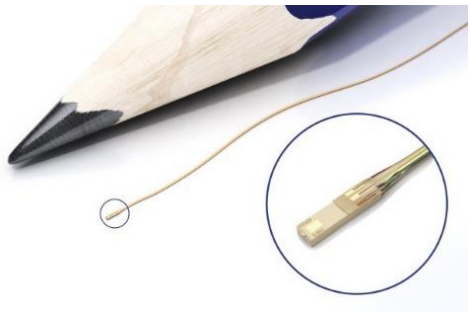
CALIBRATED INTRASENSE

1-FRENCH WIRE-CONNECTED PRESSURE SENSOR



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 easily integrated. 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 -300 mmHg to +500 mmHg (460 mmHg to 1260 mmHg absolute) and from 10°C to 60°C. The output is stable in 37°C liquid, and every part is calibrated and tested in DI water.

These devices are delivered with an attached PCB with a 5-pin right angle header offering fully temperature-compensated output, with both digital and amplified analog noise-filtered outputs.

Features

- Miniature sized sensor: 750 µm × 220 µm × 75 µm.
- Fits within 1-French catheter tubes.
- Typical drift <2 mmHg over the lifetime
- PCB with a 5-pin connector on the proximal end
- Fully temperature-compensated digital and amplified analog outputs.
- RoHS and REACH Compliant.
- Biocompatible Materials

Applications

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

NOTE: The device manufacturer is responsible for determining suitability for use in their specific equipment.

Absolute Maximum Ratings[a], [b]

All parameters are specified for sensors in 37°C DI water, 3.3 V or 5.0 V supply and 20°C back-end electronics, unless otherwise noted. Clinical pressure is defined as having a zero point at 760 mmHg above absolute vacuum. Values are for devices without gel or other added encapsulant.

Characteristic	Symbol	Medium	Min	Max	Units
DC Excitation Voltage	V_{SUPPLY}	N/A	−0.3	6.0	V
Storage Temperature[c]	T_{STG}	Air	−25	70	ºC
Processing Temperature[d]	T_{PROC}	Air	-	135	ºC
ESD Rating: Standard Device[e]	V_{ESD}	Air	N/A	2	kV
Operating Pressure[f]	P_A	Water	−400	600	mmHg clinical
Proof Pressure[g]	P_{PROOF}	Air or Water	−400	4000	mmHg clinical
Brust Pressure[h]	P_{BRUST}	Air or Water	0	4000	mmHg clinical
Service Life	T_{LIFE}	41 ºC Water	N/A	24	Hours
Bend Radius	R_{BEND}	Air	1.7	N/A	mm
Trifilar Tensile Strength[i], Distal	TS	Air	60	N/A	grams
Trifilar Tensile Strength[i], Proximal	TS	Air	60	N/A	grams

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) At the distal end of the device, wire insulation, and epoxy are rated up to 135°C and can withstand 135°C in the air for short duration operations (<10 min). This does not include the shipping method (spool) and shipment packaging.
(e) Human body model.
(f) The minimum pressure the device can withstand in liquid is the vapor pressure (boiling point) of the liquid, which is a function of temperature.
(g) Pressure excursions above this pressure could result in loss of performance upon returning to the operating pressure range.
(h) The device could fail catastrophically above these pressures, generating fragments.
(i) Force required to break wires from the sensor when pulled parallel to the long axis of the sensor.
(j) 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.

Recommended Operating Conditions

The recommended operating conditions must not be exceeded in order to ensure the proper functionality of the device. Operating ranges assume use in water unless otherwise specified.

Description	Symbol	Min	Typ	Max	Units
Supply Voltage	V_{DD}	4.75	5.0	5.25	V
		3.0	3.3	3.6	
Operating Pressure Range	P_{RANGE}	−300	-	500	mmHg clinical
Distal End Operating Temperature	T_{OP}	10	-	60	ºC
Proximal End (PCBA) Operating Temperature	T_{OP_PROX}	15	-	40	ºC
Compatible Media	Suitability for use in vivo must be confirmed by the end user				
Compatible Sterilization Method	Ethylene Oxide gas				

Operating Characteristics – Specification.

All parameters are specified for sensors in 37°C DI water, 3.3 V or 5.0 V supply and 20°C back-end electronics. All values assume 100 cm trifilar length. Clinical pressure is defined as 0 = 760 mmHg above absolute vacuum. Values were established for SMI-1B variant, without gel or other added encapsulant.

Characteristic		Symbol	Min	Typ	Max	Units
Low Level Output Voltage at Digital I/O, 3.3 V supply		$V_{IN,I2C,LO}$	-	-	0.3	V
Low Level Output Voltage at Digital I/O, 5.0 V supply			-	-	0.5	
High Level Output Voltage at Digital I/O, 3.3 V supply		$V_{IN,I2C,HI}$	2.7	-	-	
High Level Output Voltage at Digital I/O, 5.0 V supply			4.25	-	-	
Current Consumption		$I_{VDD(AO)}$	-	7.5	-	mA
Digital Pressure Output @ -300 mmHg		D_{OUT_MIN}	-	−26214	-	Counts
Digital Pressure Output @ 500 mmHg		D_{OUT_MAX}	-	26214	-	Counts
Digital Full-Scale Span		DFS	-	52428	-	Counts
Digital Pressure Resolution[a]		-	-	-	16	Bit
Digital Output Accuracy[b]		DACC	−8	±2	8	mmHg
Analog Pressure Output @ -300 mmHg		A_{OUT_MIN}	-	10	-	$\%V_{DD}$
Analog Pressure Output @ 500 mmHg		A_{OUT_MAX}	-	90	-	$\%V_{DD}$
Analog Full-Scale Span		AFS	-	80	-	$\%V_{DD}$
Analog Output Accuracy[b]		AACC	−12	-	12	mmHg
Light Sensitivity[c]	Standard (SMI-1A)	S_{LIGHT}	-	25	-	mmHg
	Light Shielded (SMI-1B)		-	10	-	mmHg

Notes:

(a) Analog output is converted from 16-bit digital output.
(b) This specification includes the combination of offset, sensitivity, linearity, and hysteresis errors over full ranges of pressure, temperature, and supply voltage.
(c) Determined per ANSI/AAMI BP22 testing.

Digital Output

This section is a reference for a possible coding method to achieve pressure and status for IntraSense part readings using I^2C. For more general information on how to interface using the I^2C protocol please refer to Application Note 40AN7000. IntraSense devices have been calibrated with a 3.3 V or 5.0 V supply voltage, which should also be used during readout.

- The default I^2C slave address is 0x6C HEX.
- The default ADC sample rate is 2 kHz.

For additional questions, please consult TE Connectivity.

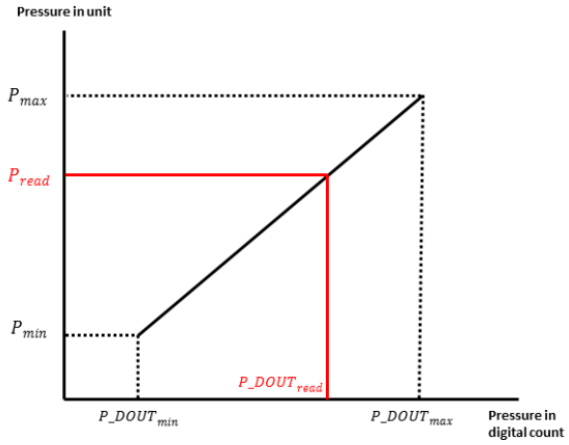
Sensor Transfer Function

$$P_{read} = P_{min} + \frac{P\_DOUT_{read} - P\_DOUT_{min}}{P\_DOUT_{max} - P\_DOUT_{min}}(P_{max} - P_{min})$$

P_{min} and P_{max} *are* **460 mmHg** and **1260 mmHg** absolute, respectively (−300 mmHg and +500 mmHg, clinical respectively).

P_DOUT_{min} and P_DOUT_{max} are **−26214** and **+26214**, respectively.

P_DOUT_{read} is the digital reading from the output and P_{read} is the converted pressure output based on P_DOUT_{read}.



For example, the P_{min} and P_{max} for the sensor are specified as −300 and +500 clinical mmHg. The D_{OUT_MIN} and D_{OUT_MAX} are −26214 and +26214.

Interface Timing Parameters – I²C Interface

Description	Symbol	Min	Typ	Max	Units
I²C Clock Frequency[1)]	f_{SCK}			400	KHz
I²C Clock low time[1)]	t_{LO}	1300			ns
I²C Clock high Time[1)]	t_{HI}	800			ns
I²C Setup time for repeated start condition hold time	t_{SH}	600			ns
I²C Data setup time	t_{SU}	100			ns
I²C Data hold time	t_{H}	0			ns
I²C repeated START setup time	t_{RSU}	600			ns
I²C stop condition setup time[1)]	t_{PSU}	600			ns
I²C rise time[1)]	t_{R}			300	ns
I²C fall time	t_{F}			300	ns
I²C bus free time between STOP and START conditions	t_{BUF}	600			ns
Low output voltage SDA pin	V_{LO}			10	%VDD
High output voltage SDA pin	V_{HI}	85			%VDD

Notes:

[1)] This specification includes the combination of offset, sensitivity, linearity, and hysteresis errors over full ranges of pressure, I²C.

Amplified Analog Output

For more general information on how to interface using the I²C protocol please refer to Application Note 40AN7000.
IntraSense devices have been calibrated with a 3.3 V or 5.0 V supply voltage, which should also be used during readout.
EXAMPLE 1:

If the supply voltage is 3.3 V and the readout is 1.75V, then the clinical pressure is calculated as follows:

Output at $P_{MIN} = (3.3\ V\ \times 0.1)P_{MIN};\ \ P_{MIN} = -300\ mmHg$
Output at $P_{MAX} = (3.3\ V\ \times 0.9)P_{MIN};\ \ P_{MIN} = 500\ mmHg$
Slope pf this line is $\frac{(500-(-300))}{((0.9\times3.3)-(0.1\times3.3))} = 303.03\ mmHg/V$. Intercept of this line is -400.
Pressure at $1.75\ V = (1.75\ \times 303.03) - 400 = 130 mmHg$

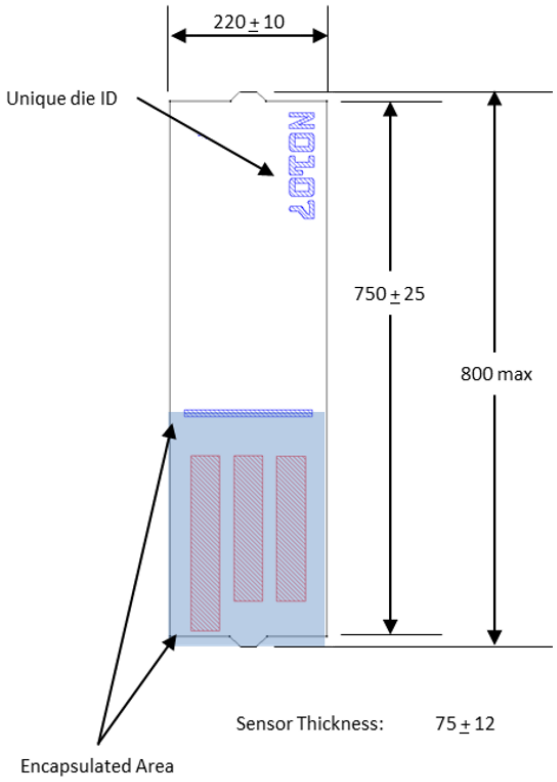
EXAMPLE 2:

If the supply voltage is 5.0 V and the readout is 0.8 V, then the clinical pressure is calculated as follows:

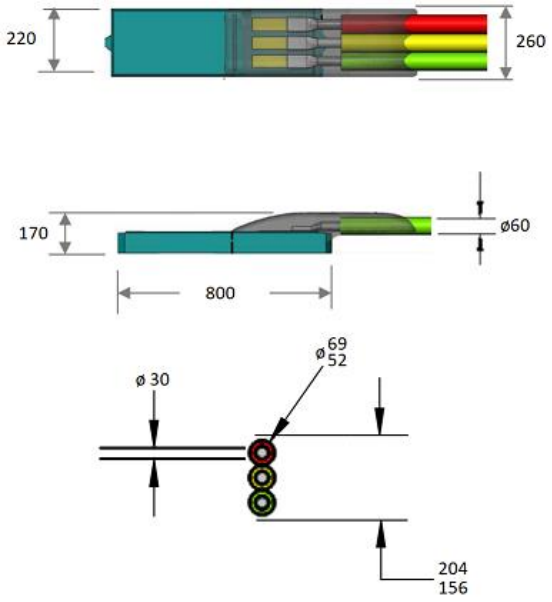
Output at $P_{MIN} = (5.0\ V\ \times 0.1)P_{MIN};\ \ P_{MIN} = -300\ mmHg$
Output at $P_{MAX} = (5.0\ V\ \times 0.9)P_{MIN};\ \ P_{MIN} = 500\ mmHg$
Slope pf this line is $\frac{(500-(-300))}{((0.9\times5.0)-(0.1\times5.0))} = 200\ mmHg/V$. Intercept of this line is -400.
Pressure at $0.8\ V = (0.8\ \times 200) - 400 = -240 mmHg$

Diagram and Dimensions

Sensor Die (microns)



Assembled Sensor Die (microns)

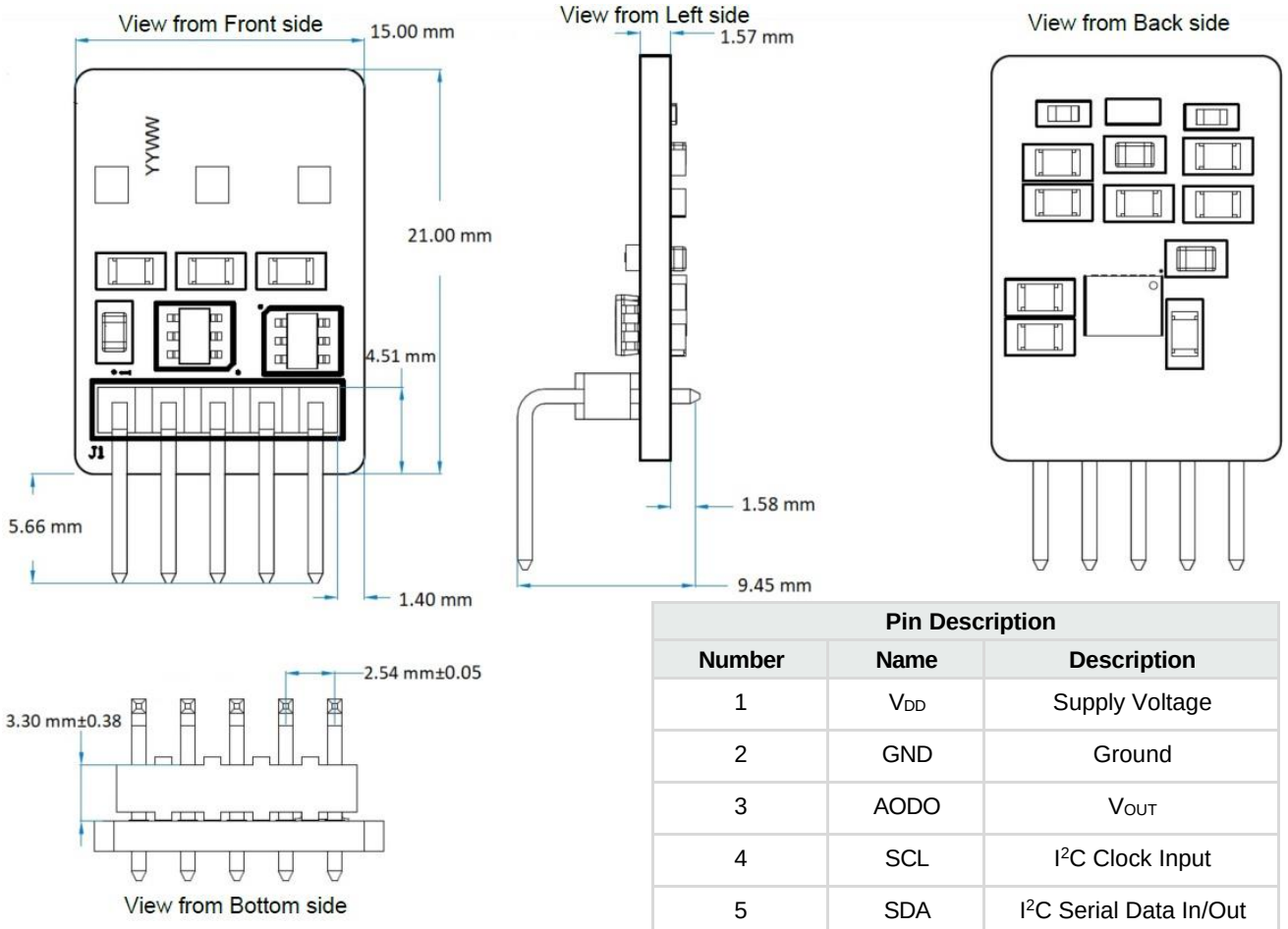


Wire Description		
Wire Color	**Soldered Pin**	**Signal**
Green	BP1	V_{SUPPLY}
Yellow	BP2	V_{SIG^+}
Red	BP3	V_{SIG-}

Typical wire length tolerance:

- ±1 cm typical up to 100 cm.
- ±1% typical of wire length cm for 100 cm or longer.

Proximal End Dimensions



Pin Description		
Number	**Name**	**Description**
1	V_{DD}	Supply Voltage
2	GND	Ground
3	AODO	V_{OUT}
4	SCL	I^2C Clock Input
5	SDA	I^2C Serial Data In/Out

Recommended External Components

External I^2C Pull-Up Resistors		
Characteristic	**Value**	**Unit**
Resistor x2	4.7	kΩ

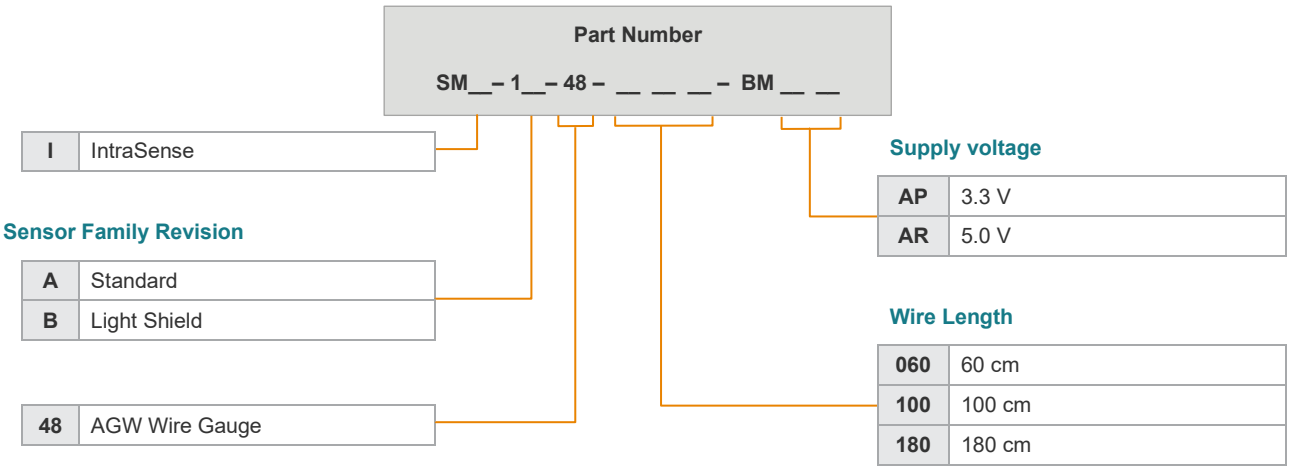
One Resistor is used for SCL and a second one for SDA external buses.

Ordering Information (Standard Configurations).

Part Number	Pressure Range (mmHg)	Compensated Temperature Range (°C)	Supply Voltage (V)	Design Feature
SMI-1A-48-060-BMAP	-300 to +500	10 to 60	3.3	60 cm Cable, standard sensor
SMI-1A-48-100-BMAP				100 cm Cable, standard sensor
SMI-1A-48-180-BMAP				180 cm Cable, standard sensor
SMI-1B-48-060-BMAP				60 cm Cable, light shielded sensor
SMI-1B-48-100-BMAP				100 cm Cable, light shielded sensor
SMI-1B-48-180-BMAP				180 cm Cable, light shielded sensor
SMI-1A-48-060-BMAR			5.0	60 cm Cable, standard sensor
SMI-1A-48-100-BMAR				100 cm Cable, standard sensor
SMI-1A-48-180-BMAR				180 cm Cable, standard sensor
SMI-1B-48-060-BMAR				60 cm Cable, light shielded sensor
SMI-1B-48-100-BMAR				100 cm Cable, light shielded sensor
SMI-1B-48-180-BMAR				180 cm Cable, light shielded sensor

Parts are shipped on individual spools sealed in ESD bags.
For other calibration ranges, wire lengths, or custom features, contact TE Sensor Sales.

Part number Key.



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 a duration <24 hours.

Qualification Standards

ISO 9001

ISO 14001

ISO/TS 16949

RoHS Compliant

REACH Compliant

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