



Bioprocess monitoring using the Virsa™ Raman analyser

With thousands of installations in many of the world's leading institutions, Renishaw's Raman systems are now being utilised for real-time monitoring of bioprocessing in accordance with the US FDA's framework on process analytical technologies (PAT).

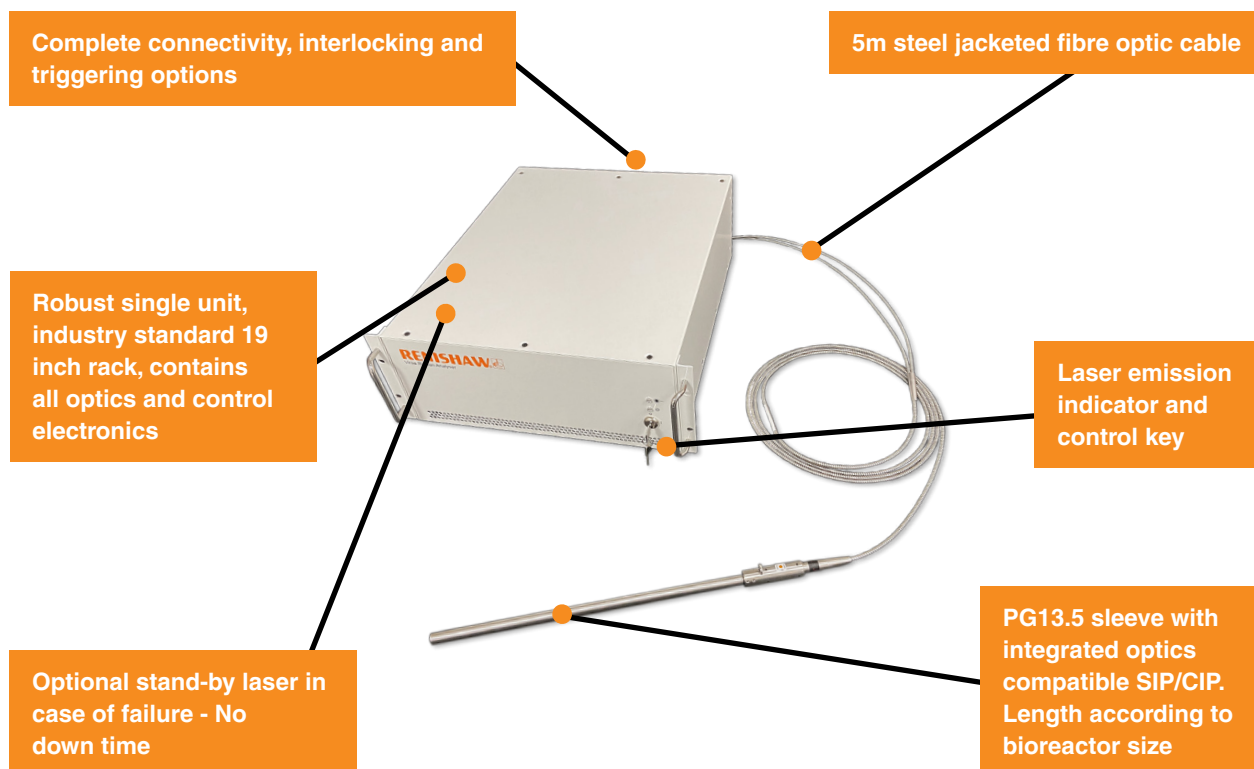
The Renishaw Virsa Raman analyser enables non-destructive measurements of solids, liquids and suspensions providing chemical and structural information. The system is ideal for the analysis of aqueous suspensions of living systems and can accurately measure the concentrations of media components such as glucose and lactate. The Virsa Raman analyser can be easily installed on a variety of different bioprocessing reactors including *in-situ* using an immersion probe or through bags or optical windows.

With the ability to utilise predictive models and our advanced WiRE™ software, our Raman systems enhance understanding of chemical processes, making them particularly suited to PAT strategies in a QbD (Quality by Design) approach to produce biopharmaceuticals. In both upstream and downstream manufacturing, Raman spectroscopy can improve yield and minimise the need for quality assurance by offline techniques such as high-performance liquid chromatography (HPLC).

With a rich heritage at the forefront of Raman instrument technology for over 30 years, backed by a global support structure, Renishaw is a partner you can rely on, now and in the future.

The Virsa Raman analyser

The Virsa analyser is a compact, optical fibre-based spectrometer, engineered for continuous in-situ process monitoring. You can study liquids, without sample preparation, by directly sampling with an immersion probe.

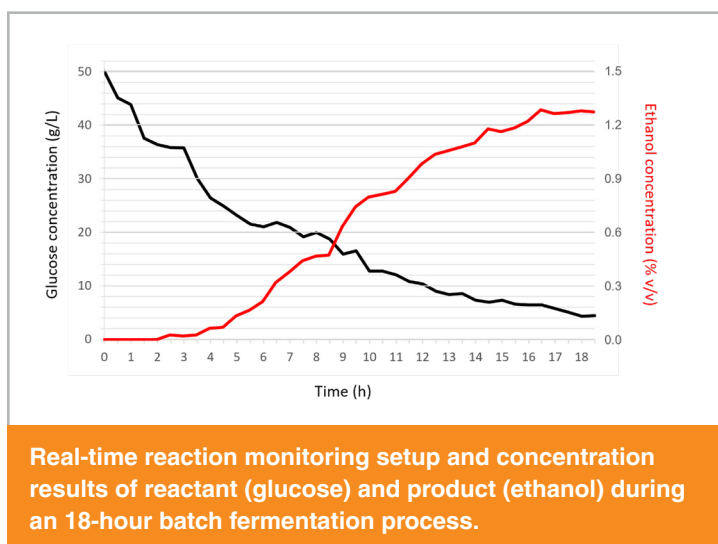


Benefits of the Virsa Raman analyser:

- **Speed:** Best-in-class sensitivity for faster measurement time
- **Accuracy:** Build strong models for better specificity when measuring nutrient and metabolite concentrations, or other key performance indicators (KPI) and critical quality attributes (CQA)
- **Reliability:** Add a stand-by laser to avoid downtime when the primary laser reaches its lifetime
- **Versatility:** Up to two laser wavelengths for the analysis of a wide variety of samples
- **Scalability:** Suitable for small single-use bioreactors to full-scale continuous manufacturing
- **Quality:** In-built spectral calibration on probe without a need for external referencing. IQ/OQ on installation
- **Compliant :** 21 CFR part 11 compliant under GMP environment
- **Support :** Local service and training from a global company. <https://www.renishaw.com/contactraman>

The Virsa analyser in action

The Virsa analyser can continuously monitor the concentration of analytes or metabolites during a bioprocess in real time, using an *in-situ* immersion probe. Continuous monitoring does not perturb the reaction, as Raman spectroscopy is non-destructive and does not interfere with living systems. Adding the Virsa analyser to your fermentation or cell culture vessel to conduct online analysis for real-time quality assurance is easy. In addition this data can be used to control your process.



A configuration that grows with your needs

The highly adaptable Virsa analyser can meet your measurement requirements in combination with:

- Single-use bags through a sterile interface
- Glass or plastic bioreactor through the PG13.5 port
- Stainless steel bioreactors systems through an optical interface

The Virsa analyser offers full transferability and scalability, from laboratory-scale process development, to continuous manufacturing with feedback control loop.

Software

Renishaw's Windows®-based Raman Environment (WiRE™) software controls the acquisition of Raman data with dedicated data processing and analysis options. Renishaw's WiRE software supports compliance with the US FDA's 21 CFR part 11 regulations.

The Monitor™ software module performs spectral analysis based on chemometric models. This produces simple readouts, and trends of required parameters during the process. You can easily monitor changes and reactions in real time. Data is easily transferred to third-party applications for pass/fail criteria or feedback control loops.

External connectivity

Compatible with third party multivariate data analysis and knowledge management software including synTQ and SIMCA®. OPC-UA interfacing is available between the Virsa Raman analyser and process control system in a production environment. You can also control your Raman measurements using simple electronic hardware triggering or fully customisable Python or LabView™ scripts.



When performance really matters, choose Renishaw

We launched our first Raman spectroscopy product in 1992, and have been continuously developing Raman instrumentation ever since. Decades of experience ensure that our products can be trusted to deliver the results you need. Our Raman systems are built with parts manufactured in-house. These are put through extensive and rigorous testing to ensure they are highly stable and reliable.

Please visit www.renishaw.com/virsa for more information.

www.renishaw.com/raman



#renishawraman

+44 (0) 1453 524524  raman@renishaw.com

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