



FISO Catheter Life Sciences series

FOR ANIMAL USE ONLY
USER GUIDE
MAN-00089 R2

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Units of measurement in this document conform to SI standards and practices.

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Recommended Accessories

In order to function as a complete pre-clinical pressure test instrument, the FISO Catheter needs to be connected to an FPI-LS Series Signal Conditioning Module, which is correspondingly inserted into an Evolution Series EVO-SD Chassis.

Model	Description
EVO-SD	Evolution Series Chassis with 2 or 5 slots
FPI-LS	FPI Series Signal Conditioning Module, compatible with FISO Catheters
CFO-LS	Extension Cable between FPI-LS and the FISO Catheters

Please consult the FISO Catheter datasheet for an up to date listing of manufacturing part numbers corresponding to the Model numbers listed above.

All accessories are sold separately

Certification Information

FISO certifies that this equipment has met its published specifications at the time of shipment from the factory.

The FISO Catheter is a pre-clinical instrument that is for animal use ONLY.

This product is not be used on humans.

Safety Information

Safety Conventions

Before using the product described in this manual, you should understand the following conventions:

DANGER	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury. Do not proceed unless you understand and meet the required conditions.
WARNING	Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. Do not proceed unless you understand and meet the required conditions.
CAUTION	Indicates a potentially hazardous situation which, if not avoided, may result in component damage. Do not proceed unless you understand and meet the required conditions.
IMPORTANT	Refers to information about this product you should not overlook.

Safety Information

While connected to the FPI-LS signal conditioner, the level of radiation emitted out the sensing end of the FISO Catheter is below the level known to cause eye injury through accidental short-term exposure. However, avoid prolonged exposure to light emitted from the fiber and do not stare directly at a light beam, visible or not.

The following safety instructions must be observed whenever the **FISO Catheter** is operated. Failure to comply with any of these instructions or with any precaution or warning contained in this user guide is in direct violation of the standards of design, manufacture and intended uses of the **FISO Catheter**. FISO assumes no liability for the customer failure to comply with these safety requirements. THIS PRODUCT IS NOT DESIGNED FOR USE IN LIFE SUPPORT OR CRITICAL APPLICATIONS.

In no case will FISO be liable to the buyer, or to any third parties, for any consequential damage or indirect damage which is caused by product failure, malfunction, or any other problem.

WARNING

This equipment must be used as specified or the protection provided by the equipment may be compromised. You must use this product in a normal mode and should not deviate from the written instructions provided.

CAUTION

There are no user serviceable parts in the FISO Catheter, other than the ones specified in the **Maintenance** section. Adjusting parts inside the unit can affect instrument performance. If you adjust parts, you will need to verify the equipment for good performance. Refer servicing of any other parts to qualified personnel.

IMPORTANT

As the FISO Catheter is used exclusively with the Evolution Series Chassis, the User should read the "Evolution Chassis and Software User Manual", MAN-00079. Both manuals must be read prior to use of the FISO Catheter.

FISO Catheter Overview

The FISO Catheter is a low cost reusable catheter designed for physiological research of small animals.

The FISO Catheter combines a miniature optical pressure sensor at the distal end of the catheter with a fiber-optic connector at the proximal end.

The pressure sensing element is based on patented Fabry-Perot technology and pressure measurements are made by optically interrogating, and then analyzing the reflected signal from the sensor in order to correlate changes in the Fabry-Perot cavity length to changes in external pressure.

The FISO Catheter is an embodiment of all the benefits of fiber optics, designed specifically for small animal research, enabling unique capabilities such as:

- Re-use of the transgenic mice and rats owing to femoral insertion capability (with 0.9Fr model)
- Accurate measurements while the animal is inside an MRI machine as the fiber optics technology is immune to interference from RF and EMI
- Forward-facing pressure readings at the exact location of interest, and thus no side-facing sensor measurement artifacts such as is commonly encountered by proximity to vessel wall

The **FISO Catheter** comes in different models, which primarily differ in tip-diameter size, although other differences also exist. For example:

- ▶ FISO-LS-PT9 is intended for use with mice and rats and has a 0.9 French tip size
- ▶ FISO-LS-2FR is intended for use with rats and has a 2 French tip size
- ▶ FISO-LS-3FR is intended for use with rabbits, and other small animals and has a 3 French tip size

Please consult the latest FISO Catheter datasheet for a complete list of specifications.

The FISO Catheter has two ends: (i) one side containing the pressure sensing fiber-optic element, and meant for insertion into the small animal, and (ii) the other side being a standard fiber-optic connector meant for connecting with the FPI-LS Signal Conditioner, via the CFO-LS extension cable connection box, or connected directly.

The two sides are easily distinguishable from each other, as illustrated in Figures 1-3.

Figure 1: Catheter Insertion Tip Detail (Magnified)

The diameter is very small, always less than 1mm with sensor recessed from the tip, and appears just like a standard optical fiber to the naked eye.



Figure 2: Mechanical Drawing of the Catheter, showing typical dimensions

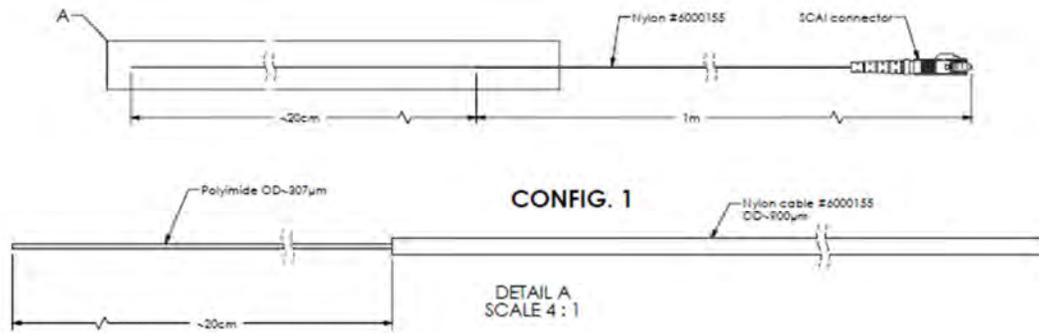


Figure 3: Catheter Optical Connector Side Connected to CFO-LS Extension Box

During measurements, the fiber optic connector side of the Catheter is always connected to the FPI-LS Module or CFO-LS Extension.



Getting started with your FISO Catheter

Unpacking and Inspection

The catheters are packaged in a way that provides maximum protection during shipment. If the outside of the shipping carton is damaged, notify your receiving department immediately. Your receiving department may want to notify the carrier.

If the shipping case is not damaged, carefully remove and identify all of the components listed below. Contact FISO or your local representative if any of the components are missing. We recommend you save the shipping case for future storage or transportation.

The FISO Catheter package should include the following components:

- ▶ **FISO-LS series Catheter**
- ▶ Optical fiber cleaning kit (for connector side of the product)
- ▶ Catheter cleaning kit (for sensor side of the product)
- ▶ User guide

Immediately upon receipt of the catheter, and prior to its initial cleaning, disinfection, and use, the customer should verify that the Catheter is operational.

CAUTION

Use care in handling fiber optic connectors. Always clean the fiber-optic connector end prior to insertion into the FPI-LS or CFO-LS for optimum performance and to avoid measurement errors. For details on connector handling and maintenance, please refer to section **Handling the** .

To Connect the Catheters to the FPI-LS or CFO-LS:

1. Align the connector key with the slot on the mating sleeve.
2. Slide the connector into the sleeve until you hear a clicking sound.

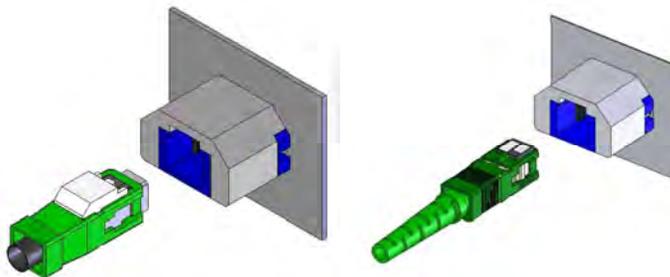


Figure 1: SCAI-type 1 and SCAI-type 2 mating sleeves and connectors

Maintenance

Handling the Catheters

Read the following precautions prior to installing and when using the catheters:

- ▶ Avoid sharp bending radius in the fiber-optic cable (< 50 mm).
- ▶ Avoid tension, pinch points or twisting of the fiber-optic cable.
- ▶ Do not pull on fiber-optic cable to clear tangles; instead, carefully unwind.
- ▶ Do not allow the fiber-optic connectors to drop or scrape on hard surfaces.
- ▶ Keep the surface of the fiber-optic connector clean.

- ▶ Always use protector caps on the fiber-optic connectors when sensors are disconnected from the signal conditioner.
- ▶ When the fiber optic connectors are connected to the FPI-LS module or CFO-LS extension box, store the protector caps on their side, in a closed container to avoid dust or other materials from accumulating inside the cap.

CAUTION

Sharp pinching of the fiber will almost always break the fiber, as will subjecting the fiber to a <10mm bend radius.

Cleaning a Fiber Optic Connector

To make good optical measurements, it is extremely important to clean the fiber-optic connector before each connection. Dirt on the connector can degrade the reliability of the measurement and cause permanent damage to the connector resulting in non-functional sensors.

Modern fiber-optic connectors rely on a glass-to-glass contact to reduce Fresnel reflections at the connector interface. A dirty or damaged connector on the cable can damage the input connector. Always use a good quality cable connector. If there is any question about the surface quality on the tip of the cable connector, inspect it under a microscope for scratches or debris.

Some general recommendations:

- ▶ Never use a metal or other hard object for cleaning; it would scratch the ferrule.
- ▶ Do not apply index-matching gel or oils.
- ▶ Always keep connectors covered for protection when not in use.

To clean the end of the connector on the fiber-optic cable:

1. Deposit one drop of isopropyl alcohol on a lint-free wiping cloth.
2. Gently wipe the entire ferrule (and especially the end) in a straight-line motion.
3. Using a dry lint-free wiping cloth, gently wipe the same surfaces to ensure that the connector and ferrule are perfectly dry.
4. Throw out wiping cloths after one use.
5. As soon as the connector is clean, insert it in the panel or cover it for later use.

Cleaning FPI-LS Signal Conditioner Ports

It is equally important to make good optical connections and to clean the fiber-optic detector port before each connection. Dirt on the detector can degrade the reliability of the measurement and cause permanent damage to the connector resulting in an expensive repair.

To clean the connector on the fiber-optic detector port:

1. Moisten a cleaning swab with one drop of isopropyl alcohol.
2. Insert the cleaning tip into the connector using a slow clockwise rotating movement until it reaches the ferrule inside.
3. Gently rotate the cleaning tip one full turn.
4. Continue to turn as you withdraw the cleaning tip.
5. Repeat steps 2 to 4, but this time, use a new dry cleaning swab.

Cleaning the Catheter Sensing Tip

The catheter tip should be cleaned immediately after every use.

Approved Cleaners

Type	Trade Name	Manufacturer	Active Ingredient	Soak Time and Temperature
Enzymatic Detergent	Enzol (R)	Advanced Sterilization Products [J&J]	Propylene Glycol	15 minutes at Room Temperature
	Terg-A-Zyme (R)	Alconox	Sodium Dodecylbenzene	15 minutes at Room Temperature

CAUTION : **DO NOT USE :**

- Glutaraldehyde solutions containing surfactants (ex. Cidex 7, Cidex Plus 28 Day).
- Solutions containing hydrogen peroxide (ex. Sporox).
- Cidex PA solution

CAUTION: Do not submerge the entire Catheter. This may damage the fiber-optic connector side of the catheter and void its warranty. Wipe only with the recommended cleaner and gauze.

CAUTION : Use only the listed cleaners for the times/temperatures indicated.

CAUTION : Delays in rinsing greatly reduce the cleaning effectiveness.

CAUTION : Prepare and handle the cleaners as per the manufacturer's instructions.

1. Wipe catheter with wetted gauze immediately after use to remove any bulk contaminants.
2. Submerge only the distal contaminated portion of the catheter in room-temperature water up to the Optical Connector. (Do not use Hot Water).
3. Wipe the outer surface of the catheter with soft gauze.
4. Prepare the cleaning solution. Place the distal portion of the catheter in the cleaning solution.
5. Wet soft surgical gauze with the cleaning solution. Wipe the other surface of the catheter with the gauze.
6. Soak the distal portion of the catheter in a cleaning solution for the time specified, and then remove.
7. Gently wipe the catheter clean with a soft wet gauze, or tissue.
8. Immediately rinse the catheter at least three times with sterile, pyrogen-free water. Do not reuse the water from each rinse, as it will contain residuals from the cleaner.
9. Dry the outside of the catheter with a soft gauze.
10. Re-package for sterilization.

CAUTION : Failure to clean according to directions may void the Catheter warranty.

Disinfecting the Catheter Sensing Tip

Approved Disinfectants

Type	Trade Name	Manufacturer	Active Ingredient	Soak Time and Temperature
High-Level Disinfectant	Cidex (R) OPA	Advanced Sterilization Products [J&J]	Orthophtalaldehyde	15-30 minutes at 20C
	MetriCide (R)	Metrex	Glutaraldehyde	1-2 hours at 25C

1. The catheter must be cleaned, rinsed and dried prior to disinfection. Soil, debris, proteins, and water can interfere with the effectiveness of the following procedure. Note that some disinfectants have a limited life after activation or opening of the container. Failure to follow such warnings can inhibit the effectiveness of the disinfection process.
2. Prepare the disinfectant solution.
3. Submerge the distal part of the catheter into the disinfectant, covering the region wishing to be disinfected, at least as far as the nylon coating begins, but not further than the beginning of the optical-fiber connector.
4. Soak the catheter in the disinfectant at the temperature and time interval listed.
5. Rinse the device by submerging all exterior disinfected surfaces into sterile pyrogen-free water. The volume of the water should be at least 7.5 liters, and the soak time should be at least one minute.
6. At least three separate rinses are required. Do not reuse any of the water used for rinsing since it will be contaminated by the disinfectant.

CAUTION : Prepare and handle the disinfectants as per the manufacturer's instructions.

Replacing Parts

When handling optical fibers and fiber-optic connectors, follow the general recommendations presented in this section.

There are no user serviceable parts in the **FISO Catheter**, other than the ones specified in the **Maintenance** section. Adjusting parts inside the unit can affect the accuracy of the instrument. If you adjust parts, you will need to verify the accuracy of the measurements.

Troubleshooting

Solving Common Problems

The following troubleshooting notes were designed to help you solve technical problems. If you conclude that the unit has to be returned for repairs, or if you need assistance, please contact FISO Technical Support at support@fiso.com.

The most common problem encountered when using the FISO Catheter is ensuring a good optical connection between Catheter and FPI-LS or CFO-LS. Please check that when the connector is inserted that there is a clicking sound heard – which indicates that a connection has been made.

The next most common problem is a broken fiber due to mishandling. This sort of failure is usually visible by a close visual inspection of the fiber, as the fiber will appear “dented” and not smooth as when first delivered. If a suspicious area is noted, document with a macro-mode photograph and send by email, along with the problem description to FISO Technical Support.

As the FISO Catheter is used exclusively with the Evolution Series Chassis, for a more complete list of problem descriptions and probably causes, please consult the “Evolution Chassis and Software User Manual”, MAN-00088.

Contacting FISO Technical Support

To obtain after-sales service or technical support for this product, contact FISO at one of the following numbers. Technical Support is available from Monday to Friday, from 8:00 a.m. to 5:00 p.m. (Eastern Time in North America).

FISO Technologies Inc. 500, St-Jean-Baptiste Avenue, Suite 195 Québec (Québec) G2E 5R9 CANADA	Telephone: Fax: E-mail: URL:	(418) 688-8065 (418) 688-8067 support@fiso.com http://www.fiso.com
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To accelerate the process, please have information such as the name and the serial number of your product as well as a description of your problem close at hand.

Warranty

General Information

FISO Technologies Inc. (FISO) warrants this product against defects in material and workmanship for a period of ninety (90) days from the date of original shipment. FISO also warrants that this equipment will meet applicable specifications under normal use.

During the warranty period, FISO will, at its discretion, repair, replace, or issue credit for any defective product, as well as recalibrate the product free of charge should the equipment need to be repaired or if the original calibration is erroneous.

IMPORTANT

The warranty can become null and void if:

- ▶ The product has been tampered with, repaired, or worked upon by unauthorized individuals or non-FISO personnel.
- ▶ The product serial number has been altered, erased, or removed.
- ▶ The product has been misused, neglected, or damaged by accident.

Liability

FISO shall not be liable for damages resulting from the use of the purchased product, nor shall be responsible for any failure in the performance of other items to which the purchased product is connected or the operation of any system of which the purchased product may be a part.

FISO shall not be liable for damages resulting from improper usage or unauthorized modification of the product, its accompanying accessories and software.

Exclusions

FISO reserves the right to make changes in the design or construction of any of its products at any time without incurring obligation to make any changes whatsoever on units purchased.

Service and Repairs

FISO commits to provide product service for three years following the date of purchase.

The FISO Catheter product series is generally not repairable if the damage occurs in the sensing tip or inserted sections. Repair may be possible for damage done to the optical connector and nylon covered portion of the catheter.

To send any equipment for service:

Call your local FISO products representative or FISO head office. Support personnel will determine if the equipment requires service, repair, or calibration.

If the equipment must be returned to FISO or to a local distributor, support personnel will issue a Return Merchandise Authorization (RMA) number, a detailed instruction sheet, and provide an address for return.

Pack the equipment in its original shipping material. Be sure to include a statement or report fully detailing the defect and the conditions under which it was observed.

Return the equipment, prepaid, to the address given to you by support personnel. Be sure to write the RMA number on the shipping slip. FISO will refuse and return any package that does not bear an RMA number.

Note: A test setup fee will apply to any returned unit that, after test, is found to meet the applicable specifications. Likewise, a fee will apply if the only trouble found is related to a dirty connector.

After repair, the equipment will be returned with a repair report. If the equipment is not under warranty, the customer will be invoiced for the cost appearing on this report. Return-to-customer shipping costs will only be paid by FISO for equipment under warranty. Shipping insurance is at the customer's expense.

Transportation

Maintain a temperature range within specifications when transporting the unit. Transportation damage can occur from improper handling. The following steps are recommended to minimize the possibility of damage:

- ▶ Pack the unit in its original packing material when shipping.
- ▶ Avoid high humidity or large temperature fluctuations.
- ▶ Keep the unit out of direct sunlight.

Avoid unnecessary shock and vibration.

FISO Customer Service

If you require service or need information about our products, contact your local representative or FISO head office (contact details below).

FISO Technologies (head office) 500 St-Jean-Baptiste Avenue, Suite 195 Québec City (Quebec) G2E 5R9 CANADA	Telephone: (418) 688-8065 Fax: (418) 688-8067 Email: support@fiso.com
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