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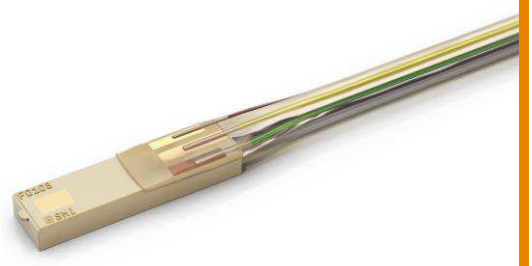
IntraSense Invasive Pressure Sensor

1-French disposable catheter tip sensor



Description

The IntraSense series absolute pressure sensors are 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, with typical drifts of <2mmHg absolute maximum per 24 hours. The device is available either as a sensor plus cable, or with an optional 4-pin PCB board attached to the proximal end.

A calibrated version is currently in development, please contact us for more details at customercare.mlpt@te.com The device is compatible with ETO sterilization and is intended for single use. The device is not sterile as shipped.

Features

- Miniature sized sensor: 750µm × 220µm × 75µm
- Pressure type: absolute
- Pressure range: 460mmHg to 1260mmHg
- Connected to 3-strand insulated cable
- Fits within 1-French catheter tubes
- Fully encapsulated for ease of integration
- Millivolt output
- Compliant with applicable AAMI/ANSI BP22 performance standards
- For acute procedures (up to 24 hours)
- RoHS and REACH Compliant
- Biocompatible materials
- Optional Lightshield

Applications

- Embolization
- Hemodynamics / Thermodilution
- Intracranial Pressure
- Compartment Syndrome
- Atrial Ablation
- Microvascular Obstruction
- Fractional Flow Reserve (FFR)
- Endourology
- Atherectomy
- Animal testing
- Reproductive Health
- Glaucoma
- Hemorrhage control
- Endoscopy
- Aortic Control
- Cochlear Implant

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1. Absolute Maximum Ratings[a, b]

All parameters are specified for sensors in 37°C DI water, 2.4V supply and 20°C back-end (proximal) 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. Dry clean air defined as atmospheric conditions at sea level with 30-60% RH.

Characteristic	Symbol	Medium	Min	Max	Units
DC Excitation Voltage	V_{SUPPLY}	N/A	-0.2	+3	Volts
Storage Temperature[c]	T_{STG}	Air	-25	+70	°C
Processing Temperature[d]	T_{PROC}	Air	-	+135	°C
ESD Rating[e]	V_{ESD}	Air	-	2	kV
Proof Pressure[f, g]	P_{PROOF}	Air or Water	-400	+4000	mmHg clinical
Burst Pressure[h]	P_{BURST}	Air or Water	-	+4000	mmHg clinical
Service Life	t_{LIFE41}	41°C water	-	+24	Hours
Mechanical Shock Withstand[i]	MSW	Air	-	300	g
Tensile Strength[j], Distal	TS_D	Air	50	-	grams
Trifilar Tensile Strength[k], Proximal	TS_P	Air	50	-	grams
Bend Radius	R_{BEND}	Air	1.7	-	mm
Compatible Media[l]	Ethylene Oxide (ETO), Air, water, saline solution Suitability for use in vivo 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 distal end of the device may be exposed for up to one hour at the listed temperatures during assembly without degradation in performance.
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) Shock withstand: tested in proprietary secondary catheter tip. 300G peak half sinewave in < 1.5 ms
j) Force required to break wires from the sensor when pulled parallel to the long axis of the sensor
k) 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
l) Operation of device verified in clean dry air and de-ionized (DI) water after 2x ETO sterilization. Functionality in saline solution verified in assembled catheters in concept validation phase (refer to warnings section 9)

2. Recommended External Components

Circuit descriptions are given in Section 5.

External bridge resistors for full Wheatstone bridge configuration					
Characteristic	**Symbol**	**Min**	**Target**	**Max**	**Units**
Quantity	Qty	-	2	-	units
Resistance	R_{PCB}	-	2500 to 2740	-	Ohm
TCR of External bridge resistor [a]	TCR_{PCB}	-25	± 2	25	ppm/°C

Notes:

a) Mismatched TCR between the two external resistors will result in additional TC offset error when ambient temperature of the proximal end electronics is varying. Recommend TCR to be less than ± 2 ppm/°C, which will result in a maximum additional TC error of 0.2 mmHg/°C for proximal end electronics temperature variation

3. Recommended Operating Conditions

The recommended operating conditions must not be exceeded 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 distal end use in water unless otherwise specified.

Distal End Characteristic	Symbol	Min	Typical	Max	Units
Operating Temperature Range	T_{OP}	+10	-	+60	°C
Operating Pressure Range	P_{RANGE}	-300	-	+500	mmHg
Operating Bridge Supply Voltage	V_{SUPPLY}	-	2.4	2.7	Volts

Proximal End Characteristic	Symbol	Min	Typical	Max	Units
Operating Temperature Range	T_{OP_prox}	+10	-	+45	°C
Compatible Media	Dry clean air [a]				

Notes:

a) Dry clean air defined as atmospheric conditions at sea level with 30-60% RH

4. Operating Characteristics

All parameters are specified for sensors in 37°C DI water, 2.4V supply and 20°C back-end (proximal) 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 for SMI-1B variant without gel or other added encapsulant, unless noted otherwise.

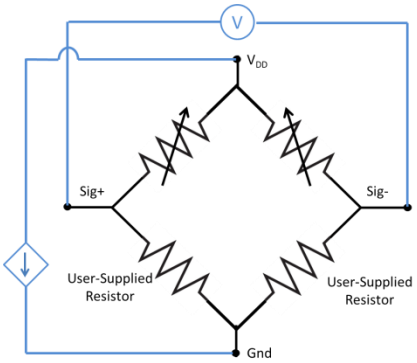
Characteristic	Symbol	Min	Typical	Max	Units
Current Consumption	I_{SUPPLY}		0.7		mA
Bridge Resistance	R_B	2750	3440	4150	Ohms
Clinical Offset	V_{OFFSET}		+12		mV/V
Absolute Vacuum Offset[a]	V_{ZERO}	-35	+8.5	+35	mV/V
Pressure Sensitivity, SMI-1A	S_V	+3.0	+5.5	+11.0	µV/V/mmHg
Pressure Sensitivity, SMI-1B	S_V	+3.0	+5	+10.0	µV/V/mmHg
Nonlinearity – terminal based	NL	-1	± 0.07	+1	%FS
Pressure Hysteresis	P_{HYST}	-	± 0.05	-	%FS
Temperature Hysteresis[b]	T_{HYST}	-	± 0.1	-	%FS
Temperature Coefficient of Zero Offset[b]	TCZ	-45	- 7	+45	µV/V/°C
Temperature Coefficient of Sensitivity[b]	TCS	-0.35	-0.18	-0.10	$\%S_V$/°C
Temperature Coefficient of Resistance[b]	TCR	+0.05	+0.11	+0.35	$\%R_b$/°C
Output Drift at 41°C, 24 hours[c]	$\lvert\Delta V_{OUT}\rvert$	0	1.4	4.5	mmHg
Light Sensitivity[d], SMI-1A Standard	S_{LIGHT}	-	25	-	mmHg
Light Sensitivity[d], SMI-1B Light-Shielded	S_{LIGHT}	-	10	-	mmHg
Frequency Response [e]	BW	-	1130	-	Hz

Notes:

a) Measured in 37°C DI water from -300 to +500 mmHg %FS means expressed as a percentage of the total output across the pressure range measured. Offset extrapolated with BSFL method to -760 mmHg (vacuum) from the data at the pressure test points
b) Measured from 37°C to 60°C
c) Measured in DI water at 0mmHg and 2.4V bridge supply. Calculated as |max deviation| from initial measurement. Based on qualification data from multiple lots (total of > 30 units) and established as mean+6sigma. Customer packaging and handling can affect performance and customer verification in customer's final package is recommended.
d) Tested per procedure in AAMI/ANSI BP22
e) Tested per AAMI BP22 specification and AAMI TIR9:1992 procedure

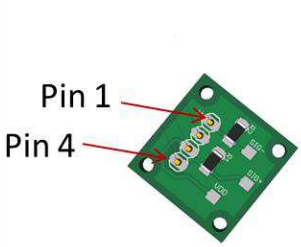
5. PCB Circuit Description

Full-Bridge Intrasense Absolute Pressure Sensor Connected to 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.

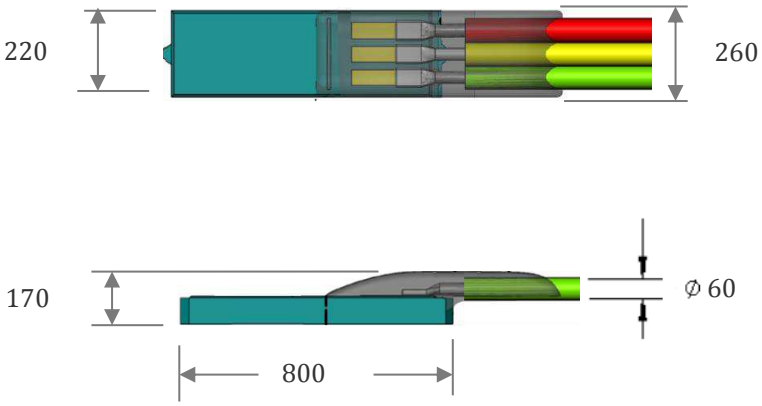
Contact factory for ISO 60601 Risk Current compliant solutions.



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

6. Diagrams and Dimensions

Distal Dimensions - typical (microns)

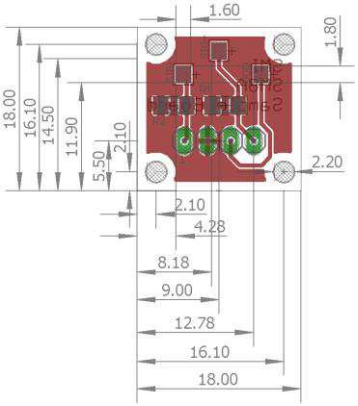


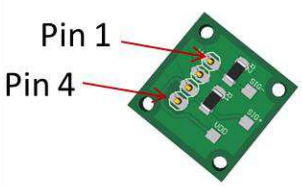
Wire Description		
Wire Color	**Wire Name**	**Pad Function**
Green	V_{DD}	V_{SUPPLY}
Yellow	R_{Center}	Sig+
Red	R_{Edge}	Sig-

Typical wire length tolerance:

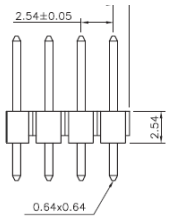
- ± 2 cm typical up to 100 cm
- ± 2% typical of wire length cm for 100 cm or longer

Proximal Dimensions - typical (mm)





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



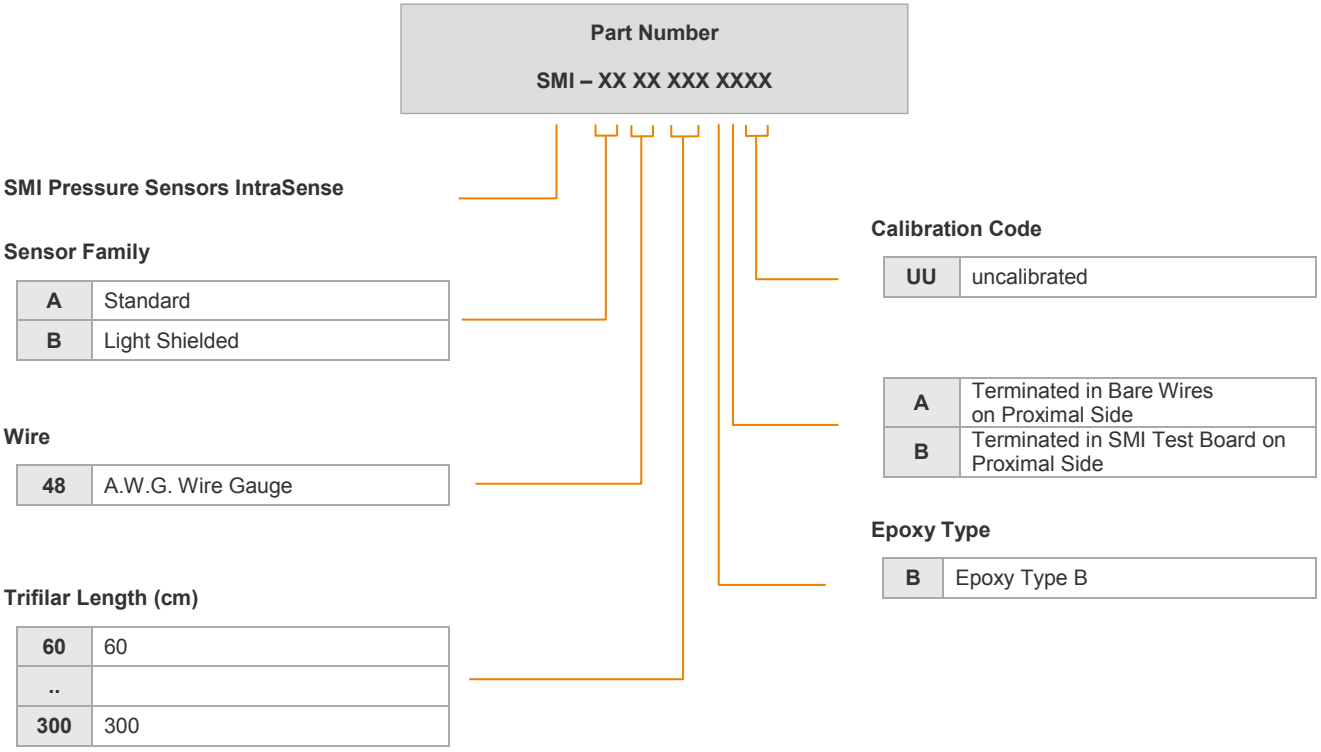
PCB thickness is 1.57mm. Straight pin, through-hole pin headers have 2.54mm pitch, 6mm mating length and 3mm termination post length.

7. Ordering Information (Standard Configurations)

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 Available wire lengths from 60 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	

8. Part Numbering Key

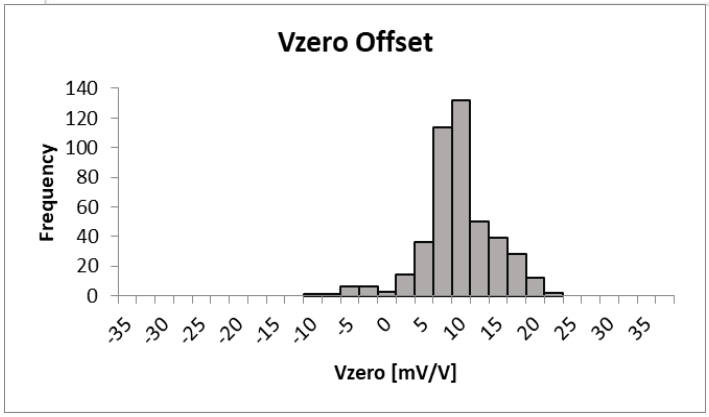


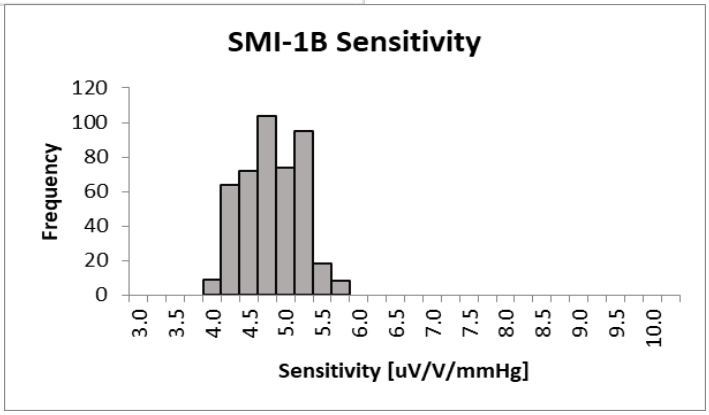
9. Warnings

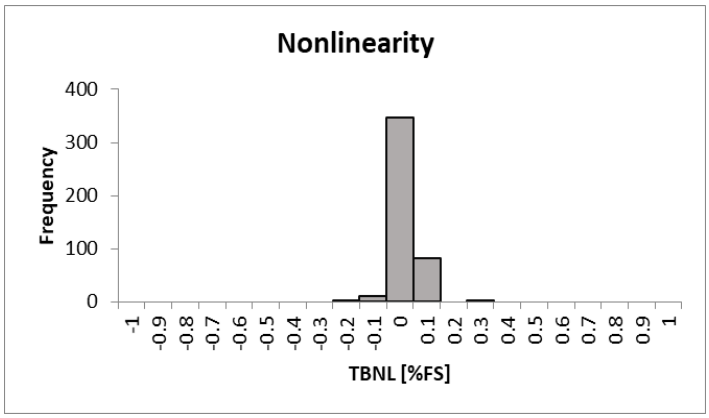
- This pressure transducer is not protected against defibrillation discharges. It must be used only with monitors labeled as having an isolated defibrillator-protected patient connection.
- Devices must be sterilized before use.
- Not for use in oxygen-rich environments.
- IntraSense absolute pressure sensor has not been qualified as an implantable or reusable device. It is designed for single use of duration ≤24 hours at 37°C
- Customer mounting, handling and pressure media can affect performance and customer verification in customer's final package and pressure media is recommended. TE Connectivity is not liable for change in performance or damage due to customer mounting, packaging, handling and effects of pressure media.

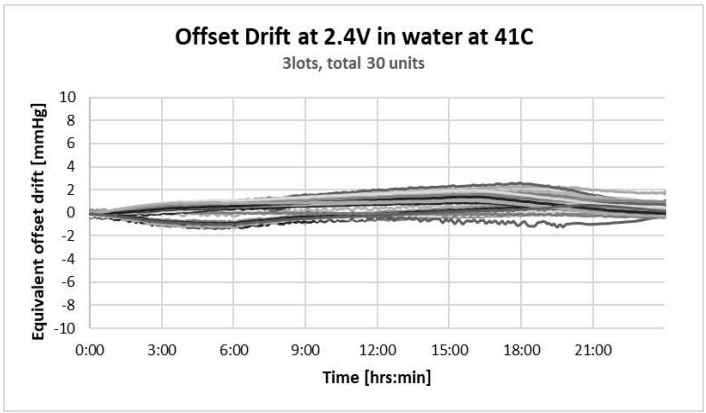
10. Typical Characteristics

All parameters are specified for sensors in 37°C DI water, 2.4V supply and 20°C back-end (proximal) 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 for SMI-1B variant without gel or other added encapsulant, unless noted otherwise.





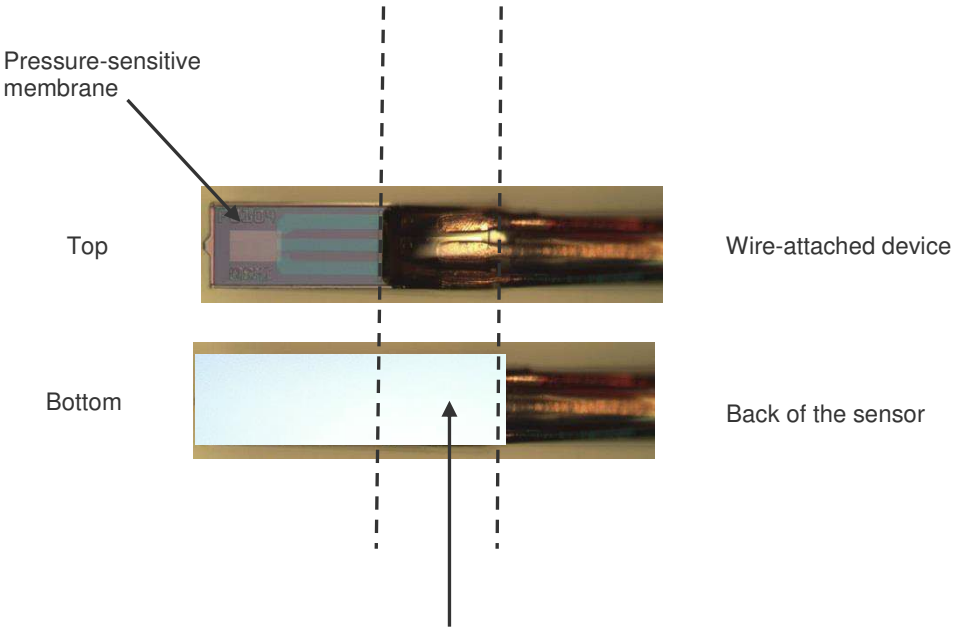




11. Qualification Standards

IATF 16949
ISO 9001
ISO 14001
REACH Compliant
RoHS Compliant
PFOS/PFOA Compliant

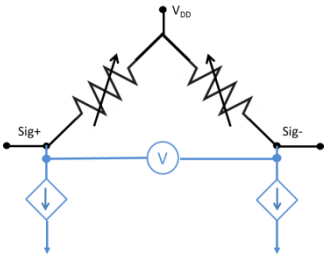
Appendix 1: Guide to Die Mounting



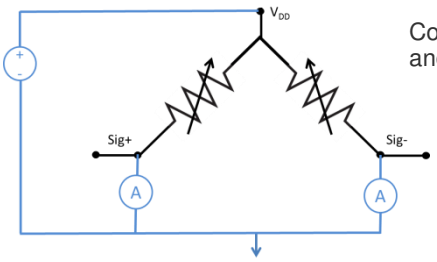
Device should be mounted to a rigid, immobile surface. To avoid potentially cutting or damaging tissue, the corners of the IntraSense sensor must be surrounded by a more rounded surface. Apply die attach/adhesive on the backside of the die in this region to avoid unwanted stress on membrane. Low-stress, biocompatible polysiloxane-based die-attach material is recommended for die attach. Using hard die-attach materials could result in mechanical stresses being transmitted to the pressure-sensitive membrane, leading to loss of accuracy. Customer mounting and handling can affect performance and customer verification in customer's final package is recommended. Sensors pre-mounted in carriers are currently in development contact customercare.mlpt@te.com for more information.

Appendix 2: Alternate circuits

Intrasense Absolute Pressure Sensor 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.

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Version 1 12/2020