The PROBESENS project involved the development of an innovative, non-invasive, and biocompatible fiber-optic sensing probe that facilitates simultaneous pressure and temperature monitoring in a highly novel approach. The probe is based on a low-cost, all-glass design and can easily be inserted in standard medical catheters.

The main application area of PROBSENSE has been urodynamics, which involves real-time pressure monitoring of the urinary channel in a patient. Using the optical fibre sensor it has been possible to achieve diagnostic performance with higher accuracy than with existing technologies, and to obtain a better detection of bladder outlet obstruction (BOO) in male patients. *In-vivo* tests, at Federico II University, Naples, Italy, were undertaken in this project.

The optical fibre probe has many other applications, which have been explored e.g. in: cardiovascular monitoring and fractional flow reserve (FFR) detection; monitoring temperature and pressure in radiofrequency thermal ablation of liver tumors; integrated in robotic tools, force axial and 3D lateral force detection in robotic micro-surgery.

The OFSRC team has established a manufacturing procedure for pressure/temperature optical fiber sensors, with performance better than the state of the art. Table 1 presents a performance comparison of EFPI/FBG sensors against typical existing commercial instruments

Table 1. Comparison of UL's EFPI/FBG technology with main players in the medical pressure probes market – as of Sept 2014.

	UL	Opsens	St Jude	Druck
Product	EFPI/FBG	OPP-M	Pressurewire	DPI-601
Technology	Fiber optic	Fiber optic	Wired MEMS	Fluidic
Accuracy	0.05 mmHg	1 mmHg	2 mmHg	2 mmHg
Range	1500 mmHg	300 mmHg	300 mmHg	750 mmHg
Speed	100 Hz	250 Hz	25 Hz	50 Hz
Stability	0.2 mmHg/hr	4 mmHg/hr	>5 mmHg/hr	2.6 mmHg/hr
Thermal	0.03 mmHg/°C	6 mmHg/°C	>2 mmHg/°C	NA
Compensat.	Yes (0.5°C)	No	No	No
Size (diam.)	0.2 mm	0.55 mm	0.35 mm	>1 mm
Package	Catheter	Catheter	Guidewire	Tube
Biocompat.	Yes	Not-FDA	Yes	Yes
Multipoint	Yes	No	No	No

A large number of clinic based urodynamic tests were conducted during two on-site testing visits to Federico II University which represented a unique opportunity for access to real patient testing.

The significance of these tests has been demonstrating the operation of the sensors in *in-vivo* bladder pressure recording. A single catheter, incorporating two fiber-optic probes, was designed for each patient, and inserted in the. The recorded pressure measurements show an exceptional stability over time, and excellent reproduction of all pressure events (e.g. patient coughing, urination, contractions, other stimuli). The analysis of the pressure differential can be correlated to the presence of obstructions, which has been diagnosed with standard PICO2000 equipment in the "traditional" way; and will allow the team to build a clinical case for further in-depth analysis of such tool. Fig. 1 and show results recorded using the optical fibre probe compared to the existing standard clinical test equipment (in Fig 2) for typical clinical urodynamic measurement cycles.

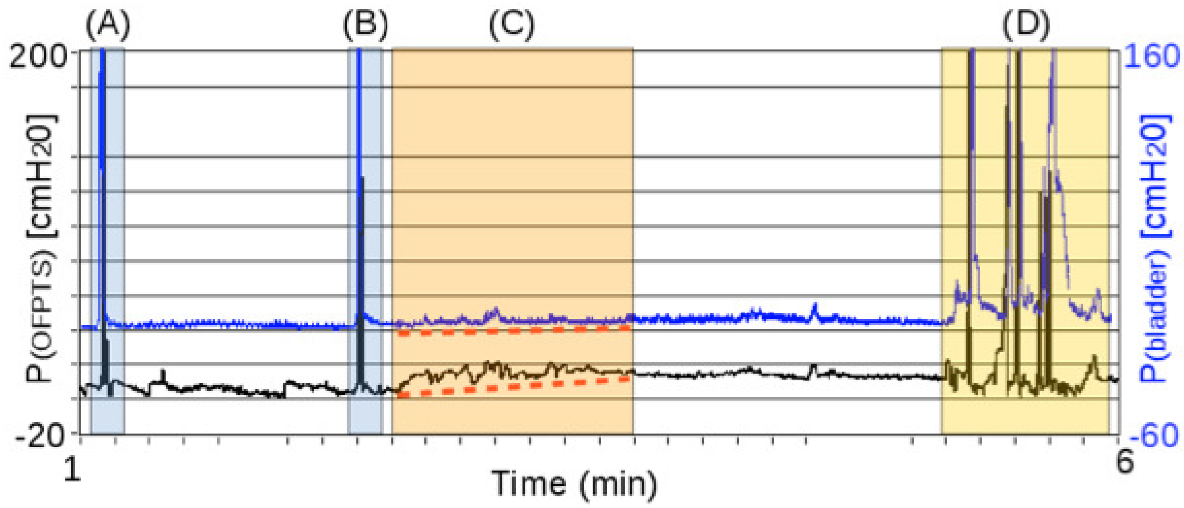

Fig. 1. Urodynamic analysis for a female patient, comparing the fiber-optic pressure sensor (black, left) with a reference sensor (blue, right). (A,B) patient coughing to stimulate a pressure event in the trace; (C) patient's bladder is filled with saline solution at a constant rate; (D) bladder is voided by patient through urination, whereas additional coughs record high-pressure events.

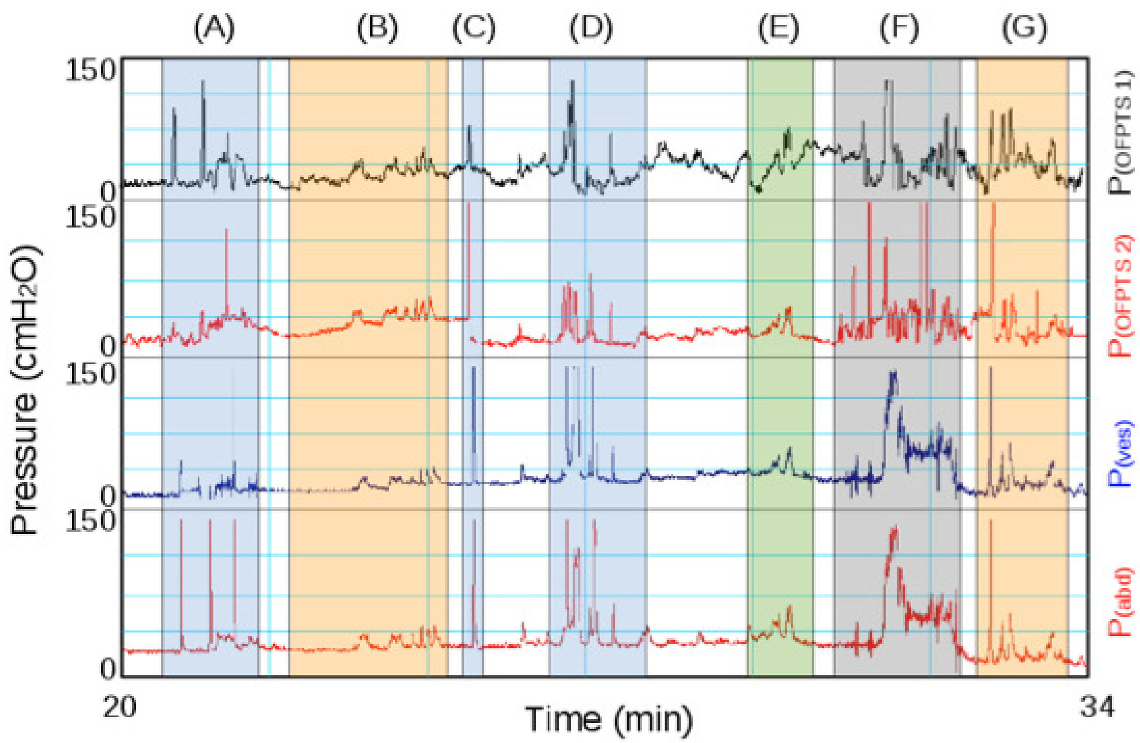

Fig. 2. Pressure recording of a whole urodynamic test, including the traces acquired (from top to bottom) from the fiber-optic EFPI sensor, a similar sensor positioned at 1 cm distance in the same catheter, bladder reference sensor, and abdominal pressure reference sensor. The first two sensors are recorded by one fiber-optic interrogator, while the other two sensors are recorded by a URODYN machine for urologic measurement.

The trace of Fig 2 displays several pressure events: (A) Patient coughing; (B) Bladder filled with saline solution until the patient reaches urination stimulus; (C) and (D) pressure recording events induced by coughing; (E) the patient records unsustainable urination stimulus, although the bladder-infusion process is interrupted; (F) the patient moves to a stand-up position and leaves the bed; (G) urination and bladder voided.

In conclusion the work undertaken under the PROBESENS project has completely met the objectives that had been set out in terms of designing and developing a clinically useable optical fibre combined pressure and temperature sensor whose performance exceeds the current state of the art. Tests undertaken at the Urology clinic of Frederico II Hospital, Naples have confirmed this. Work undertaken within the PROBESENS project has shown that technology has also highly applicable for use in other medical applications such as Cardiology and Radio Frequency Ablation (RFA) treatment of tumours.

Although the technology developed under PROBESENS is at an early stage of development into a full commercial product the success of the tests undertaken to date have led to a number of commercial related activities being initiated. A patent has been secured on the original pressure and temperature probe and a company in Galway, Ireland has undertaken commercial licencing for cardiovascular applications. Further interest has also accrued for the use of the probe in Radi Frequency Ablation (RFA). This is a strong indicator the that technology is ready to be developed into a commercial entity which will result in the creation of high end employment in the medical electronics sector in Ireland and potentially across Europe with Intellectual Property Rights (IPR) currently residing with University of Limerick.