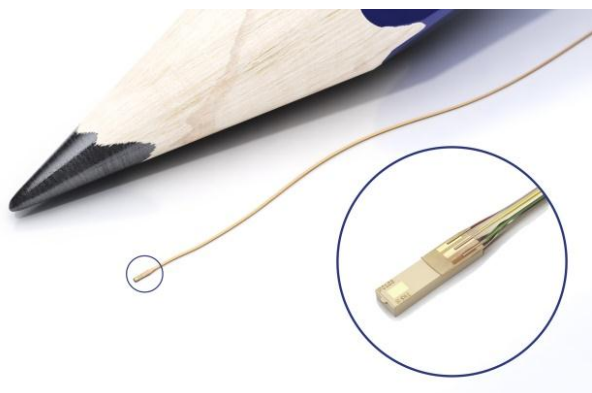


## 1-French Wire-Connected Pressure Sensor SMI-1A and SMI-1B Families



### 1. FEATURES

- Miniature sized sensor: 750µm × 220µm × 75µm
- Connected to 3-strand insulated cable
- Fits within 1-French catheter tubes
- Fully encapsulated for ease of integration
- Unamplified, non-temperature-compensated output
- Compliant with AAMI/ANSI BP22 performance standards
- For acute procedures (up to 24 hours)
- RoHS and REACH Compliant
- Biocompatible materials

### 2. DESCRIPTION

The IntraSense® series are absolute pressure sensors designed to fit into a 1-French hypo tube. The sensor comes pre-attached to cabling, simplifying the connection for the end user. The fully encapsulated electronics allow the device to be used without additional gel or encapsulant. This sensor compares pressure *in vivo* to an onboard vacuum cavity for reference to an absolute standard. It delivers accurate and stable pressure for acute procedures in the clinically useful range of -300mmHg to +500mmHg (460mmHg to 1260mmHg absolute) and from 10°C to 60°C. The output is stable in 37°C saline, and every part is tested in water. The device is available either as a sensor plus cable, or with an optional 4-pin PCB board attached to the proximal end.

For calibrated devices, please see our product pages at <https://www.si-micro.com/products/in-vivo-sensors.html> or contact [sales@si-micro.com](mailto:sales@si-micro.com)

The sensor has been qualified to AAMI/ANSI BP22 and ISO 60601 performance standards. The device is compatible with ETO sterilization.

IntraSense® is intended for single use.

### Typical Indications

|                       |                               |                     |  |
|-----------------------|-------------------------------|---------------------|--|
| Embolization          | Atrial Ablation               | Atherectomy         | Resuscitative Balloon Occlusion of the Aorta |
| Thermodilution        | Microvascular Obstruction     | Animal testing      | Endoscopy                                    |
| Intracranial Pressure | Fractional Flow Reserve (FFR) | Reproductive Health | Aortic Control                               |
| Compartment Syndrome  | Endourology                   | Glaucoma            | Cochlear Implant                             |

### 3. ABSOLUTE MAXIMUM RATINGS<sup>a,b</sup>

All parameters are specified for sensors in 37°C water, 2.4V supply and 20°C back-end electronics, unless otherwise noted. All values assume external resistors of 2740 Ohms to complete a full Wheatstone bridge and 300cm trifilar length. Clinical pressure is defined as having a zero point at 760mmHg above absolute vacuum. Values are for devices without gel or other added encapsulant.

| No. | Characteristic                                      | Symbol  | Medium       | Minimum | Maximum | Units         |
|-----|---|---|--------------|---------|---------|---------------|
| 1   | DC Excitation Voltage                               | $V_{SUPPLY}$  | N/A          | -0.3    | +TBD    | V             |
| 2   | Supply Current                                      | $I_{SUPPLY}$  | N/A          | TBD     | TBD     | μAmps         |
| 3   | Storage Temperature <sup>(c)</sup>                  | $T_{STG}$   | Air          | -25     | +70     | °C            |
| 4   | Processing Temperature <sup>(d)</sup>               | $T_{PROC}$  | Air          | TBD     | +150    | °C            |
| 5   | ESD Rating: Standard Device                         | $V_{ESD}$   | Air          | N/A     | TBD     | kV            |
| 6a  | ESD Rating: Light-Shielded Device                   | $V_{ESD}$   | Air          | N/A     | TBD     | kV            |
| 6b  | Operating Pressure <sup>(e)</sup>                   | $P_A$   | Water        | -600    | +500    | mmHg clinical |
| 7   | Proof Pressure <sup>(f)</sup>                       | $P_{PROOF}$   | Air or Water | -360    | +4000   | mmHg clinical |
| 8   | Burst Pressure <sup>(g)</sup>                       | $P_{BURST}$   | Air or Water | -760    | +4000   | mmHg clinical |
| 9a  | Service Life  | $t_{LIFE}$  | 41°C saline  | N/A     | +24     | Hours         |
| 9b  | Service Life  | $t_{LIFE}$  | 60°C saline  | N/A     | +5      | Hours         |
| 10  | Creepage Distance                                   | N/A   | Air          | TBD     | TBD     | microns       |
| 11  | Mechanical Shock Withstand                          | MSW   | Air          | TBD     | TBD     | g             |
| 12  | Trifilar Tensile Strength <sup>(h)</sup> , Distal   | TS  | Air          | 15      | N/A     | grams         |
| 13  | Trifilar Tensile Strength <sup>(i)</sup> , Proximal | TS  | Air          | 15      | N/A     | grams         |
| 14  | Bend Radius   | $R_{BEND}$  | Air          | 1.7     | N/A     | mm            |
| 15  | Compatible Media                                    | Air, water, saline, Ringer's Solution<br>Suitability for use <i>in vivo</i> must be confirmed by the end user |              |         |         |               |

**Notes:**

- a. Beyond these limits the device may suffer permanent damage
- b. Limits established during PV testing; tested per BP22 and/or ISO 60601 whenever applicable
- c. The minimum temperature the device can withstand in liquid is just above the freezing temperature of the liquid or -25°C, whichever is higher.
- d. The device may be exposed for up to one hour at the listed temperatures during assembly without degradation in performance.
- e. The minimum pressure the device can withstand in liquid is the vapor pressure (boiling point) of the liquid, which is a function of temperature
- f. Pressure excursions above this pressure could result in loss of performance upon returning to the operating pressure range
- g. The device could fail catastrophically above these pressures, generating fragments
- h. Force required to break wires from the sensor when pulled parallel to the long axis of the sensor
- i. Force required to break wires from the PCB when pulled parallel to the top surface of the PCB and in the direction of the wire length

#### 4. RECOMMENDED EXTERNAL COMPONENTS

Circuit descriptions are given in Section 7

| External bridge resistors for full Wheatstone bridge configuration |                                 |                    |      |        |      |        |
|--|---------------------------------|--------------------|------|--------|------|--------|
|  | Characteristic                  | Symbol             | Min  | Target | Max  | Units  |
| 1  | Quantity                        | Qty                | N/A  | 2      | N/A  | units  |
| 2  | Resistance                      | R <sub>PCB</sub>   | 1500 | 3300   | 6000 | Ohm    |
| 3  | TCR of External bridge resistor | TCR <sub>PCB</sub> | -25  | --     | 25   | ppm/°C |

#### 5. RECOMMENDED OPERATING CONDITIONS

The recommended operating conditions must not be exceeded in order to ensure proper functionality of the device. All parameters specified in the following sections refer to these recommended operating conditions in full Wheatstone bridge configurations, unless stated otherwise. Operating ranges assume use in water unless otherwise specified.

|   | Characteristic                  | Symbol   | Minimum | Typical | Maximum | Units |
|---|---------------------------------|--|---------|---------|---------|-------|
| 1 | Operating Temperature Range     | T <sub>OP</sub>  | +10     | -       | +60     | °C    |
| 2 | Operating Pressure Range        | p <sub>RANGE</sub>   | -300    | -       | +500    | mmHg  |
| 3 | Operating Bridge Supply Voltage | V <sub>SUPPLY</sub>  | 1.6     | 2.4     | TBD     | Volts |
| 4 | Compatible Media                | Air, water, saline, Ringer's Solution<br>Suitability for use <i>in vivo</i> must be confirmed by the end user. |         |         |         |       |

## 6. OPERATING CHARACTERISTICS

All parameters are specified for sensors in 37°C water, 2.4V supply and 20°C back-end electronics, unless otherwise noted. All values assume 300cm trifilar length and external resistors of 2740 Ohms to complete a full Wheatstone bridge. Clinical pressure is defined as 0 = 760mmHg above absolute vacuum. Values were established without gel or other added encapsulant.

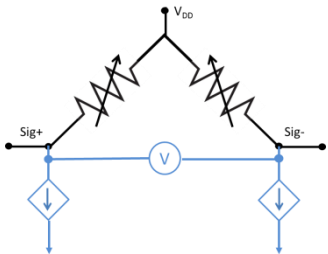
|     | Characteristic  | Symbol                   | Minimum | Typical | Maximum | Units     |
|-----|---|--------------------------|---------|---------|---------|-----------|
| 3   | Current Consumption                                   | $I_{\text{SUPPLY (AO)}}$ | TBD     | TBD     | TBD     | mA        |
| 4   | Bridge Resistance                                     | $R_B$                    | +2750   | +3450   | +4150   | Ohms      |
| 5   | Clinical Offset                                       | $V_{\text{OFFSET}}$      | TBD     | +9.4    | TBD     | mV/V      |
| 6   | Absolute Vacuum Offset                                | $V_{\text{ZERO}}$        | -35     | +5.5    | +35     | mV/V      |
| 7a  | Pressure Sensitivity, Standard                        | $S_V$                    | +3.0    | +6.5    | +11.0   | uV/V/mmHg |
| 7b  | Pressure Sensitivity, Light-Shielded                  | $S_V$                    | +3.0    | +5.5    | +10.0   | uV/V/mmHg |
| 8   | Nonlinearity  | NL                       | -1      | +0.07   | +1      | %FS       |
| 9   | Pressure Hysteresis <sup>(a)</sup>                    | $P_{\text{HYST}}$        | TBD     | ±0.2    | TBD     | %FS       |
| 10  | Temperature Hysteresis <sup>(b)</sup>                 | $T_{\text{HYST}}$        | TBD     | ±0.5    | TBD     | %FS       |
| 11  | Temperature Coefficient of Zero Offset <sup>(b)</sup> | TCZ                      | -45     | ± 7     | +45     | μV/V/°C   |
| 12  | Temperature Coefficient of Sensitivity <sup>(b)</sup> | TCS                      | -0.35   | -0.21   | -0.10   | %S/°C     |
| 13  | Temperature Coefficient of Resistance <sup>(b)</sup>  | TCR                      | +0.05   | +0.11   | +0.35   | %Rb/°C    |
| 14  | Output Drift, 4 hours <sup>(c)</sup>                  | $\Delta V_{\text{OUT}}$  | 0       | ±0.5    | TBD     | mmHg      |
| 15  | Output Drift, 24 hours <sup>(c)</sup>                 | $\Delta V_{\text{OUT}}$  | 0       | TBD     | TBD     | mmHg      |
| 16a | Light Sensitivity <sup>(d)</sup> , Standard           | $S_{\text{LIGHT}}$       | TBD     | TBD     | TBD     | mmHg      |
| 16b | Light Sensitivity <sup>(d)</sup> , Light-Shielded     | $S_{\text{LIGHT}}$       | 0       | 2       | TBD     | mmHg      |

### Notes:

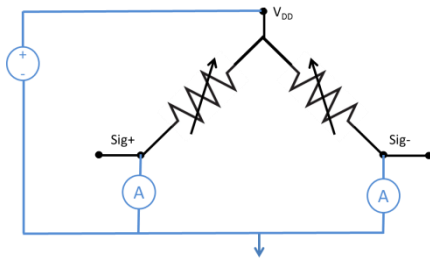
- Measured in 37°C water from -300 to +500 mmHg. %FS means expressed as a percentage of the total output across the pressure range measured.
- Measured at 0mmHg from 10°C to 60°C
- Measured in 37C water at +40mmHg and 2.4V bridge supply
- Tested per procedure in AAMI/ANSI BP22

**7. CIRCUIT DESCRIPTIONS**

**IntraSense Half-Bridge**

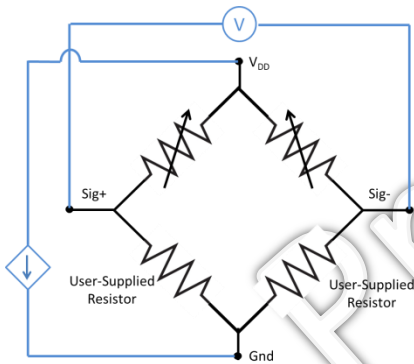


Constant Current Mode: Current level should be chosen for patient safety, signal-to-noise and lifetime requirements. (Blue portions of circuit supplied by customer.) Refer to ISO 60601 for patient risk current safety limits.



Constant Voltage Mode: Voltage level should be chosen for patient safety, signal-to-noise and lifetime requirements. Refer to ISO 60601 for patient risk current safety limits.

**Full-Bridge IntraSense® Connected to SMI Test Board**



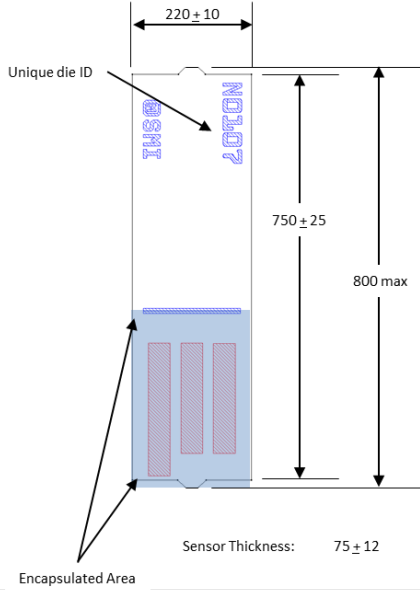
In this configuration, a constant voltage is maintained between Vdd and Gnd and the voltage drop from Sig+ to Sig- is proportional to pressure. Bridge can be driven in constant current or constant voltage mode.

|  | Pin | Connection | Purpose        |
|--|-----|------------|----------------|
|  | 1   | Sig-       | Signal Low     |
|  | 2   | Power      | Ground         |
|  | 3   | Power      | Supply Voltage |
|  | 4   | Sig+       | Signal High    |

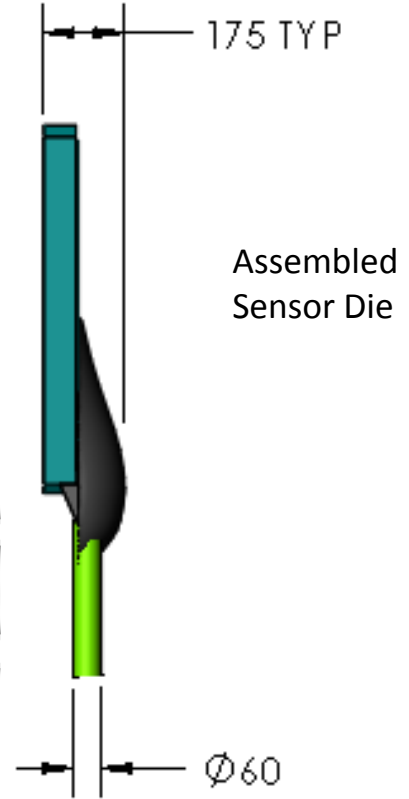
**8. DIAGRAMS AND DIMENSIONS**

**Distal Dimensions (microns)**

Sensor Die

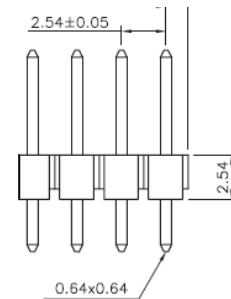
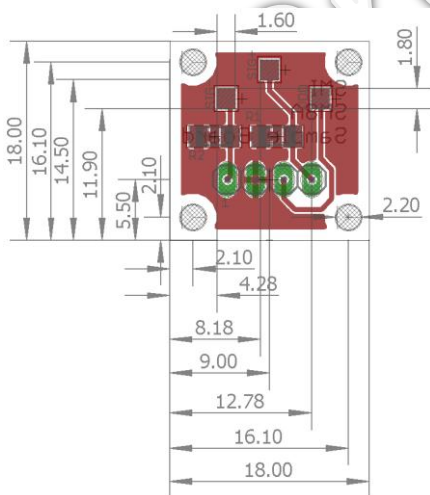


| Wire Description |                     |                     |
|------------------|---------------------|---------------------|
| Wire Color       | Wire Name           | Pad Function        |
| Green            | V <sub>DD</sub>     | V <sub>SUPPLY</sub> |
| Yellow           | R <sub>Center</sub> | Sig+                |
| Red              | R <sub>Edge</sub>   | Sig-                |



Assembled Sensor Die

**Proximal Dimensions (mm)**



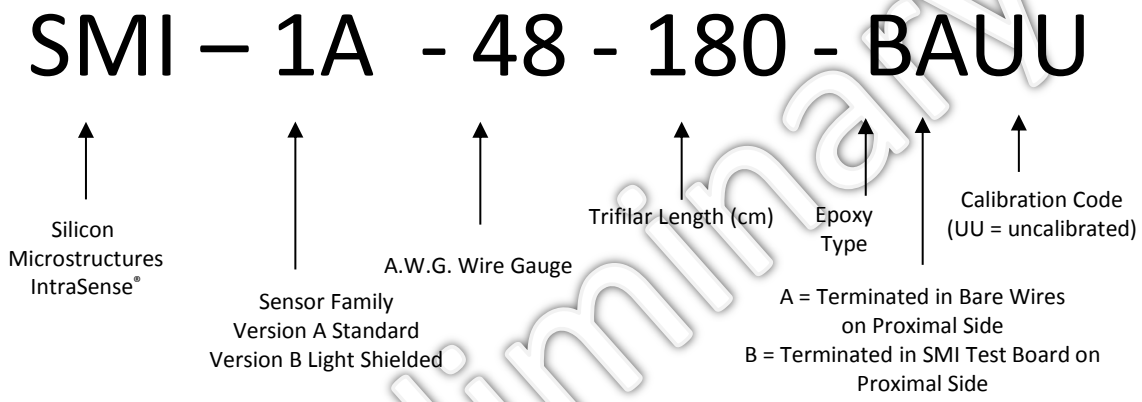
PCB thickness is 1.57mm. Straight pin, through-hole pin headers have 2.54mm pitch, 6mm mating length and 3mm termination post length.

**9. ORDERING INFORMATION: SMI-1A are Standard, SMI-1B are Light-Shielded**

| Order Code         | Sensor Type  | Proximal Termination | Other  |
|--------------------|--------------|----------------------|--|
| SMI-1A-48-XXX-BAUU | Standard     | 3 stripped wires     | XXX is the wire length in cm<br>Available wire lengths from 50 to 300 cm |
| SMI-1A-48-XXX-BBUU | Standard     | 4-Pin PCB            |  |
| SMI-1B-48-XXX-BAUU | Light Shield | 3 stripped wires     |  |
| SMI-1B-48-XXX-BBUU | Light Shield | 4-Pin PCB            |  |

For other calibration ranges, wire lengths or custom features, contact SMI Sales at (408) 577-0100 or [sales@si-micro.com](mailto:sales@si-micro.com)

**10. PART NUMBER LEGEND**



Parts are shipped on individual IEC 60264-2-1 K40 spools sealed in ESD bags.

**11. WARNINGS**

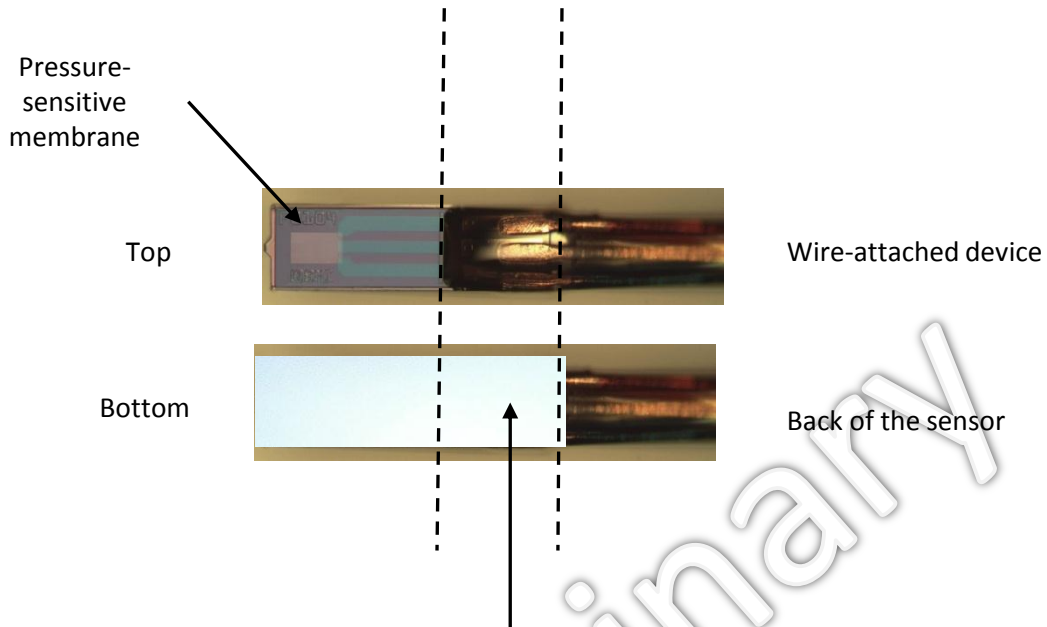
- This pressure transducer is not protected against defibrillation discharges. It must be used only with monitors labeled as having an isolated defibrillator-protected patient connection.
- Devices must be sterilized before use.
- Not for use in oxygen-rich environments.
- IntraSense® has not been qualified as an implantable or reusable device. It is designed for single use of duration ≤ 24 hours.

**12. QUALIFICATION STANDARDS**

REACH Compliant  
 RoHS Compliant  
 PFOS/PFOA Compliant  
 For qualification specifications, please contact Sales at [sales@si-micro.com](mailto:sales@si-micro.com)



**APPENDIX: GUIDE TO DIE MOUNTING**



Device should be mounted to a rigid, immobile surface. To avoid potentially cutting or damaging tissue, the corners of the IntraSense® sensor should be surrounded by a more rounded surface.

Apply die attach / adhesive on the backside of the die in this region to avoid unwanted stress on membrane. Pursil 80A from DSM or MED1511RTV from NuSil are both low-stress, biocompatible die-attach materials. Using hard die-attach materials could result in mechanical stresses being transmitted to the pressure-sensitive membrane, leading to loss of accuracy.

Sensors pre-mounted in carriers are currently in development at SMI. Please contact [Sales@si-micro.com](mailto:Sales@si-micro.com) for more information.



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