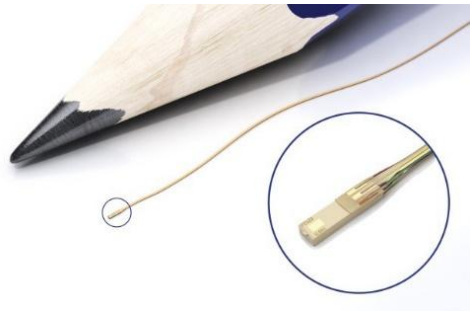


CALIBRATED INTRASENSE PRESSURE AND TEMPERATURE DIGITAL OUTPUT

1-FRENCH WIRE-CONNECTED PRESSURE SENSOR

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 4-pin vertical. connector on the proximal end
- Fully temperature-compensated digital output.
- RoHS and REACH Compliant.
- Biocompatible Materials

Possible Applications

- Embolization.
- Ureteroscope
- 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

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 pressure) and from 10 °C to 60 °C.

The Calibrated IntraSense Digital Output series is delivered with an attached PCB with a 4-pin vertical header offering fully temperature-compensated digital outputs. There are two different versions depending on accuracy needs:

- **Standard Version:**
  - Pressure Accuracy (after autozero):
    - ±3mmHg.
  - Temperature Accuracy:
    - ±1°C.
- **Lean Version:**
  - Pressure Accuracy (after autozero):
    - ±8mmHg.

NOTE: For specific details see operating characteristics tables

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

Absolute Maximum Ratings[a]

All parameters are specified for sensors at 37 °C, 5.0 V supply and the distal end at 25 °C. All values assume 100 cm trifilar length. Clinical pressure is defined as 0 = 760 mmHg above absolute vacuum. Values were established for the light shielded variant, without gel or other added encapsulant.

Characteristic	Symbol	Min	Max	Units
DC Excitation Voltage	V_{SUPPLY}	−0.3	6.0	V
Storage Temperature[b]	T_{STG}	−25	70	ºC
Processing Temperature[c]	T_{PROC}	-	135	ºC
ESD Rating: Standard Device[d]	V_{ESD}	-	2	kV
Maximum Operating Pressure	P_A	−400	600	mmHg clinical
Proof Pressure[e]	P_{PROOF}	−400	4000	mmHg clinical
Brust Pressure[f]	P_{BRUST}	0	4000	mmHg clinical
Service Life @ 41°C	T_{LIFE}	-	24	Hours
Bend Radius	R_{BEND}	1.7	-	mm
Trifilar Tensile Strength[h], Distal	TS_{DIST}	55	-	grams
Trifilar Tensile Strength[i], Proximal	TS_{PROX}	60	-	grams

Notes:

(a) Beyond these limits, the device may suffer permanent damage.
(b) The minimum temperature the device can withstand in liquid is just above the freezing temperature of the liquid or -25 °C, whichever is higher.
(c) 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.
(d) Human body model.
(e) Pressure excursions above this pressure could result in loss of performance upon returning to the operating pressure range.
(f) The device could fail catastrophically above these pressures, generating fragments.
(g) Tested in DI water.
(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.

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
Operating Pressure Range		P_{RANGE}	−300	-	500	mmHg clinical
Operating Temperature Ranges	Distal End	T_{OP_DIST}	10	-	60	ºC
	Proximal End	T_{OP_PROX}	15	-	40	ºC
Compatible Media		Suitability for use in vivo must be confirmed by the end user.				
Compatible Sterilization Method[a]		Ethylene Oxide gas (ETO) must be confirmed by the end user.				

(a) Other sterilization methods might be utilized but must be confirmed by the end user.

Operating Characteristics – Specification.

All parameters are specified for sensors at 37 °C, 5.0 V supply and the distal end at 25 °C. All values assume 100 cm trifilar length. Clinical pressure is defined as 0 = 760 mmHg above absolute vacuum. Values were established for the light shielded variant, without gel or other added encapsulant.

Characteristic			Symbol	Min	Typ	Max	Units
Low Level Output Voltage at Digital I/O, 5.0 V supply			$V_{IN,I2C,LO}$	-	-	0.5	V
High Level Output Voltage at Digital I/O, 5.0 V supply			$V_{IN,I2C,HI}$	4.25	-	-	
Current Consumption			$I_{VDD(AO)}$	-	4.5	-	mA
Digital Pressure Output at -300 mmHg			D_{OUT_MIN}	-	−26214	-	Counts
Digital Pressure Output at 500 mmHg			D_{OUT_MAX}	-	26214	-	Counts
Digital Full-Scale Span			DFS	-	52428	-	Counts
Digital Pressure Resolution[a]			-	-	-	16	Bit
Light Sensitivity[b]		Light Shielded	S_{LIGHT}	-	10	-	mmHg
Lean Version	Pressure Accuracy[c,d]	Over the entire temperature and pressure operating ranges	P_{ACCY}	-	±8	-	mmHg
	Temperature Accuracy		T_{ACCY}	-	±5	-	ºC
Standard Version	Pressure Accuracy[c,d]	Distal End at 37 ºC and between 700 and 860 mmHg.	P_{ACCY}	-	±3	-	mmHg
		Over remaining temperature and pressure operating ranges.		-	±6	-	
	Temperature Accuracy	Distal End at 37 ºC and between 700 and 860 mmHg.	T_{ACCY}	-	±1	-	ºC
		Over remaining temperature and pressure operating ranges.		-	±2	-	

Notes:

(a) Output is scaled to 16-bit.
(b) Tested per procedure in AAMI/ANSI BP22
(c) This specification includes the combination of offset, sensitivity, linearity, and hysteresis errors over full ranges of pressure, temperature, and supply voltage.
(d) Pressure accuracy after AUTOZERO. If autozero is not performed, the readings may have an offset error. Autozero can be performed by the user in user software by storing the offset reading at a reference pressure and subtracting this stored reference offset value from actual readings when in use at system level. Autozero can be used to compensate offset shifts that can be a result of the assembly process, and it is not recommended with parts showing extremely large shifts due to digital output ASIC.

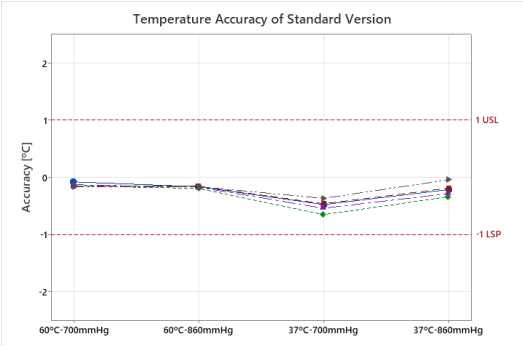


Figure 2. Temperature Accuracy of Standard Version

Autozero

Calibrated IntraSense is an absolute pressure sensor, and it is recommended to perform an autozero by choosing a reference value. Figure 3.a. shows the raw accuracy values from the Calibrated IntraSense sensor at different testing points under controlled conditions before autozero. On Figure 3.b., the fifth test point acts as the ZERO reference, then the autozero'ed accuracy values of the other testing points are calculated by subtracting the zero-reference reading at **37 °C and 860 mmHg** from each measurement.

Example 1:

Absolute accuracy **before autozero** at 10 ℃ @ 1260 $mmHg$: $Accy_{10℃@1260mmHg} = 5.599$ mmHg
Zero reference: Absolute accuracy before autozero at 37 ℃ @ 860 $mmHg$: $Accy_{37℃@860mmHg} = 5.498$ mmHg
Relative accuracy **after autozero** at 10℃@1260m: $Accy_{10℃@1260mmHg} - Accy_{37℃@860mmHg} = 5.599\ mmHg - 5.498\ mmHg = 0.101\ mmHg$

Example 2:

Absolute accuracy **before autozero** at 37 ℃ @ 460 $mmHg$: $Accy_{37℃@460mmHg} = 5.656$ mmHg
Zero reference: Relative accuracy at 37 ℃ @ 860 $mmHg$: $Accy_{37℃@860mmHg} = 5.498$ mmHg
Relative accuracy **after autozero** at 37℃@460$mmHg$: $Accy_{37℃@460mmHg} - Accy_{37℃@860mmHg} = 5.656\ mmHg - 5.498\ mmHg = 0.158\ mmHg$

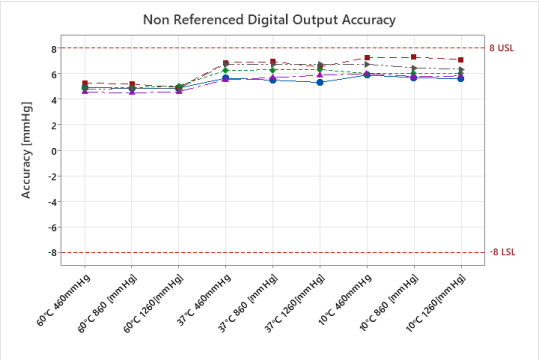


Figure 3.a. Raw accuracy values **before autozero.**

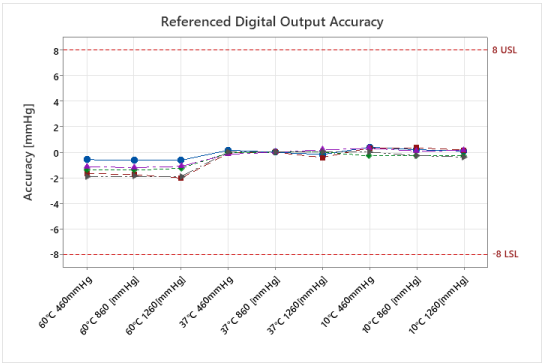


Figure 3.b. Accuracy values **After autozero** (zero referenced at 37℃ and 460$mmHg$).

Digital Output

This section is a reference for a possible coding method to achieve pressure and status for IntraSense part readings using I²C protocol. IntraSense Digital Output devices have been calibrated with a 5.0 V supply voltage, which should also be used during readout.

- The default I²C slave address is 0x6C HEX.
- The default ADC sample rate is 2 kHz.

Temperature Transfer Function

$$T_{read} = (T_{out} \times 0.0051562) + 42.5$$

Where:

T_{out} Is the digital temperature reading from the output in counts.

T_{read} is the converted temperature output based on T_{out} in ℃.

Pressure Transfer Function

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

Where:

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 in counts.

P_{read} is the converted pressure output based on P_DOUT_{read} in mmHg.

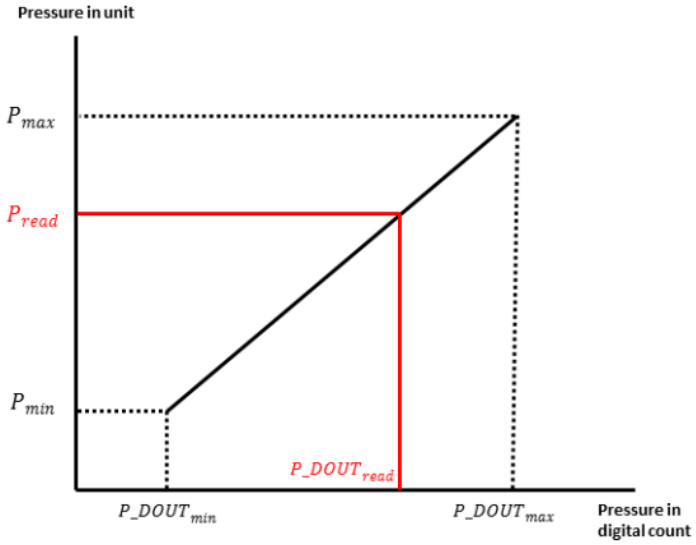


Figure 1. Sensor's calibration curve

Interface Timing Parameters – I²C Interface

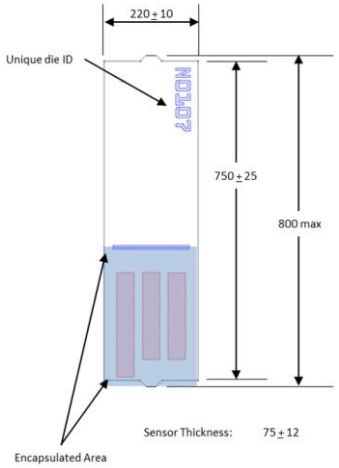
Description	Symbol	Min	Typ	Max	Units
I²C Clock Frequency[1)]	f_{SCK}			400	KHz
I²C Clock low time[1)]	t_{LO}	1300			ns
I²C Clock high Time[1)]	t_{HI}	800			ns
I²C Setup time for repeated start condition hold time	t_{SH}	600			ns
I²C Data setup time	t_{SU}	100			ns
I²C Data hold time	t_{H}	0			ns
I²C 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:

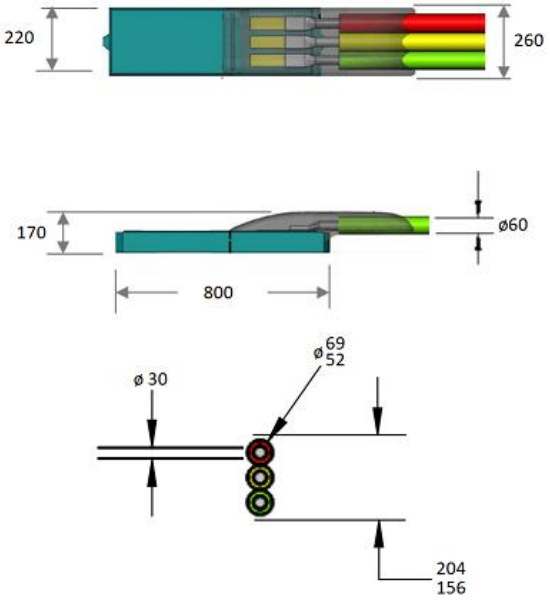
[1)] For more general information on how to interface using the I2C protocol please refer to Application Note 40AN7000.

Diagram and Dimensions

Sensor Die (microns)



Assembled Sensor Die – Distal End (microns)

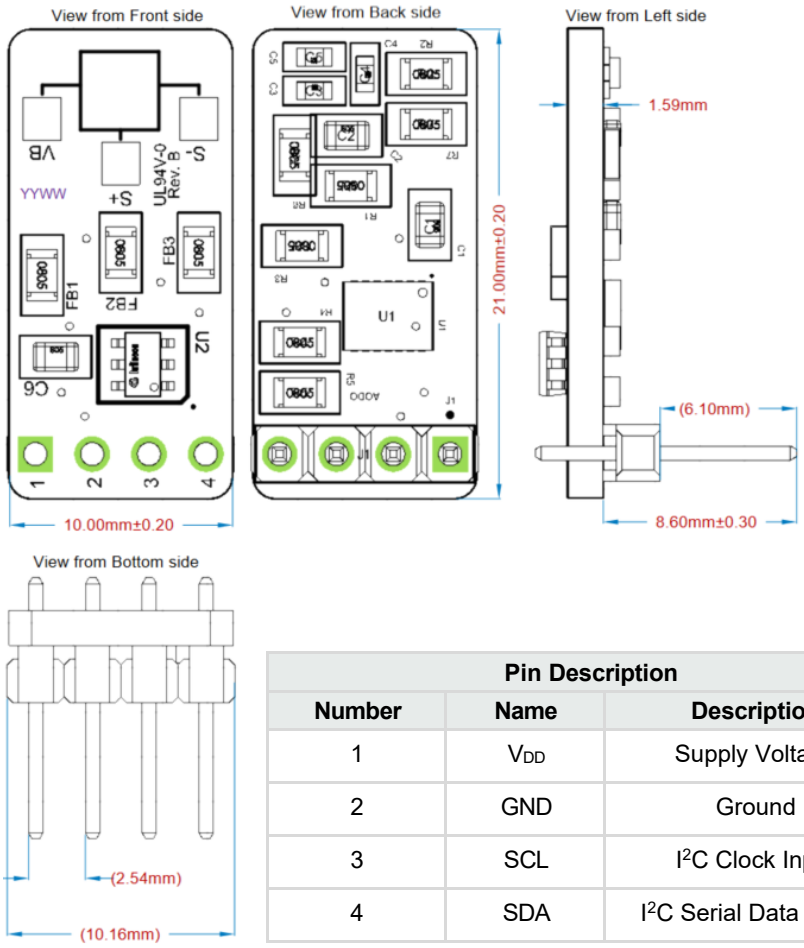


Wire Description		
Wire Color	**Soldered Pin**	**Signal**
Green	VB	V_{SUPPLY}
Yellow	S+	V_{SIG}^{+}
Red	S-	V_{SIG}^{-}

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	SCL	I^2C Clock Input
4	SDA	I^2C Serial Data In/Out

Recommended External Components

External I^2C Pull-Up Resistors		
Characteristic	**Value**	**Unit**
2 x Resistor[(a)]	4.7	kΩ

(a) One Resistor is used for SCL and a second one for SDA external bus lines.

Ordering Information (Standard Configurations).

Part Number	Supply Voltage (V)	Wire Length[(a)] (cm)	Version	Design Feature
20033135-00	5	100	LEAN	Cal IntraSense 100 cm, 5.0 V Digital Output
20033136-00		180		Cal IntraSense 180 cm, 5.0 V Digital Output
20033137-00		100	STD	Cal IntraSense 100cm, 5.0V, typ to 1 °C temp accy
20033138-00		180		Cal IntraSense 180 cm, 5.0 V, typ to 1°C temp accuracy

Parts are shipped on individual ESD tubes.

(a) Wire lengths might observe a minimum length of 96cm and 175cm of effective wire for the version of 100cm and 180cm respectively.

For other calibration ranges, wire lengths, or custom features, contact TE Sensor Sales.

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.
- Customer mounting, handling and pressure media can affect performance and customer verification in the customer's final package and pressure media is strongly recommended. TE Connectivity is not liable for change in performance or damage due to customer mounting, packaging, handling and effects of pressure media.

Qualification Standards

ISO 9001

ISO 14001

ISO/TS 16949

RoHS Compliant

REACH Compliant