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Block and Pfizer to speed drug manufacturing with laser spectroscopy

Quantum cascade laser (QCL) technology expert and the pharmaceuticals giant sign collaborative agreement.

Block Engineering, the quantum cascade laser (QCL) spectroscopy specialist, has signed a strategic agreement with the "big pharma" firm and Viagra maker Pfizer, under which the two companies plan to develop a new light-based system for use in pharmaceuticals manufacturing.

The aim is to design a real-time, non-contact system for cleaning verification of vessels used in the production process.

Photo: iStockphoto LP

The technology is based on Block's commercially available "LaserScan" analyzer.

According to Block and Pfizer, accurate cleaning verification of those vessels has a significant impact in pharmaceuticals manufacturing, because of the potential health risks of cross-contamination between products.

To ensure that the walls of the vessels meet stringent US Food and Drug Administration (FDA) cleanliness standards, swabs are applied to collect samples for off-line analysis currently. The swabs are then analyzed, typically with wet chemistry instruments like high-pressure liquid chromatography (HPLC) systems.

Those measurements can take several hours or more per vessel - during which time the it usually remains idle, creating a production bottleneck. "The key value proposition of the proposed technology is to eliminate this bottleneck and provide a handheld, battery-operated, barcode-scanner-like device capable of providing real-time, noncontact verification of the cleanliness of the vessel walls," the two companies say.

Using QCL spectroscopy should mean that the manufacturing equipment can be scanned for contamination in just minutes, identifying any areas that require additional cleaning without any need for sampling with swabs.

"Cleaning verification is a critical step in the drug manufacturing process and Pfizer is committed to the development of technologies that could decrease inspection times, reduce costs and improve supply assurance," said Steve Hammond, head of Pfizer's process analytical sciences group (PASG).

Award-winning tech

The QCL technology developed by Block has hitherto been used largely in defense and environmental sensing applications – exploiting the mid-infrared "chemical fingerprint" region of the spectrum in which the QCLs emit. In recognition of those applications, Block won a Prism Award in the "defense and security" category at the Photonics West show in 2011 (this year's winners were announced February 6).

Petros Kotidis, Block Engineering's CEO, commented: "Block's QCL-based infrared spectrometers are opening new markets and cleaning verification is one of the most exciting and high-impact applications. Pfizer's dominant and pioneering position in the introduction of next-generation process analytical technologies will be a critical element in the success of this product."

The expected benefits of the LaserScan equipment at Pfizer include reduced labor, material and consumables costs compared with swab-based verification. According to Pfizer, key initiatives in the pharmaceutical industry today are focused on inventory reduction and "just-in-time" inventory implementation. The QCL system should reduce manufacturing equipment idle time.

Molecular "fingerprint"

LaserScan identifies chemicals by analyzing mid-infrared light from the QCL that is either absorbed or reflected by the target samples. The mid-infrared is excellent for identifying organic chemicals because this part of the spectrum is characterized by the presence of specific vibrational and rotational frequencies of chemical bonds – information that can be used to identify substances accurately via their spectroscopic "fingerprint".

Although conventional lamp-based Fourier Transform infrared (FTIR) spectrometers can be used to extract the same kind of information, they are too bulky for a handheld "barcode reader" style product. The much higher spectral radiance of a QCL also improves detection of highly absorbing chemicals, while its tiny size enables the kind of system miniaturization desired.

Block's handheld devices are based on QCLs covering the 5-14 µm range and mercury cadmium telluride detectors, and are said to deliver measurements in less than a second. Earlier this month the company revealed that its spectrometers were also set to be used by the US Army to identify buried improvized explosive devices (IEDs).

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Sponsored Editorial

Smart Spectrometer Technology expands applications for Miniature Spectrometers

Introduction

Limitations in spectral manipulation, data transfer speed and multichannel measurement capabilities have limited the use of traditional miniature spectrometers for applications that can be particularly demanding. A new "smart" spectrometer technology has been developed based on an embedded processor to improve signal-to-noise ratio, provide a significant enhancement in the speed of transferring data, and deliver simultaneous synchronization of up to 32 channels of data. This smart design (referred to as Exemplar technology) makes these spectrometers ideal for demanding applications such as high speed reaction kinetics, laser-induced breakdown spectroscopy (LIBS), and real-time process monitoring. This innovation is the first of many steps in propelling smart spectrometers to become the new standard across the industry.

Figure 1: Exemplar Series Smart Spectrometers from B&W Tek

On-board Data Processing

Exemplar technology utilizes an embedded processor on board the spectrometer to carry-out data manipulation without having to first send it to an external computer. Some of the many advantages of this approach include:

- Rapid averaging, smoothing, and automatic dark compensation to improve signal-to-noise ratio
- USB 3.0 communication for data transfer at unprecedented speed
- Simple multi-channel configurations with ultra-short trigger delay and gate jitter

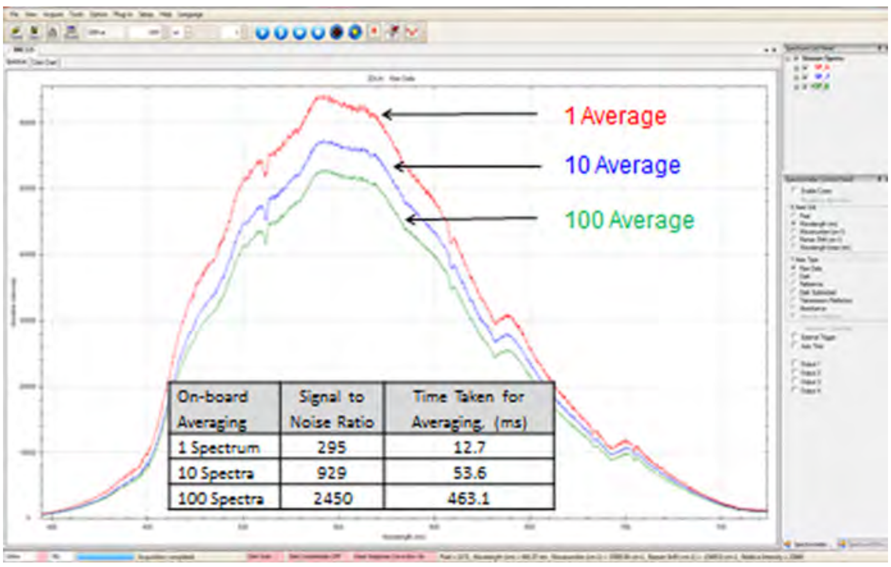
In addition to traditional post data manipulation using an external PC, Exemplar technology offers two state-of-the-art spectral acquisition scan modes:

- **Smart Scan Mode** is used to carry out data processing within the spectrometer's on-board processor
- **Burst Scan Mode** is used to facilitate continuous measurement of kinetic applications

Smart Scan

Smart scan allows for data manipulation to take place in the spectrometer's on-board processor including averaging, smoothing and dark compensation. When a smart scan mode acquisition command is sent to the spectrometer, it will first perform the averaging, then the smoothing, and finally dark compensation.

To demonstrate the advantages of Exemplar technology, 100 spectra were run over a fixed wavelength range of 350-1050nm and the signal to noise ratio of each spectra was calculated, as well as the time needed for each different method of data processing. Figure 2 shows three different sets of spectral data (averaged at 1, 10 and 100 spectra) using a measurement integration time of 1ms showing typical signal to noise ratios and the total time taken to carry-out the averaging using the on-board processor.



On-board Averaging	Signal to Noise Ratio	Time Taken for Averaging, (ms)
1 Spectrum	295	12.7
10 Spectra	929	53.6
100 Spectra	2450	463.1

Figure 2: Average of 1, 10 and 100 spectral scans, with respective time for processing utilizing embedded processing

It can be seen that for 100 spectra to be accumulated, the total time taken is less than 0.5 seconds.

In Table 1, it can be seen that even when smoothing and dark compensation took place, the total processing time to generate the spectral information was only slightly longer than before. Even if 1,000 spectra were chosen, the overall processing time would be less than 5 seconds, which is significantly faster than sending the data to an external computer to be processed. In addition, all of the processing is done in parallel, so even if the number of channels is increased to 32, it will still only take less than 0.5 seconds to average 100 spectra or 5 seconds to average 1000 spectra.

Burst Scan

Burst Scan is the fastest spectral acquisition mode and takes advantage of both the transfer speed of USB 3.0 as well as the spectrometer's on board data storage capabilities. In burst scan mode, data will continuously be sent back to the PC with zero down time between individual spectral acquisitions until the preset number of spectra is reached. For the best results, the minimum integration time should be in the order of 1ms, so that the two events (signal integration and spectral readout) are processed simultaneously. This allows for continuous measurement which is optimal for kinetic applications.

Figure 3 illustrates the timing relationship between the start of the trigger pulse and the integration process. This confirms that there is no down time between integrations, as stated above. To demonstrate this, acquisition frame rates were measured using different integration times, which are summarized in Table 2. At an integration time of 1.05ms, an acquisition frame rate of 936 spectra per second was achieved. This represents approximately one spectrum every

Table 1: Total processing time for on-board averaging, smoothing and dark current compensation				
Processing	Estimated Time Needed (ms)	1 Spectrum	10 Spectra	100 Spectra
Smoothing	23.5	23.5	23.5	23.5
Dark Compensation	7.2	7.2	7.2	7.2
Averaging N Spectra	T = 4.55 x N + 8.13	12.7	53.6	463.1
Total Processing Time (ms)		43.4	84.3	493.8

millisecond with no time gap between consecutive integration periods.

It's also important to emphasize that the trigger delay of this integration process (Td in Figure 3), is equal to 14ns ±1 ns. This extremely fast external trigger mode allows for the synchronizing of up to 32 channels of data simultaneously, without the need to assign primary, secondary or subsequent units or the use of additional hardware or circuitry.

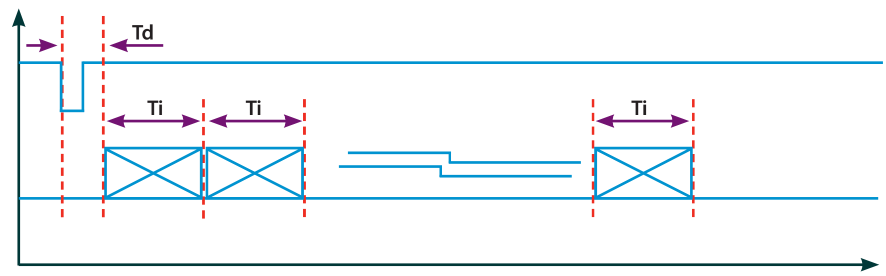


Figure 3: Burst scan mode timing diagram showing relationship between integration time and trigger delay

Table 2: Frame rate as a function of integration time in burst scan mode	
Integration Time (µs)	Frame Rate (spectra/second)
1,050	936.3
1,100	894.4
1,200	821.1
1,500	658.8
2,000	495.5
5,000	199.3
10,000	99.8

Applications that Benefit from Miniature Spectrometers with Embedded Microprocessors

Miniature spectrometers have many advantages over traditional (bench-top) spectrometers due to their compact form factor and high sampling utility. As a result, they have been carrying out routine applications for the past 20 years, including transmission/reflection/absorption studies using UV, Vis, and NIR spectroscopy, Fluorescence spectroscopy, Raman spectroscopy, wavelength identification, and reflected color applications. Additionally, they are commonly used as components which are integrated into larger systems, such as spectrophotometers, portable analyzers and metrology systems. However, they have been restricted in their scope and flexibility due to limitations in computing and data transfer speed. The enhanced capability of "smart" spectrometers using embedded processing has opened up the technology to applications that were previously beyond its capability. It remains to be seen what the practical benefits will be, but some of the more demanding applications that could possibly be addressed by this new development include:

Monitoring the kinetics of a chemical or biochemical reaction: By measuring a distinctive change in the IR or UV absorbance transmission or fluorescence characteristics over time, it is possible to understand when a reaction is complete or a new product has been formed. This is particularly applicable to molecular diagnostic testing where hundreds of samples need to be rapidly tested in micro plate readers in order to measure an expressed protein or organic molecule that confirms a disease, cancer or cell mutation.

Industrial process monitoring using optical and laser-based techniques for quality control purposes: Some of these techniques include on-line surface inspection, 3-D imaging, and fiber-optic sensors as well as spectroscopic and light-scattering process analyzers. The ability to monitor many process lines at the same time is ideally-suited to this technology.

Simultaneous multichannel analysis such as fast fiber optic multichannel spectrometers: For simultaneous measurements of visible and NIR absorption in the confirmation and measurement of defects in crystals, the speed of data capture over a spectral range 400- 1100 nm is critical for the basis for these kinds of experiments.

Time of Flight (TOF) spectroscopy: This method samples all incoming photons at exactly the same moment in time and transmits them to the detector, which requires the rapid simultaneous measurement of the transmitted photons. This process could be easily addressed by the burst scan mode as there is no gap between the two adjacent integration periods and spectral acquisition.

Multi-element analysis using laser induced breakdown spectroscopy (LIBS): This process needs simultaneous detection capability, because the emitted spectral wavelengths that correspond to the elemental fingerprint of a sample have to be detected and measured simultaneously. The ability to synchronously measure up to 32 channels of data would be very advantageous for this measurement regime.

Spectro-radiometric applications: These require high speed binning & sorting for the testing of visible illumination products such as LED, lighting, lamps, bulbs etc. The much faster data transfer capability of the "smart" technology could be well suited for this process.

Conclusion

Miniature spectrometers can offer many advantages over traditional spectrometers due to their compact form factor, high sampling utility and their ability to be optically-configured to meet the application requirements. With the recent development of Exemplar smart spectrometer technology miniature spectrometers have the potential of tapping into applications areas that were never before thought possible.

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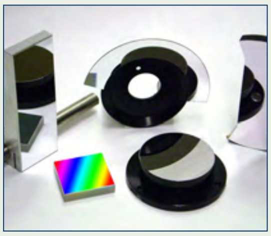

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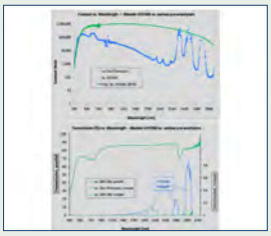

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