Wireless Magnetoelastic Monitoring of Biliary Stents

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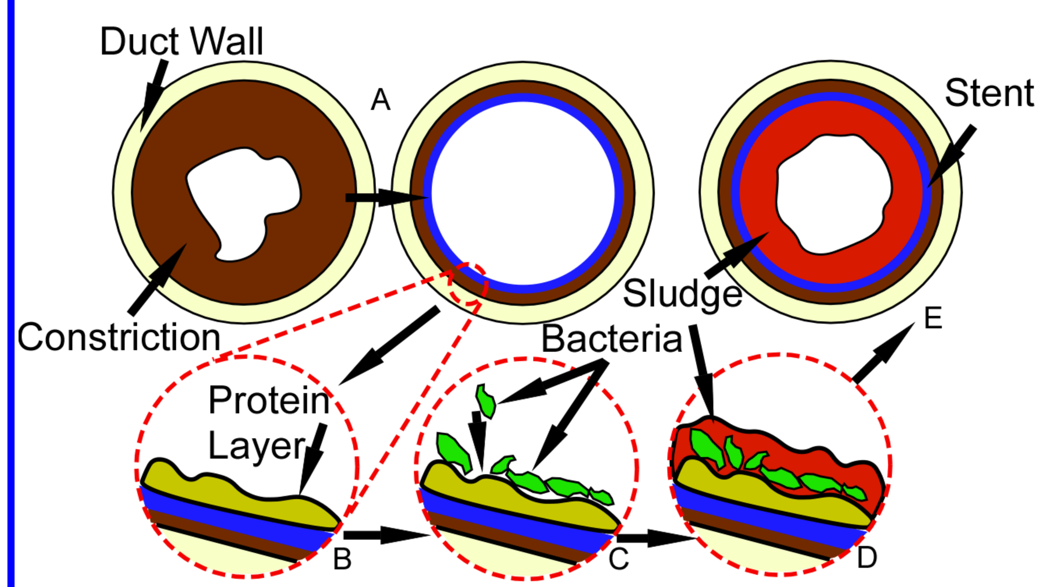
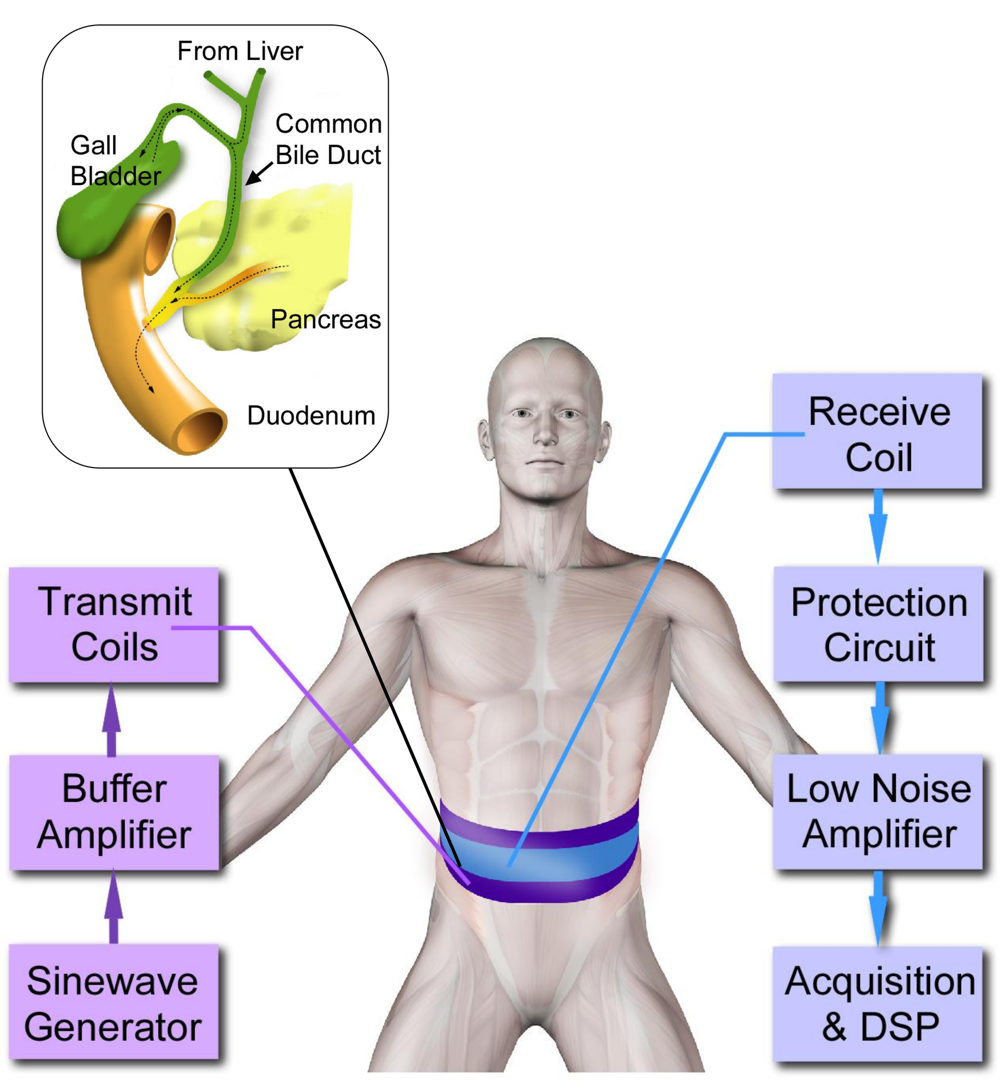
Summary: Stents are intraluminal prostheses used to impart and maintain patency in a variety of otherwise constricted vessels and ducts. Implanting a stent relieves symptoms caused by the constriction, but it will also elicit an immune response that results in the encapsulation of the foreign surfaces. Biliary stents, for example, are commonly used in the bile duct to palliate benign biliary obstructions but the accumulation of biliary "sludge" will clog the duct in 1-6 months. Unfortunately, current medical practice cannot diagnose the biliary obstruction until the blockage becomes significant, which can lead to cholangitis, sepsis, and death. This project seeks to apply wireless integrated sensors in plastic biliary stents to provide a direct, non-invasive measurement of sludge accumulation for timely intervention. The major advance of this work is a "talk and listen" interrogation approach and a series of signal processing steps for measuring resonator ringdown in between transmit periods.

1 MOTIVATION AND CONCEPT



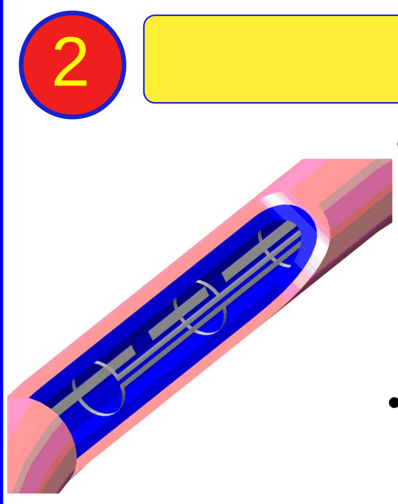


Common Bile Duct:
Common bile duct connects liver and gall bladder to the pancreas and duodenum (upper part of small intestine). Transports bile, which is used in digestive processes, becomes constricted due to tumor ingrowth, cholangitis, or pancreatitis.

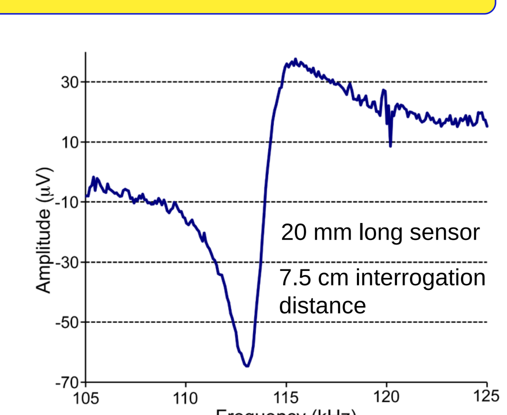
Sludge Accumulation:
After stent implantation, a protein layer forms on the stent surfaces. This promotes the adhesion of bacteria that are normally present in bile. The bacteria congregate and produce "sludge". The sludge clogs the duct in 1-6 months.

Wireless Magnetoelastic Sensing:
A resonant sensor, driven and measured by external coils, is integrated along the inner sidewall of the stent. The sludge accumulation process imparts viscous and mass loads on the sensor, altering the sensor resonant frequency. For optimal response, the sensor must be biased with a DC magnetic field, which can be provided with a layer on the stent.

2 PREVIOUS APPROACH AND RESULTS



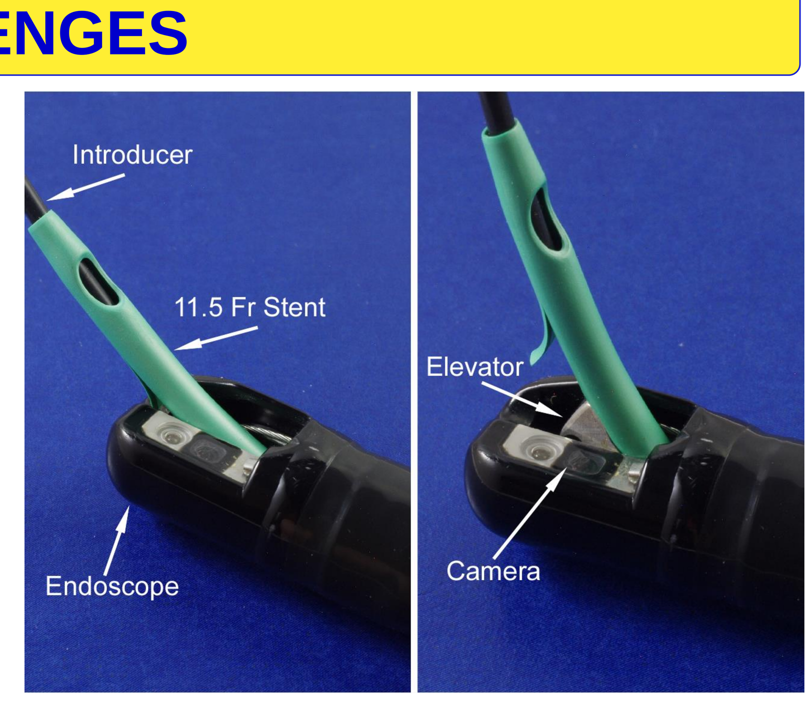
- A three-sensor array of magnetoelastic ribbon-shaped sensors was used. This array was found to be insufficiently protected for endoscopic delivery. A continuous transmit and receive interrogation method was used.
- Measured magnitude response of a 20 mm long resonator. The instrumented stent is full of bile and located in between lobes of the liver of a swine carcass.

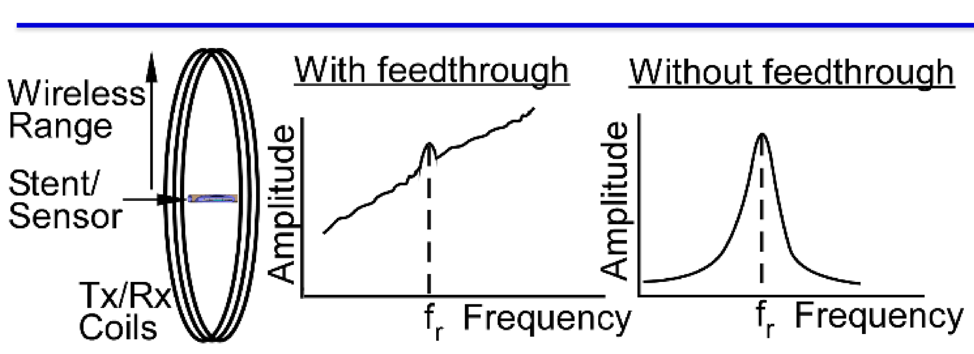


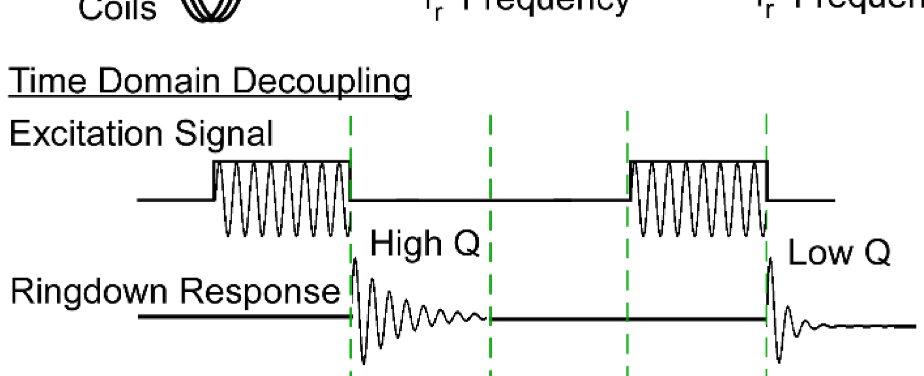
3 CHALLENGES

Implantation Challenges:

- The introducer and the endoscope are used for delivering the biliary stent to the designated position.
- Lifting and lowering the elevator at the open end of the endoscope help to ease the implantation process.
- The sensor and its anchor may be damaged by the introducer and lifted elevator.







Interrogation Challenges:

- The feedthrough of the transmit coil is much larger than the sensor signal, which obscures the sensor signal and disturbs the phase measurement. Time domain decoupling can solve this issue.
- The measured sensor signal reduces dramatically with the increasing interrogation distance so additional signal processing is necessary to recover the signal.

Acknowledgements
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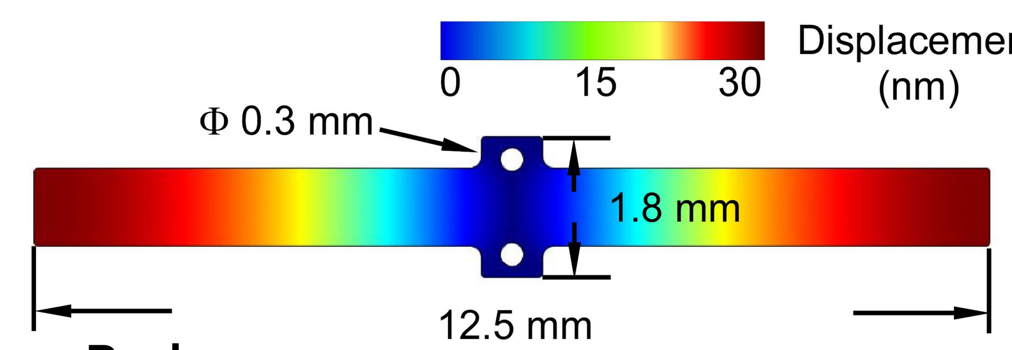
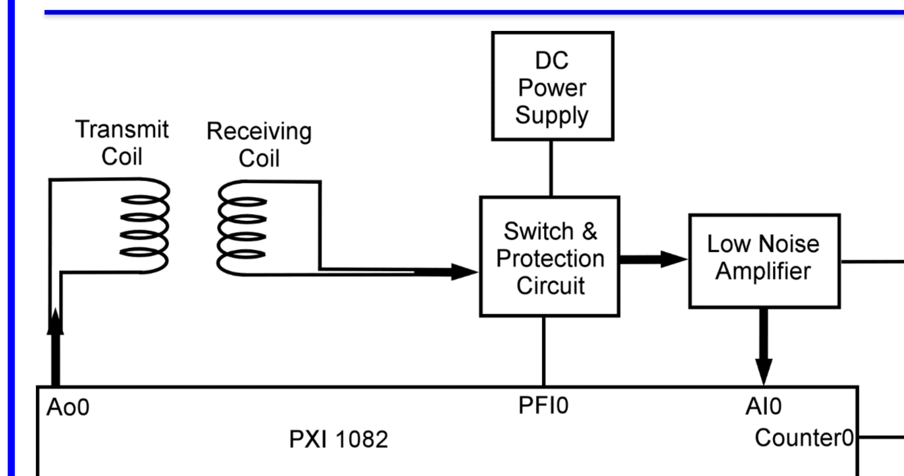
4 SENSOR DESIGN AND INTERROGATION SYSTEM

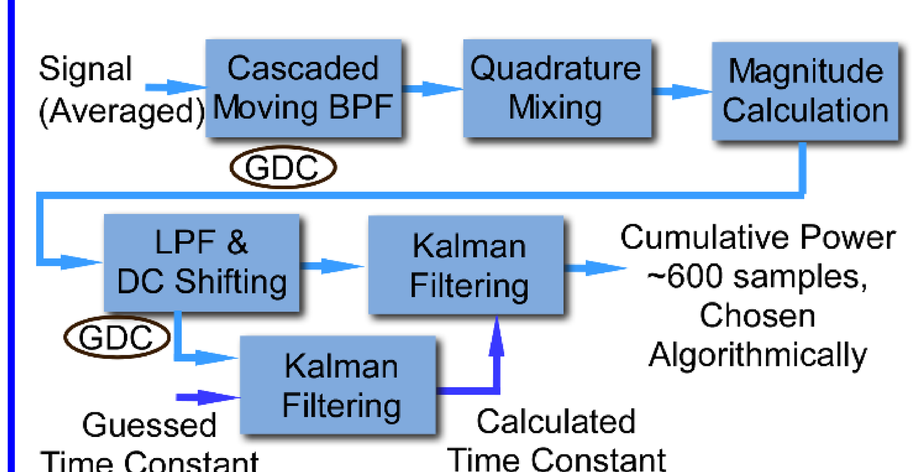
Magnetoelastic Sensor:
Electrical discharge machined (EDMed) winged sensors. Sensor is 12.5 mm x 1 mm x 60 μm, with wire holes in the wings. 100 Å ALD coated Al_2O_3 on both sides.

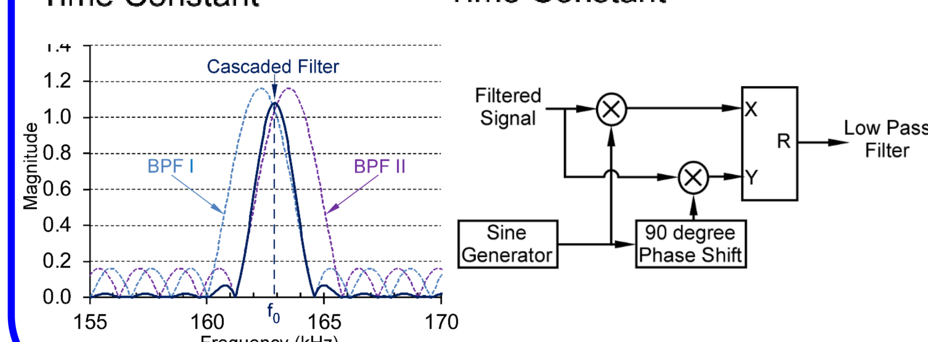


Magnetic Strips:
Two magnetic strips are fixed at the two ends of the sensor tips to provide an optimal magnetic field bias (~400 A/m). The strips are ALD coated and have coercivity of 300 Oe (24 kA/m).

Package:
The sensor and the magnetic strips are packaged in a biocompatible flexible package to prevent damage during the surgery of implantation. Perforations in the package allow fluidic communication to the sensor. The package is then mounted on the inside wall of the stent.



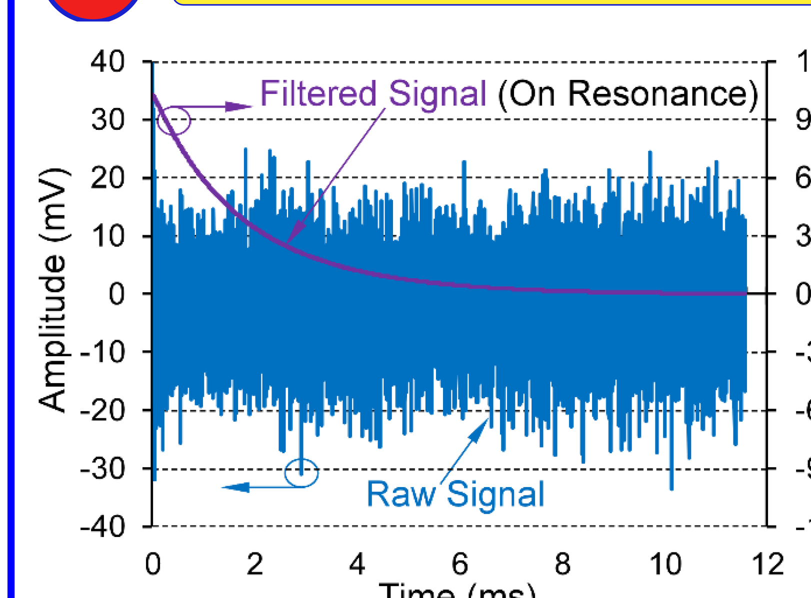


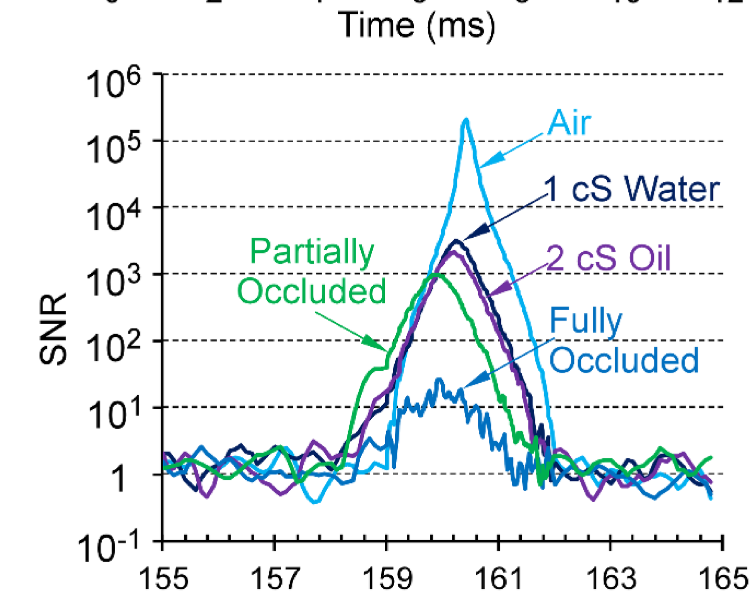


Interrogation System:

- Time domain decoupling is used to avoid the superposition of the excitation magnetic field while measuring the very small sensor response.
- The coils are designed for ease-of-use, and can be placed on a patient like a "belt", with snap-together
- A protection circuit and switch are designed and implemented in order to protect this LNA from any high current flow during the transmission phase.
- A low noise amplifier (LNA) is used in order to improve the received signal to noise ratio.
- A combined signal generator and data acquisition device (Nat. Instr. PXI 1082) is used to generate the excitation signal and acquire and process data.
- Noise reduction methods like averaging, filtering, and quadrature mixing are involved in the signal processing.

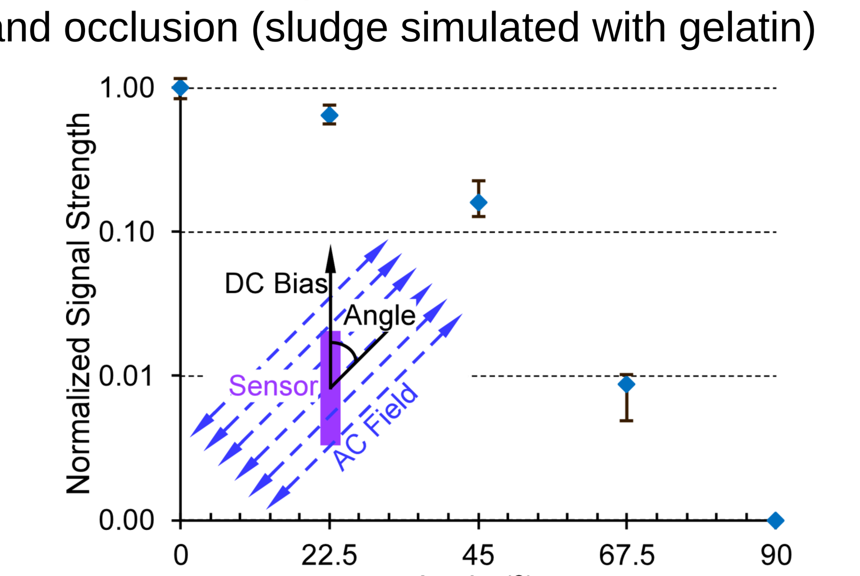
5 EXPERIMENTAL RESULTS

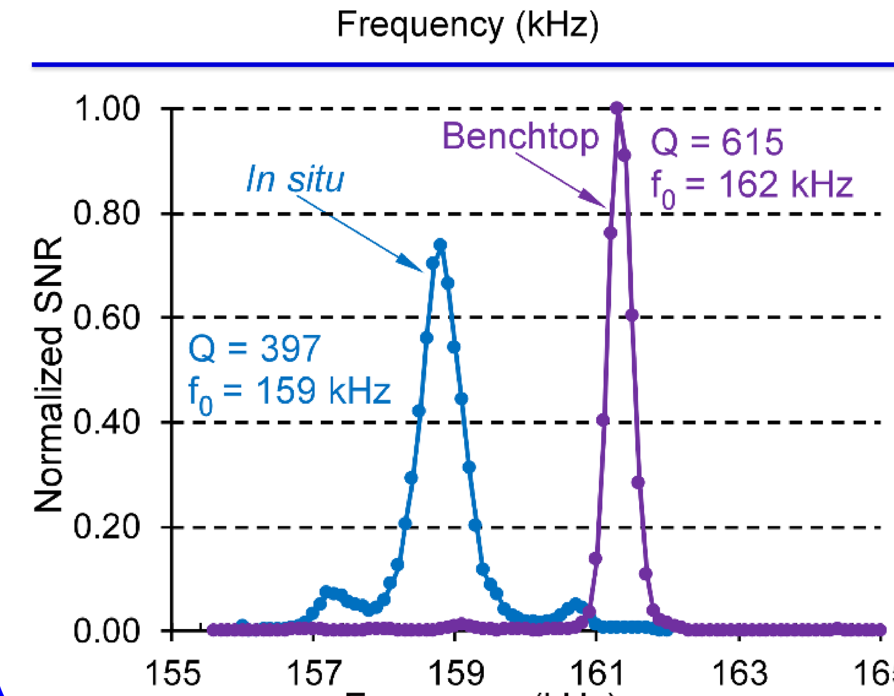




Benchtop Results:

- (Top left) Raw signal (blue) and the filtered signal (purple) after signal processing for a frequency near resonance.
- (Middle right) Normalized sensor signal decreases with increased angle between the sensor and the AC magnetic field.
- (Middle left) The resonant frequency and quality factor of the response is sensitive to viscosity and occlusion (sludge simulated with gelatin)





***In situ* Result:**
•(Bottom right) The fluoroscopic image of an implanted smart plastic biliary stent.
•(Bottom left) Normalized SNR of a sensor-mounted stent in the bile duct, immersed in bile fluid. Wireless range is ≈10 cm.