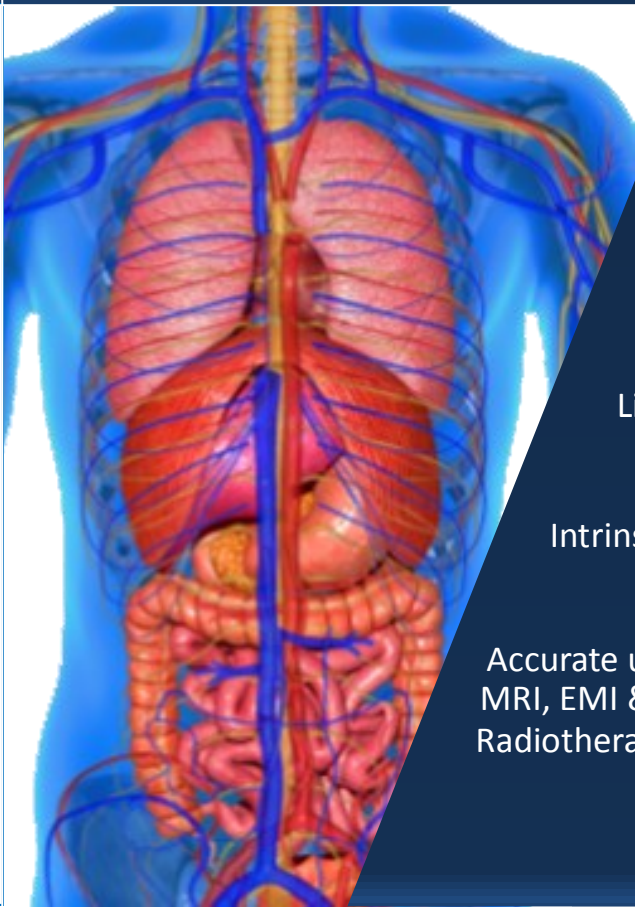




MEDICAL PRESSURE MONITORING

FISO offers the smallest fiber optic pressure sensors and temperature probes for medical devices available in the market today.

Through the use of robots and automated work stations, FISO produces hundreds of thousands of sensors a year, making FISO the world leader in the supply of fiber-optic sensors for OEM medical devices.



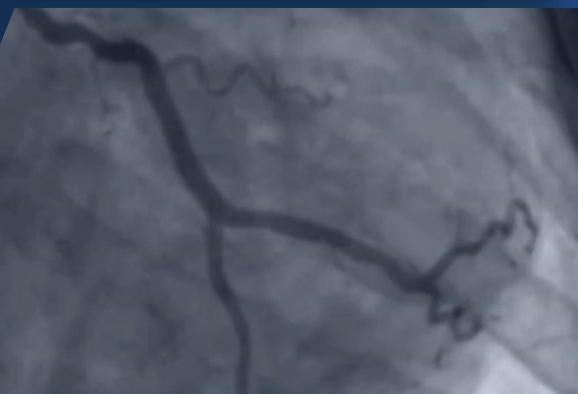
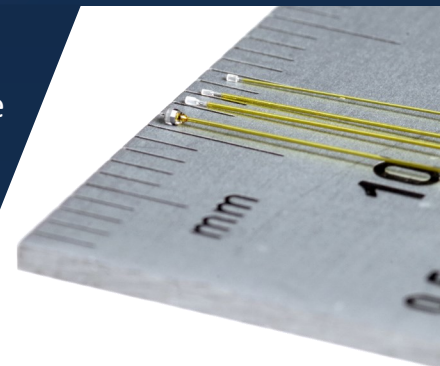
Minimally Invasive

Flexible &
Kink Resistant

Lightweight

Intrinsically Safe

Accurate under
MRI, EMI &
Radiotherapies

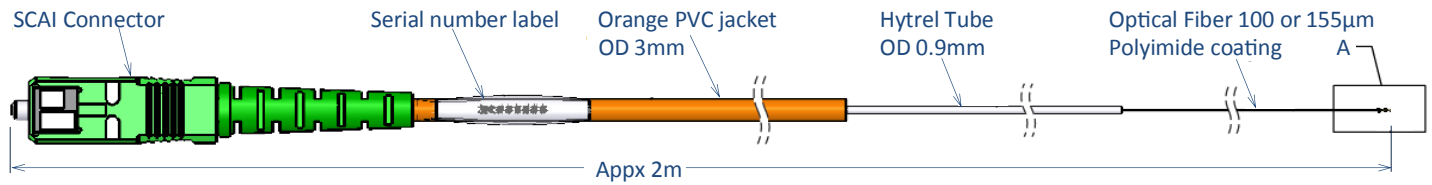




Pressure sensor FOP-M200

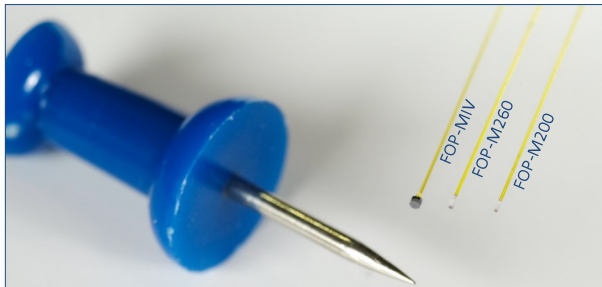
MEDICAL

Fiber Optic Pressure Sensors, distal tip as small as 200 μ m



Applications

- ▶ Cardiovascular: LV pressure, arterial BP
- ▶ Pharmacology: Drug and Fluid injection
- ▶ Neurosciences: Intracranial pressure
- ▶ Spine/Bones: Intradiscal/Intramedullary pressure
- ▶ Urology: Bladder/Ureter pressure
- ▶ Ophthalmology: Intraocular pressure
- ▶ MRI RFI
- ▶ Arterial blood or LV pressure for image gating
- ▶ Respiratory / Pulmonology
- ▶ Endoscopy



Models

Detail A	Item #
<u>Bare</u>	
100 μ m	FOP-M200-NS-1200A
100 μ m	FOP-M200-NS-1200B
200 μ m	FOP-M200-NS-1199A
155 μ m	FOP-M200-NS-1199B
225 μ m	
<u>Polyimide Protection</u>	
100 μ m	FOP-M200-NS-1200C
100 μ m	FOP-M200-NS-1200D (w/ gel)
155 μ m	FOP-M200-NS-1199C
272 μ m	FOP-M200-NS-1199D (w/ gel)
<u>Stainless Protection</u>	
100 μ m	FOP-M200-NS-1200E
307 μ m	FOP-M200-NS-1199E

Specifications

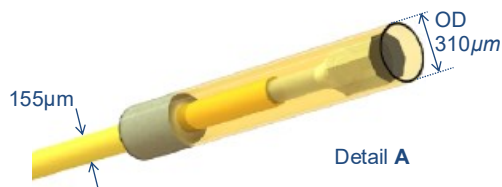
Pressure range	-300mmHg to 300mmHg (relative to atmospheric pressure)
Resolution ¹	0.1mmHg
Sensor accuracy	± 1 mmHg
System accuracy ²	± 3 mmHg or 3%
Sensitivity thermal effect ³	< 0.3 mmHg/ $^{\circ}$ C
Operating conditions	Humidity: 0-100% ; Temperature: 15 to 45 $^{\circ}$ C
Storage conditions	Humidity 0-95%, non condensing ; Temperature: -30 to 85 $^{\circ}$ C
Cable sheathing & Length	PVC and hytrel cable / other material possible / length can also be customized
Tip termination	Bare / Sheathed with polyimide or SS / with or without gel. can be customized : nitinol / radio-opaque
Connector	SCAI, SCA connector with smart chip communicating calibration data to the reading module

1. With a SKR module and a filter of 30Hz applied
2. The M200 sensor and SKR module together are 3mmHg or 3% and includes reproducibility (sensor/module exchange), repeatability and hysteresis, non-linearity, scale error, offset error, conditioner temperature compensation error
3. Determined between 10 $^{\circ}$ C and 70 $^{\circ}$ C at atmospheric pressure (~ 760 mmHg)



Pressure sensor FOP-M260

MEDICAL



Polyimide sheath with gel: Item# **FOP-M260-21**

Polyimide sheath no gel: Item# **FOP-M260-20**



Bare sensor: Item# **FOP-M260-10**

Applications

- ▶ Cardiovascular: LV pressure, arterial BP
- ▶ Pharmacology: Drug and Fluid injection
- ▶ Neurosciences: Intracranial pressure
- ▶ Urology: Bladder/Ureter pressure
- ▶ MRI RFI: Arterial blood pressure or LV pressure for image gating
- ▶ Spine/Bones: Intradiscal /Intramedullary pressure
- ▶ Respiratory / Pulmonology
- ▶ Otorhinolaryngology: Inner ear pressure
- ▶ Ophthalmology: Intraocular pressure
- ▶ Gastro intestinal
- ▶ Endoscopy

Fiber Optic Pressure, OD260µm (FOP-M260)

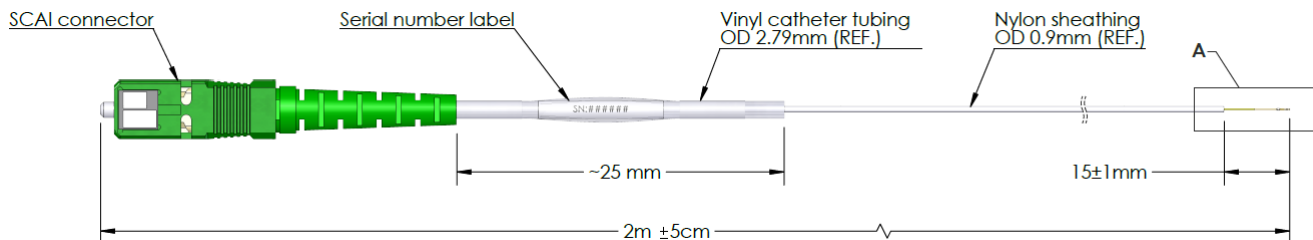


Photo shows a M260 pressure sensor of 260µm outer diameter on a finger

Specifications

Pressure range	-300mmHg to 300mmHg, relative to atmospheric pressure (can be customized)
Resolution ¹	0.1mmHg
Sensor accuracy ²	±1mmHg
System accuracy ²	±3mmHg
Sensitivity thermal effect ³	<0.3mmHg/°C
Proof pressure	>4500mmHg
Operating conditions	Humidity: 0-100% ; Temperature: 15 to 45°C
Storage conditions	Humidity 0-95%, non condensing ; Temperature: -30 to 85°C
Cable sheathing	Nylon sheathing of 0.9mmOD (can be customized)
Tip termination	Bare / Sheathed / Sheathed with gel Can be customized : stainless steel / nitinol / radio-opaque
Standard sensor length	2 Meters standard (can be customized)
Connector	SCAI*, SCAI is a SCA connector with smart chip communicating calibration data to the reading module

1. With a SKR module and a filter of 30Hz applied
2. The M260 sensor and SKR module together are ±3mmHg and includes reproducibility (sensor/module exchange), repeatability & hysteresis, non-linearity, scale error, offset error, conditioner temperature compensation error
3. Determined between 10°C and 70°C at atmospheric pressure (~760mmHg)



Polyimide sheath with gel: Item# **FOP-MIV-21** or **41**
 Polyimide sheath no gel: Item# **FOP-MIV-20** or **40**



Bare sensor: Item# **FOP-MIV-10** or **30**

Applications

- ▶ Cardiovascular: LV pressure, arterial BP
- ▶ Pharmacology: Drug and Fluid injection
- ▶ Neurosciences: Intracranial pressure
- ▶ Urology: Bladder/Ureter pressure
- ▶ MRI RFI: Arterial blood pressure or LV pressure for image gating
- ▶ Spine/Bones: Intradiscal/Intramedullary pressure
- ▶ Respiratory / Pulmonology
- ▶ Otorhinolaryngology: Inner ear pressure
- ▶ Ophthalmology: Intraocular pressure
- ▶ Gastro intestinal
- ▶ Endoscopy

Fiber Optic Pressure, OD550µm (FOP-MIV)

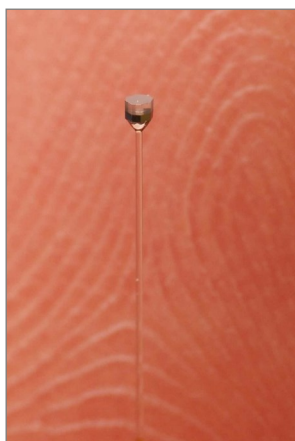
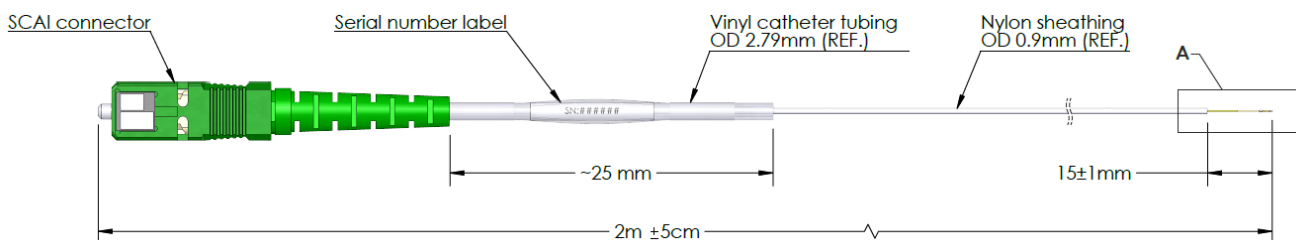


Photo shows a MIV pressure sensor of 550µm outer diameter on a finger

Specifications

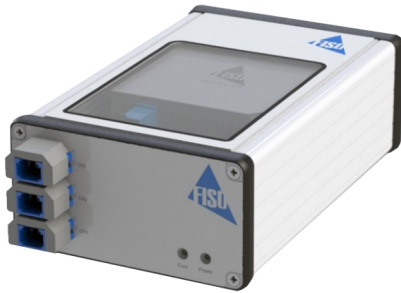
Model	FOP-MIV-10, 20, 21	FOP-MIV-30, 40, 41
Pressure range ⁴	-300 to 300mmHg	-300 to 7500mmHg
Resolution ¹	<0.3mmHg	2.6mmHg
Sensor accuracy ²	±1mmHg	±50mmHg
System accuracy ²	±3mmHg	±50mmHg
Sensitivity thermal effect ³	<0.3mmHg/°C	<3mmHg/°C
Proof pressure	>4000mmHg	>22 500mmHg
Operating conditions	Humidity: 0-100% ; Temperature: 15 to 45°C	
Storage conditions	Humidity 0-95%, non condensing ; Temperature: -30 to 85°C	
Cable sheathing	Nylon sheathing of 0.9mmOD (can be customized)	
Tip termination	Bare / Sheathed / Sheathed with gel Can be customized : Stainless steel / Nitinol / Radio-Opaque	
Standard sensor length	2 Meters standard (can be customized)	
Connector	SCAI, SCAI is a SCA connector with smart chip communicating calibration data to the reading module	

1. With a SKR module and a filter of 30Hz applied
2. The MIV sensor and SKR module together are ±3mmHg and includes reproducibility (sensor/module exchange), repeatability and hysteresis, non-linearity, scale error, offset error, conditioner temperature compensation error
3. Determined between 10°C and 70°C at atmospheric pressure (~760mmHg)
4. Relative to atmospheric pressure



Development kit Reading unit

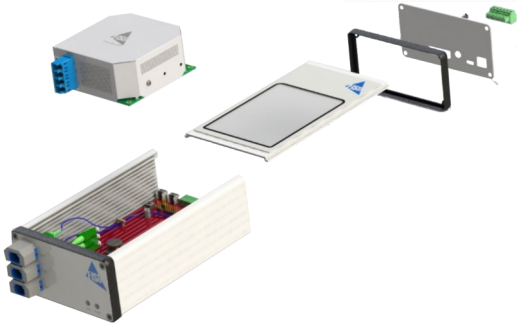
DATASHEET



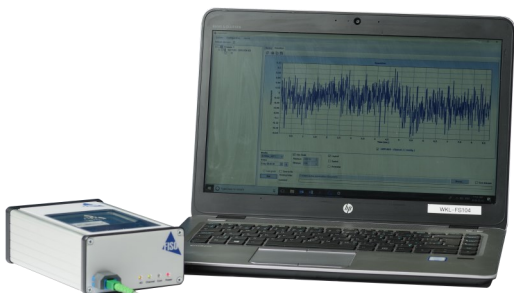
Development kit, 3 channels (SKR-DEV-003 model pictured above)



Back of the Development kit enclosure



Exploded view of the Development kit with its internal module



Evolution application software is provided with the Development Kit

The Development kit is designed for Other Equipment Manufacturer (OEM) testing, prototype integration, and firmware development.

Description

This development kit is geared towards customers who wish to evaluate and test the pressure monitoring system, both sensors and reading units, in preparation for integration into their hospital console.

The development kit, also referred to as "SKR-DEV" is compatible with FISO's Evolution application software.

SKR-DEV includes the following components:

- ▶ Power supply adaptor, USB & BNC-SMA cables
- ▶ User guide and EVOLUTION acquisition **software**
- ▶ Cleaning kit

When ready to embed the OEM module, just take the module out of the SKR-DEV casing and connect to the prototype OEM motherboard via the 34-pin connector. FISO provides the communication protocol necessary to establish communication between the host system and the OEM module either through analog or digital means.

Key Features

- ▶ Low heat emitted from LED light source
- ▶ Atmospheric self-compensation available
- ▶ LED technology: lifetime greater than 20000 hours
- ▶ Full bandwidth via analog output connectors
- ▶ Up to 3 channels



OEM reading module

Description

The OEM module is an opto-electronic reading unit with set-up, control, and data acquisition enabled through an electrical interface. Designed for embedding in hospital consoles, the module possesses robust communication capabilities, fast sampling rates, and is RoHS compliant.

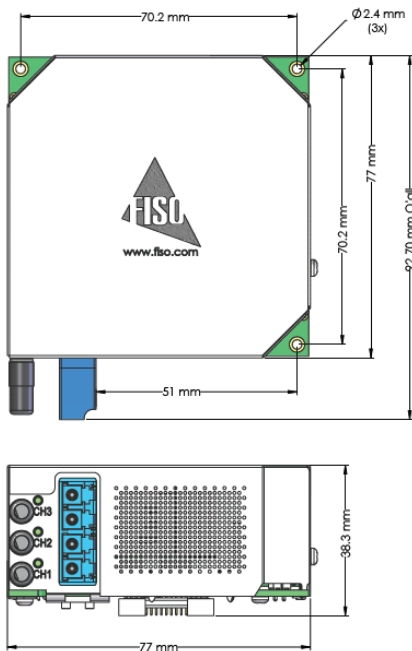
FISO provides documentation related to detailed electrical, mechanical, and communications protocol required to interface with the module.

Specifications

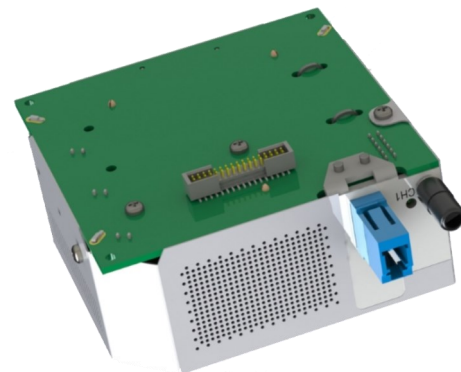
	Development kit	OEM module
Number of channels / Item #	1/ SKR-DEV-001 2/ NA 3/ SKR-DEV-003	1/ SKR-OEM-001 2/ SKR-OEM-002 3/ SKR-OEM-003
Sampling rate	up to 250Hz	
Analog reading output	0 to 4.096V	
Digital reading output	16 bits resolution	
Power consumption	3.3W(typical) 3.7W(max.)	1.8W(typical) 2.2W(max.)
Operating	+10°C to +35°C	+10°C to +55°C
Storage temperature	-40°C to 70°C	
Dimensions	W: 103mm H: 53mm L: 160/175.7mm	W: 77mm H: 38.3mm L: 77/92.7mm
Communication	USB	RS-232 TTL



One, two, and three channel OEM modules pictured above sequentially



OEM module dimensions

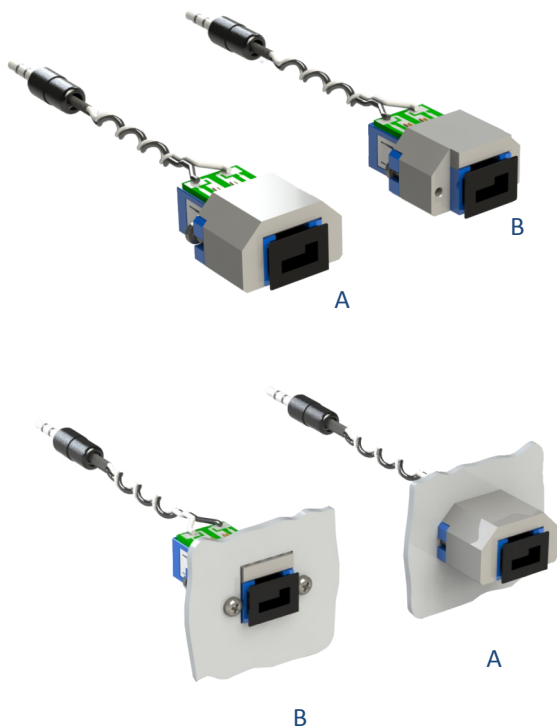


OEM module underside and the 34 pin connector



Bulkhead Optical Adapters and Internal Electrical Extensions

FISO designed bulkhead SCAI adapter and electrical extension assemblies are available to transmit the calibration data from the hospital console's bulkhead adapter to the embedded SKR-OEM module.



Bulkhead adapters as pictured above are available as protruding—type A— Item #: FSP-091 (45mm) or flush-type B. These items are usually customized. Please contact our application specialist and review with them your specifications.

Internal Optical Extensions

Use this robust optical extension with a cable outer diameter of 3mm to connect the front panel of the console to the embedded OEM module.



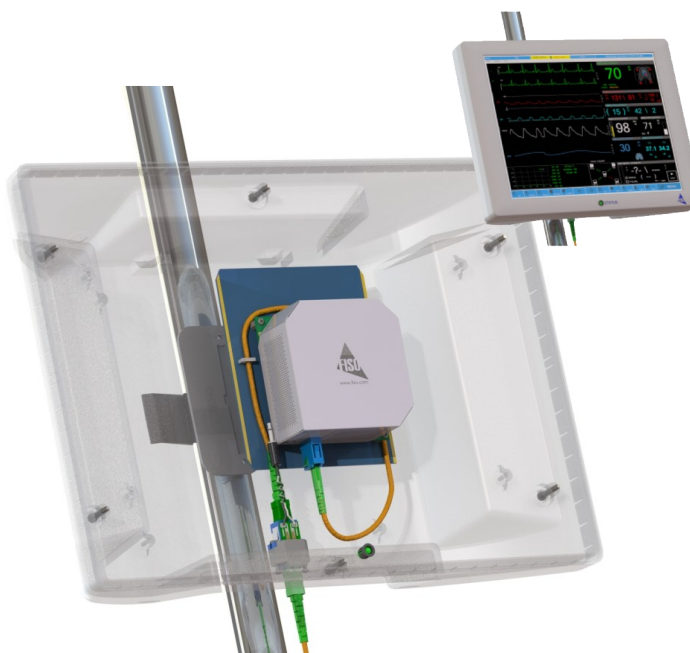
Item #: 1200047 (0.5 meter)
1200048 (1 meter)
1200049 (2 meters)

Optical & Electrical Extension Cable

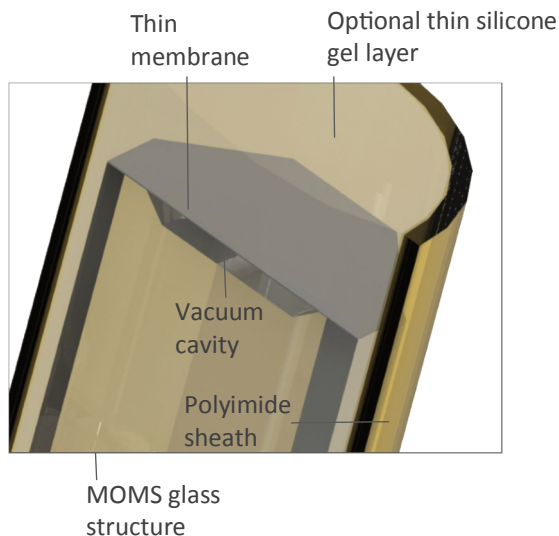
A 3 meter fiber extension having optical / electrical SCAI connectors is also available. This extension is useful when a longer working distance is required during testing in the product development phase.



3 meter extension cable: Item# CFO-LS-3M-10



Example of module within a console

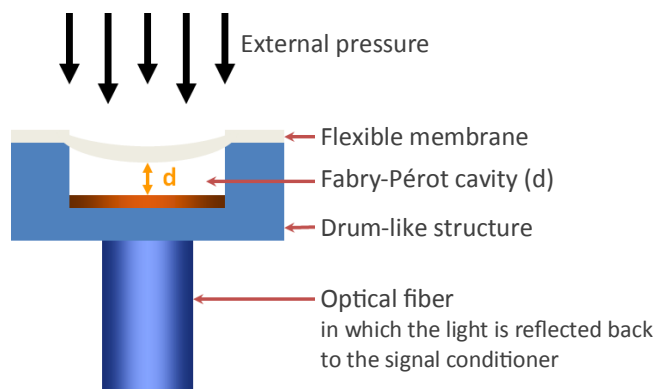
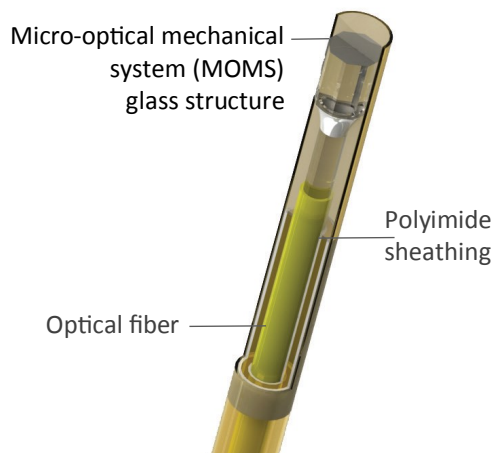


Technology Description

At the heart of FISO's medical pressure sensors is a Fabry-Pérot cavity which comprises two parallel reflecting mirrors on either side of a transparent medium, where the distance between the mirrors is known as the cavity length. The reflection spectrum of the F-P cavity has distinct peaks in wavelength as a function of the cavity length, physically corresponding to resonances of the cavity. Named after the two French physicists who mathematically modeled this optical structure well over 120 years ago.

FISO's pressure transducers are a flexible embodiment of the F-P cavity. As illustrated below, a deformable membrane is assembled over a vacuumed cavity, forming a small drum-like structure. The bottom of the drum and the inner surface of the flexible membrane form the sensing F-P cavity. When pressure is applied, the membrane is deflected towards the bottom of the drum, thus reducing the cavity length. After the NIST-traceable factory sensor calibration, the cavity length will correspond to a very precise pressure value. The signal conditioner is designed to be able to accurately determine the cavity length with nanometer precision.

In this way, the pressure transducer and signal conditioner form an extremely precise and repeatable pressure measurement system.



EASY-TO-USE

The FISO sensor has unrivaled ease-of-use as the sensor comes pre-calibrated, with the calibration data stored in a smart-ship in the fiber-optic connector for the signal conditioner to read automatically. There is no need to benchmark to an external pressure reference as the sensing technology provides precise pressure readings after nulling to the ambient pressure.

PROVEN SENSING TECHNOLOGY

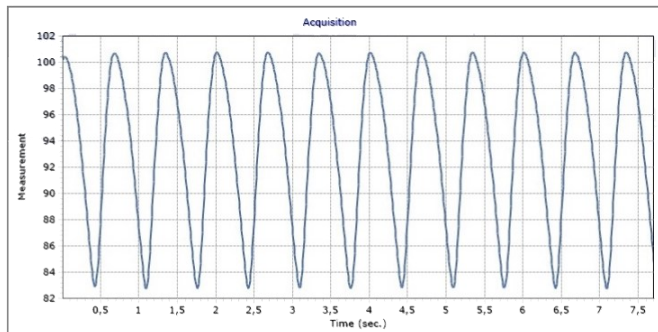
The pressure sensor transducer has been used in numerous applications in medical pressure sensing for over 15 years.



EVOLUTION Software

The application software allows users to configure and control the reading module, perform simple monitoring and real-time graphing, and also export data.

Users may choose between reading the actual single measurement (monitoring) or plotting the data with user specified screen refresh rates and graphing options. Finally, the data may be recorded and saved in multiple file formats including CSV, and XLS, while graph images may also be saved in multiple formats such as TIF or JPEG.

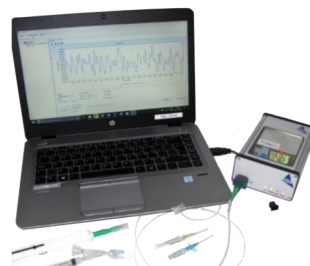


Example of "live" plot diagram . The above shows a radial artery heart beat.

Monitoring & real-time results

Users may choose reading the actual measurement, or plot in real-time with user's specified screen refresh rates.

FISO SALES PROCESS



Define your needs

Discuss with our sales engineers and explain your project. They will guide you through the best options available.

Choose sensor type

Our engineers will help you find a matching solution through our many types of sensors, sizes, measurement ranges, cable types, lengths, robustness and more.

Technology Assessment

Familiarize yourself with the FISO system by working with the SKR-DEV and real sensors. Build device prototypes with sensors and evaluate performance.

Customization

To enable mass production, FISO can customize the cable type, fiber length, tip protection and testing to match the requirements of the OEM medical device.

Products designed, manufacture and sold by FISO Technologies Inc. ("FISO"), or it's authorized distributors, agents or resellers, are not and shall not be considered or represented as being medical instruments. Such products have not been approved or certified, nor submitted for approval or certification, by applicable regulatory bodies including, without limitation, the office of device evaluation of the U.S. Food and Drug Administration of the Therapeutic Products Directorate of Health Canada. Products Purchased with the intent or for the purpose of being used as medical devices or components shall be done at purchasers or user's own risk. FISO disclaims all liability with respect to any and all use of its products as medical devices or components, or in any medical application or procedure including, without limitation, in vitro or in vivo uses. FISO products are scientific instruments whose misuse is potentially dangerous. They are intended to be installed and used only by qualified personnel. FISO's liability to purchaser for claims related to the purchase, transportation, installation or use of its products shall be limited to the aggregate value of the purchase price of the products as stated in FISO's invoice to purchaser. In no event shall FISO be liable for any direct, indirect, punitive, special incidental, or consequential damages in connection with or related to the purchase, transportation, installation or use of its products (including loss of profits, use, or other economic advantage), however arising, whether for breach of warranty or in tort, even if FISO has been previously advised of the intended use of its products or of the possibility of such damage.

FISO Technologies Inc
500 St-Jean-Batiste Ave, Suite 195
Québec (Quebec) Canada G2E 5R9
DOC: MC-00263 R8

Phone +1.418.688.8065 Email info@fiso.com
Fax +1.418.688.8067 Web www.fiso.com

FISO Technologies Inc. reserves the right to make any changes in the specifications without prior notice.

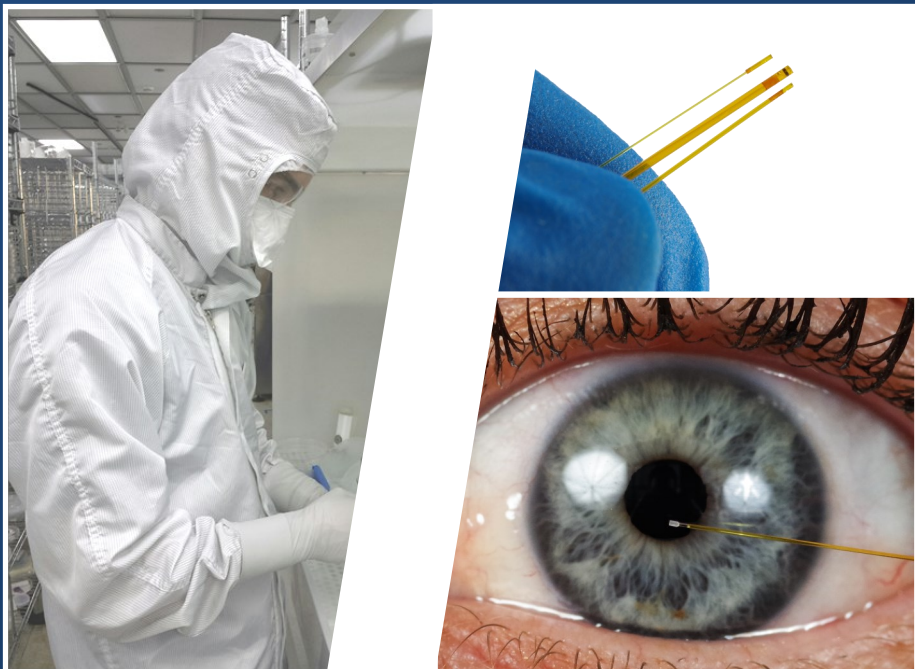


FISO Technologies Inc., a leading developer and manufacturer of fiber optic sensors and signal conditioners, is worldly recognized for its unparalleled range of fiber optic solutions. Besides being extremely small, thus minimally invasive, the advantages of fiber optic sensors are that they are highly precise, intrinsically safe and immune to radio frequencies, electromagnetic interferences and microwave radiations.

The secret to FISO's position as a leader in its field of expertise relies on the use of leading-edge technology, combined with the quality of its technical expertise, a team of experienced engineers and technicians, its product development capabilities, the highly controlled and optimised manufacturing processes and facilities, overseen by stringent Quality Control based on industry regulations and best practices. This allows FISO to meet the needs of every client, whatever challenging or demanding environments they work in.

Founded in 1994, FISO Technologies is now a part of Resonetics, the leader in advanced engineering and micro manufacturing for life sciences. FISO's products are sold in more than 75 countries through a network of representatives and distributors. Since 2003, FISO Technologies meets the requirements of the ISO 9001:2015 and ISO 13485:2016 certifications. The company is assessed and certified by the BSI Group and strictly applies its quality policy day after day.

FISO is the largest fiber optic sensor company in the world with hundreds of thousands of sensors shipped annually and continuing to grow year after year.



FISO Technologies Inc.

500 St-Jean-Baptiste Ave, Suite 195

Québec (Quebec) Canada G2E 5R9

RESONETICS