Disposable fiber-optic sensors for clinical environments

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Throwaway devices may be the key to bringing high-performance sensors to market for use in medical applications.

Optical fiber sensors (OFSs) are attracting attention in the sensing world, especially for use in health-monitoring devices. Their miniature size, good performance in harsh environments, and insensitivity to electromagnetic (EM) and radio-frequency (RF) interference all add to their appeal. But high cost continues to confine them to niches for which other solutions are not feasible, leaving few applications suitable for mass production. Discardable OFSs, however, may represent a unique opportunity for this emerging technology.

Recent advances in minimally invasive medical technologies, such as those that employ disposable instrumented catheters, demand smaller and more reliable sensors for feedback. The minuscule devices required for such interventions must not create distortion and should be insensitive to EM interference from surrounding equipment and surgical tools that use microwave or RF probes. This is especially important now that magnetic resonance imaging (MRI) of soft tissue is coming into wider use in operating theaters. Integrating miniature OFSs in state-of-the-art catheters can meet these challenges.

Still, integrating OFS technology into disposable medical tools is not trivial. It involves a variety of interdependent issues, including optical technology selection, product design and packaging materials, and cost-effective manufacturing and quality control. For instance, the entire sensor assembly must be biocompatible, unaffected by the particular sterilization methods, and resistant to damage from storage or abuse during manipulation. Medical staff will also expect OFSs to be simple ‘plug-and-play’ technology.

In other words, the OFS system should be part and parcel of a more complex device that integrates the advantages of fiber-optic technology. It usually consists of an original equipment manufacturer module (see Figure 1), including the light source and all associated electro-optic components used to measure, process, and communicate the OFS signal. Fully integrating the module into the medical device requires that the system be reliable and simple to use.

As an example, we developed and integrated a custom optical ‘intelligent connector’ (see Figure 2) that identifies the characteristics of the OFS. Our field-proven technology makes the OFS interrogation insensitive to bad sensor connection due to fiber bending or vibration. Moreover, in contrast to light intensity measurement techniques, our white-light Fabry–Pérot (F-P) in-

Continued on next page
Automated assembly line (left) developed by FISO Technologies for medical optical fiber sensors such as the miniature pressure sensor shown on the right.

Interferometric technology offers an absolute measurement of F-P cavity length, independent of light source power variations. In addition, this technology uses multimode fibers typically with a Ø50–100µm fiber core.\textsuperscript{6,7} Compared with other technologies using single-mode fibers (with cores less than Ø10µm), this minimizes adverse effects of dust particles.

As a way to both reduce overall manufacturing costs and increase quality control and product standardization, we also developed automated assembly lines (see Figure 3). Each step of medical sensor production, including packaging and shipping, is performed in a controlled clean room environment. A software system monitors manufacturing steps and maintenance procedures, with in-process and final performance parameters logged into a database for full traceability. This has enabled warranty of quality and certification by regulatory authorities, such as the US Food and Drug Administration and CE Marking.

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References

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