

Single-use Kaiser Raman probes

Available in custom Single-Use Bioreactor and Fermentor BioProcess Containers

Single-use Raman probes from Kaiser Optical Systems, Inc. enable proven process analytical technology (PAT) bioprocessing solutions for Thermo Scientific™ Single-Use Bioreactors (S.U.B.s), while offering flexibility, sterility, and a reduced cleaning burden. Single-use Kaiser Raman probes offer the following benefits:

- **Improved process performance**—enable real-time, continuous measurement and control of the bioprocess
- **Reduced operating costs**—minimize costly consumables and labor-intensive sampling practices
- **Increased repeatability and reliability**—mitigate concerns about excessive downtime and instrument-to-instrument variability
- **Proven technology for bioprocessing applications**—successfully utilized in bioprocessing applications by users since 2009
- **Scalability from process development (PD) to pilot and into cGMP manufacturing**—ensures continuity throughout the product life cycle

Thermo Scientific S.U.B. and Single-Use Fermentor (S.U.F.) BioProcess Containers (BPCs) are now available with single-use Kaiser Raman ports. Single-use ports avoid the need to spend time and labor on sterilizing connections to the BPC; this helps to mitigate process risks by increasing efficiency and significantly reducing contamination risk.



Figure 1. Single-use Kaiser Raman probe integrated into the S.U.B.

The Kaiser SUB-Optic System consists of:

- A disposable Raman S.U.B. port, shown in Figure 1 (Cat. No. SV21446.01)
- A reusable SUB-Optic probe [Kaiser model no. SUB-Optic-2016605 (785 nm) or SUB-Optic-2016676 (1,000 nm)]
- A Kaiser *RamanRxn*™ Analyzer and probe head

Data generated from Kaiser Raman SUB-Optic Systems are identical to data from reusable probes (bIO LAB, bIO PRO shown in Figure 2), allowing easy transfer of multi-attribute Raman methods across various bioreactor types and scale—from PD to cGMP.

The integrated assembly (Figure 1) is rated to process pressures of up to 1 bar (15 psi). The assembly is delivered gamma irradiated from Thermo Fisher Scientific with a protective plastic cap and clamp (Figure 3). The cap is discarded after the probe is mated, and the clamp is used to secure the probe connection (Raman probes are supplied by Kaiser Optical Systems, Inc.).

Specifications: only compatible with Kaiser Raman technology

SUB-barb fitting

Model name	SUB-Barb
Disposable barb fitting surface finish	Ra 16 or better

Materials of construction—wetted, in contact with sample

Stainless steel alloy, 316 L
FDA-compatible window, FDA Drug Master File proprietary design
Adhesive certified to USP Class VI Biocompatible (Certificate of Conformity available from Kaiser Optical Systems, Inc.)

SUB-Optic probe (not supplied by Thermo Fisher)

Model name: SUB-OPTIC-2016605	785 nm
Model name: SUB-OPTIC-2016676	1,000 nm

Temperature range by locations

Window, at tip, SUB-barb	0°C to 100°C
At probe head/fiber cable	-10°C to 70°C

General specifications

Relative humidity	Up to 95% non-condensing
Chemical resistance	Limited by materials of construction
Insertion depth (into the S.U.B.)	0.2 in.

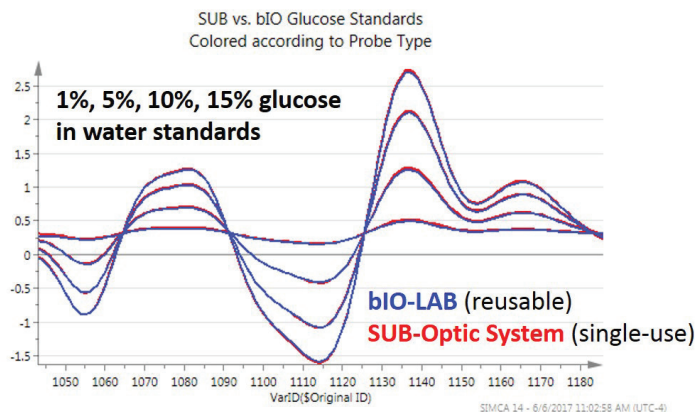


Figure 2. Comparison of SUB-Optic single-use probe data with bIO-LAB and bIO-PRO reusable probe data.

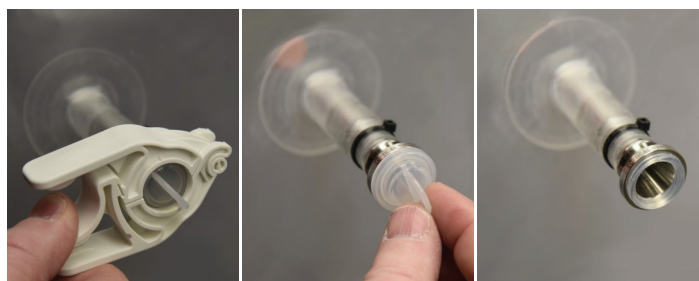


Figure 3. Disposable Kaiser Raman port, preinstalled and gamma irradiated, in the S.U.B. BPC.

- **Transmitter:** The transmitter (Kaiser *RamanRxn* Analyzer system) is not part of Thermo Fisher's scope of supply. Contact your Kaiser Optical Systems, Inc. representative.
- **Calibration:** Calibration specific to your application may be different. Refer to the probe manual or contact your Kaiser Optical Systems, Inc. representative.
- **Qualification:** Some of the qualifications of the probe port in S.U.B. BPCs included 20 Raman ports that were assembled on S.U.B. BPCs, irradiated, and aged using an accelerated aging process before testing.
- **Testing:** Probe assemblies were pressure tested to ensure that the assemblies were leak-free. All assemblies met the pressure requirement of 15 psi without leaking. Pressure tests were done at the Thermo Fisher Scientific facility in Logan, Utah. Other assemblies were subjected to leak and performance tests at Kaiser Optical Systems, Inc. All assemblies passed the defined test criteria.

Find out more at thermofisher.com/sut