb the turbulences and create laminar flow conditions.
- Consider placing a second flow restrictor such as a mesh (indicated in orange) 1-2cm after the sinter filter.
- Maximize the length of the straight inlet tube (I<sub>inlet</sub>) between the diffuser and the flow sensor.
- Design the inlet tube with a diameter equal to the inner diameter of the sensor (ID<sub>inlet</sub> = ID<sub>sensor</sub>).
- Add a few cm of straight tubing after the sensor with identical inner diameter.
- Consider the inlet conditions and sensor design-in at an early development stage.

# 4 Mechanical Fittings

## 4.1 SFM3xxx Fittings and Connectors

Table 2 below provides an overview of cone specifications, diameters, O-ring options and connector information:

| Part Number                                       | Cone<br>Standard                 | Diameter                     | O-Ring Diameter                               | Mating Connector   |  |  |  |
|---|----------------------------------|------------------------------|---|--|--|--|--|
| SFM3000, SFM3003,<br>SFM3013, SFM3019,<br>SFM3020 | ISO 5356                         | 22 mm                        | 20 mm or smaller                              | Molex DuraClik 502351-0400                                       |  |  |  |
| SFM3100, SFM3119                                  | 0, SFM3119 Inlet tube 16.6 mm ID |                              | NBR, 16.1 x 1.6 mm. 70<br>±5 Shore A          | <u>Molex Milli-Grid 87831-1041</u><br>( <u>THT)</u>              |  |  |  |
| SFM3200   | ISO 5356                         | 22 mm                        | 20 mm or smaller                              | JST B4B-ZR-SM4-TF  |  |  |  |
| FM3300 ISO 5356 22 mm (OD)<br>and 15 mm (ID)      |                                  | 22 mm (OD)<br>and 15 mm (ID) | Male-female mating of medical sockets / no O- | See AppNote <u>SFM-22</u> "Clip-<br>On Cap/Cable Evaluation Kit" |  |  |  |
| SFM3400   | ISO 5356                         | 15 mm                        | ring required                                 |  |  |  |  |

Table 2. SFM3xxx Series Fittings and Connector Specifications

More information can be found in the AppNote SFM-10 "Handling Instructions".

## 4.2 SFM4xxx Fittings and Connectors

Sensirion's SFM series with the SFM4100, SFM4200 and SFM4300 are designed for higher working pressures typically found on the gas mixing side compared to the SFM3xxx series typically found on the lower pressure and patient side. As such, the SFM4xxx series is either equipped with Legris, downmount/basemount or O-ring fittings. Please refer to the datasheet and CAD models of these components for detailed physical dimensions.



# 5 Electrical Integration

## 5.1 Pin Assignments

Our flow meter portfolio uses a variety of different pin configurations. Please refer to the datasheet for the specific layouts.

## 5.2 Digital Communication Interface

Digital communication between a microcontroller (= bus master) and the flow meter (= bus slave) runs via the standard I<sup>2</sup>C-interface for all our digital SFMs. The physical interface consists of two bus lines, a data line (SDA) and a clock line (SCL), which need to be connected via pull-up resistors to the bus voltage of the system. This will apply for all sensors other than the analog types (e.g. SFM3100, SFM3020).

For the detailed specifications of the I<sup>2</sup>C communication, please refer to the respective flow meter datasheet. While the measurement commands are the same for many variants, please note that the product number and flow rate scale factors differ per sensor variant. The required specification is noted in the sensor datasheet. Different sensors can be identified through their unique serial number. For detailed I2C protocol standards, please refer to "<u>NXP I2C-bus specification and user manual</u>".

To simplify testing and design-in of the SFM3xxx and SFM4xxx series, several helpful code snippets can be found on the useful resources link in section 6. The code snippets should only be used for the recommended part numbers and not used on different products as different chip generations may not be compatible.

| Part Number    | I2C HEX<br>Address | I2C Binary<br>Address | Recommended<br>Pull-Up Resistor | Supply<br>Voltage    |
|----------------|--------------------|-----------------------|---------------------------------|----------------------|
| <u>SFM3000</u> | 0x40               | 1000000               | 10kΩ                            | 5V                   |
| <u>SFM3003</u> | 0x28               | 0101000               | 3.3 kΩ                          | 3.05.5V <sup>1</sup> |
| <u>SFM3013</u> | 0x2F               | 0101111               | 3.3 kΩ                          | 3.05.5V <sup>1</sup> |
| <u>SFM3019</u> | 0x2E               | 0101110               | 3.3 kΩ                          | 3.05.5V <sup>1</sup> |
| <u>SFM3119</u> | 0x29               | 0101001               | 3.3 kΩ                          | 3.05.5V <sup>1</sup> |
| <u>SFM3200</u> | 0x40               | 1000000               | 10 kΩ                           | 5V                   |
| <u>SFM3300</u> | 0x40               | 1000000               | 10 kΩ                           | 5V                   |
| <u>SFM3400</u> | 0x40               | 1000000               | 10 kΩ                           | 5V                   |
| <u>SFM4100</u> | 0x40               | 1000000               | 10 kΩ                           | 5V                   |
| <u>SFM4200</u> | 0x40               | 1000000               | 10 kΩ                           | 5V                   |
| <u>SFM4300</u> | 0x2AD              | 0101010               | 3.3 kΩ                          | 3.05.5V <sup>1</sup> |

## 5.3 I2C Addresses and Pull-Up Resistors

Table 3. SFM3xxx Series Communication Specifications

## 5.4 Heater Overview for SFM3200-AW, SFM3300, SFM3400

In specific applications it may be necessary or recommended to take scenarios of condensation or even icing of the flow sensor into consideration. To allow the sensor to operate in such harsh environments, a special heater resistor has been placed on top of the PCB which is intended to be used as a heater element. Depending on the

<sup>&</sup>lt;sup>1</sup> The recommended supply voltage is 3.3V

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condition, the heater will prevent water from condensation and ice buildup inside the sensor flow body (e.g., in ambulances parking outside during winter for prolonged time). The heater resistor is specified to 51 Ohms and 0.5 W and the supplied voltage drop over the resistor should never exceed 5 V, respectively the current should not exceed 0.1 A for 100% heating power of 0.5 W. This heater option is already implemented on the microcontroller of the Nicolay connector-cap. More information on the in-cap microcontroller can be found on our AppNote <u>SFM-22</u> "Clip-On Cap/Cable Evaluation Kit".



# 6 Useful Resources

Sensirion's goal is to provide solution-oriented application notes and videos to improve integration of the SFM module series into end products. Below, please find an overview of application note links that may provide support at various points of the design process. Files can preferably be found at <u>https://www.sensirion.com/vents</u> or be requested via <u>info@sensirion.com</u>.

## 6.1 Datasheets and CAD Models

Please note that the inside details of the flow sensor have been simplified or omitted in the CAD drawings.

| Sensor                | Datasheet                                   | CAD Model   |  |  |  |  |  |
|-----------------------|---|---|--|--|--|--|--|
| SFM3000               | www.sensirion.com/file/datasheet_sfm3000    | www.sensirion.com/file/stepfile_sfm3000           |  |  |  |  |  |
| SFM3003               | Coming soon                                 | www.sensirion.com/file/stepfile sfm3003 3019 3020 |  |  |  |  |  |
| SFM3013               | Coming soon                                 | Coming soon                                       |  |  |  |  |  |
| SFM3019               | www.sensirion.com/file/datasheet_sfm3019    | www.sensirion.com/file/stepfile_sfm3003_3019_3020 |  |  |  |  |  |
| SFM3020               | www.sensirion.com/file/datasheet_sfm3020    | www.sensirion.com/file/stepfile_sfm3003_3019_3020 |  |  |  |  |  |
| SFM3100               | www.sensirion.com/file/datasheet_sfm3100    | www.sensirion.com/file/stepfile_sfm3100-vc        |  |  |  |  |  |
| SFM3119               | Coming soon                                 | www.sensirion.com/file/stepfile_sfm3119           |  |  |  |  |  |
| SFM3200-JST           | www.sensirion.com/file/datasheet_sfm3200    | www.sensirion.com/file/stepfile_sfm3200           |  |  |  |  |  |
| SFM3200-AW            | www.sensirion.com/file/datasheet_sfm3200-aw | www.sensirion.com/file/stepfile_sfm3200-aw        |  |  |  |  |  |
| SFM3300-D             | usus consision com/file/datesheet_sfm2200   | www.sensirion.com/file/stepfile_sfm3300-d         |  |  |  |  |  |
| SFM3300-AW            | www.sensirion.com/file/datasheet_sfm3300    | www.sensirion.com/file/stepfile_sfm3300-aw        |  |  |  |  |  |
| SFM3400-D             | www.sensirion.com/file/datasheet sfm3400    | www.sensirion.com/file/stepfile_sfm3400-d         |  |  |  |  |  |
| SFM3400-AW            | www.sensinon.com/nie/datasneet_sinis400     | www.sensirion.com/file/stepfile_sfm3400-aw        |  |  |  |  |  |
| SFM4100-Legris        |   | www.sensirion.com/file/stepfile_sfm4100_straight  |  |  |  |  |  |
| SFM4100-<br>Downmount | www.sensirion.com/file/datasheet_sfm4100    | www.sensirion.com/file/stepfile_sfm4100_downmount |  |  |  |  |  |
| SFM4200-<br>Downmount | www.sensirion.com/file/datasheet_sfm4200    | www.sensirion.com/file/stepfile_sfm4200           |  |  |  |  |  |
| SFM4300-Legris        |   |   |  |  |  |  |  |
| SFM4300-Push          | Coming soon                                 | www.sensirion.com/file/stepfile_sfm4300           |  |  |  |  |  |
| SFM4300-<br>Downmount |   |   |  |  |  |  |  |

Table 4. Links to datasheets and CAD models



## 6.2 Application Notes and Supporting Documents

| AppNotes and supporting documentation applicable to following sensors | SFM ID          | SFM3000 | SFM3003 | SFM3013 | SFM3019 | SFM3119 | SFM3200 | SFM3300 | SFM3400 | SFM4100 | SFM4200 | SFM4300 |
|---|-----------------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|
| I2C Functional Description <sup>2</sup>                               | <u>SFM-05</u>   | x       |         |         |         |         | x       | x       | x       |         |         |         |
| CRC Checksum <sup>3</sup>   | <u>SFM-04</u>   | x       |         |         |         |         | x       | x       | x       |         |         |         |
| Handling Instructions   | <u>SFM-10</u>   | x       | x       | x       | x       | x       | x       | x       | x       | x       | x       | x       |
| Reference and Flow Conversions  | <u>SFM-25</u>   | x       | x       | x       | x       | x       | x       | x       | x       | x       | x       | x       |
| Reference and Flow Conversions Calculator                             | <u>SFM-26</u>   | x       | x       | x       | x       | x       | x       | x       | x       | x       | x       | x       |
| Response Time Comparison  | <u>SFM-07</u> 4 | x       | x       | x       | x       |         |         |         |         |         |         |         |
| Temperature Effects   | <u>SFM-08</u> 4 | x       | x       | x       | x       |         |         |         |         |         |         |         |
| Effects of Humidity and Gas Mixtures                                  | <u>SFM-23</u> 4 |         |         |         |         |         | x       | x       | x       |         |         |         |
| High Humidity Applications  | <u>SFM-27</u>   |         |         |         |         |         | x       | x       | x       |         |         |         |
| Clip-On Cap/Cable Evaluation Kit                                      | <u>SFM-22</u>   |         |         |         |         |         | x       | x       | x       |         |         |         |
| Cleaning Methods (for -AW sensors)                                    | <u>SFM-21</u>   |         |         |         |         |         | x       | x       | x       |         |         |         |
| Sample Code SFM3000 <sup>5</sup>                                      | <u>GitHub</u>   | x       |         |         |         |         | s       | s       | s       |         | s       |         |
| Sample Code SFM3003, SFM3019 <sup>5</sup>                             | <u>GitHub</u>   |         | x       | s       | x       | s       |         |         |         |         |         | s       |
| Sample Code SFM4100 <sup>5</sup>                                      | <u>GitHub</u>   |         |         |         |         |         |         |         |         | x       |         |         |

Table 5. Links to application notes and supporting documents

## 6.3 Sensirion YouTube Videos

The following videos are provided via the YouTube channel: https://www.youtube.com/user/Sensirion

- 1. <u>SFM3xxx Inspiratory Flow Sensors for Respiratory Devices</u>
- 2. SFM3xxx Expiratory Flow Sensors for Respiratory Devices
- 3. SFM3xxx Proximal Flow Sensors for Respiratory Devices
- 4. SFM Flow Sensors for Gas Mixing Applications
- 5. Experts for Environmental and Flow Sensors

<sup>&</sup>lt;sup>2</sup> I2C details for other SFM sensors are directly included in the sensor's datasheet.

<sup>&</sup>lt;sup>3</sup> Other SFM sensors also support CRC checksum. Details are included directly in the sensor's datasheet.

<sup>&</sup>lt;sup>4</sup> Available on the www.sensirion.com/vent website after registration. Please refer to the AppNote section on the website.

<sup>&</sup>lt;sup>5</sup> x – sample code for this particular sensor, s – sample code for other sensor but similar to this type (see datasheet for details and differences)

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# 7 Regulatory Information

Sensirion's flow modules are globally integrated in medical and industrial products. Sensirion does not certify these components within the respective regulatory bodies but works with OEMs to ensure an efficient and timely submission and certification is possible. Flow modules are most often a small piece within a respiratory subsystem influenced by many other design aspects and used in a specific application outside of Sensirion's control. To ensure lowest possible risk when our customers perform testing for regulatory approval, Sensirion uses a careful material selection process to ensure compliance. Additionally, Sensirion supports customers with a more detailed confidential wetted materials list and toxicology reports for specific materials.

## 7.1 Material Selection Process

Sensirion has over 20 years of experience in the integration of medical and industrial products as well as being <u>ISO 9001</u> certified. Without a doubt, also our automotive certification ISO/TS 16949 (which is not applicable to these flow meters) helps us to continuously push our quality system within the company. Sometimes components qualified for the automotive industry will also be used in the medical products, such as for the sensing chip used in some of the most widely used flow meters. The same chip measuring the mass flow of the air intake to the engine can be found in many cars across all global markets.

This experience along with a year over year heavy investment in R&D allows us to create sophisticated and safe components that can be produced with a high degree of automation to make use of the economies of scale and offer attractive solutions. All materials in touch with the gas are deemed safe and harmless and our customers regularly pass global certifications using our flow sensor solutions. Typical norms being:

1. ISO10993-1:2018

Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process

2. USP Class VI

U.S. Pharmacopeia designates biocompatibility protocols for the plastics and polymers used in medical devices or surgical equipment, that may come in contact with human tissue. Class VI refers to one of the six designations for plastics providing guidelines for testing and certification of a material to be used within a medical device.

#### 7.2 Wetted Materials

Each Sensirion flow meter datasheet will provide a list of the wetted materials used in the module. The sections, in which this information can be found, are listed under "Materials" or "Media Compatibility".

Further documentation related to materials and applicable to some of the flow meters can be found in the download center. Quick links are listed below:

- 1. Reach and RoHS Declaration
- 2. Conflict Mineral Report for Modules
- 3. <u>Material Safety Datasheets and Sensors</u>
- 4. California Proposition 65

#### 7.3 Biocompatibility

To streamline OEMs as they proceed into their regulatory submission, Sensirion can provide toxicology reports of specific wetted materials listed in the SFM datasheets. This information will be used in the biocompatibility section of the product submission and reduces time to complete the documentation. Note that these documents are confidential and can only be made available under <u>NDA</u>.



# 8 Calibration, Lifetime and Re-Calibration

### 8.1 Calibration

Every single flow meter leaving Sensirion is uniquely factory calibrated as opposed to applying only a master calibration to batches of flow meters. As the sensor does not encompass any moving parts, has no wear or tear and the sensing chip is very robust, the sensor will keep its calibration over an extended period. Further on, the conservative specification provides sufficient margin to allow the sensor to operate well within the specification. The most likely reason for the sensor to ever operate outside the specification is when the sensing chip becomes contaminated (e.g. with oil droplets). In the medical space with clean and filtered media which has been prepared for patients to inhale this concern is extremely small.

### 8.2 Lifetime

Leaning on our automotive qualification of the SF05 sensing chip, mean-time-to-failure (MTTF) calculations for the SF05 mass flow sensor chip have been carried out. Results are based on a high-temperature-operating-life (HTOL) reliability test performed for a duration of 1863 hours at a temperature of 150°C while applying the maximum rated supply voltage of 5.5V on a total number of 231 devices.

At an elevated temperature of 80°C (176°F) the mean-time-to-failure of the sensing chip is in the range of 730 years. This impressively demonstrates the robustness of the SF05 sensing chip, the core of many of our mass flow sensors. It becomes more difficult and complex to apply above measurements on the entire flow sensor module as the other components and materials are often not able to withstand suitable elevated temperatures and models are less sophisticated and proven compared to the models for Silicon based CMOS chips.

## 8.3 Re-Calibration

Sensirion's flow sensors do not lose their calibration when operated with clean media and within specified conditions. As, such Sensirion does not offer re-calibration services.

Easy and straight forward tests to determine a possible sensor contamination are:

- Checking the zero point or flow-offset of the sensor under zero flow condition. If the sensor leaves its specified offset range, this could indicate a deposition on the sensor chip membrane
- Placing a second reference flow sensor in series with the sensor to be evaluated and comparing both readings can provide confirmation that the sensor is still operating within specifications.



## 9 Revision History

| Date     | Author                    | Version | Changes   |
|----------|---------------------------|---------|---|
| Jan 2021 | rfit, gkli,<br>Loeh, alan | 1.0     | First release with involvement of extended Medical Team |

## **10 Headquarters and Subsidiaries**

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