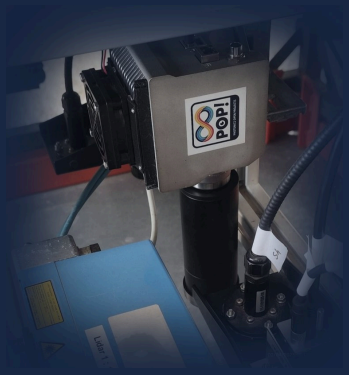
PHARMACEUTICAL · COSMETICS · R&D AND FORMULATION

# PRO-PIX

PHOTONICS OPEN PROJECTS



## FROM MEASUREMENT TO DECISION

**CAPABILITY**
Localised measurement, without contact or preparation

**MEASUREMENT**
One spectrum per zone, the sample stays available

**USE**
Identity, homogeneity, batch-to-batch comparison

**DECISION**
Pursue, adjust or drop a formulation avenue

## BEFORE / AFTER

| | |
|---|---|
| Destructive test | → **Sample kept for other analyses** |
| Sampling then deferred analysis | → **Immediate measurement on the material** |
| Average result over the sample | → **Measurement zone by zone** |
| Method fixed inside the instrument | → **Your algorithms embedded in the sensor** |

## WHICH MATERIAL, AND WHICH MEASUREMENT QUESTION?

Send us a sample and the question you are asking. We assess whether spectral measurement can answer it, under whatever contractual terms you set.

**Tel.** +33 7 83 41 41 36
sales@photonics-open-projects.com
**www.photonics-open-projects.com**

# Characterise a formulation without using up the sample or waiting for the laboratory.

*"Localised spectral characterisation, without contact or preparation, for your formulation and upstream control work."*

## 1 CURRENT LIMITATIONS

- **Today, the identity and homogeneity of a material are verified by sampling.** The analysis goes to the laboratory and consumes the sample.
  In development, every check removes material otherwise available for trials.
- **The homogeneity of a blend or a distribution cannot be judged by eye.** A visual check says nothing about how the constituents are really distributed.
  Local heterogeneity is found late, often at finished-product stage.
- **In formulation, the number of trials is the limiting factor.** Every characterisation costs time and material.
  The number of avenues explored narrows as development proceeds.

## 2 ADDRESSED MEASUREMENT

**1 OBSERVATION**
The sample or the surface, through a built-in 1080 px RGB camera that keeps its image.

**2 SEGMENTATION AND MEASUREMENT**
A segmentation model delineates the zones to analyse; the spectrometer measures each of them, in VIS/NIR or SWIR.

**3 RESULT**
One spectrum per zone, analysed on board and compared with the other zones: the scatter is available during the trial.

## 3 PRIORITY APPLICATIONS

### RAW MATERIAL IDENTITY CHECKS

**SITUATION** Goods-in, before release to development or production.
**MEASURED** Measurement on a sample, compared against a library you build yourself.
**RESULT** A supported identification, without consuming the sample.

**Rule out a material or grade error upstream of formulation.**

### HOMOGENEITY ASSESSMENT

**SITUATION** On a single surface: blend, deposit, distribution of a constituent.
**MEASURED** Measurement of several distinct zones, compared with one another.
**RESULT** A measured scatter between zones, with the image to support it.

**Locate spatial heterogeneity rather than merely suspect it.**

### FORMULATION MONITORING IN DEVELOPMENT

**SITUATION** At the bench, across the successive trials of a single campaign.
**MEASURED** Repeated measurements to a constant protocol, RGB reference retained.
**RESULT** A spectral trajectory across the formulation variants.

**Document the effect of a change without destroying the trials.**

### BATCH-TO-BATCH AND FINISHED-PRODUCT COMPARISON

**SITUATION** Upstream control or late development, on defined zones.
**MEASURED** Contactless measurement, to an identical protocol for every batch.
**RESULT** A stable basis for comparison, independent of the operator.

**Support a decision to continue, adjust or select.**

## WHAT CHANGES

**01 ON-BOARD ANALYSIS**
The scatter between zones is available during the trial.

**02 CONTACTLESS**
No preparation, no sampling: the specimen stays usable.

**03 LOCALISED MEASUREMENT**
One spectrum per identified zone, rather than a single average.

**04 PROPRIETARY METHOD**
Your analysis algorithms are implemented inside the sensor.

TECHNOLOGY LICENSED FROM ARVALIS / PHOTONICS BRETAGNE

# SPEC. PRO-PIX

PHARMACEUTICAL · COSMETICS · R&D AND FORMULATION

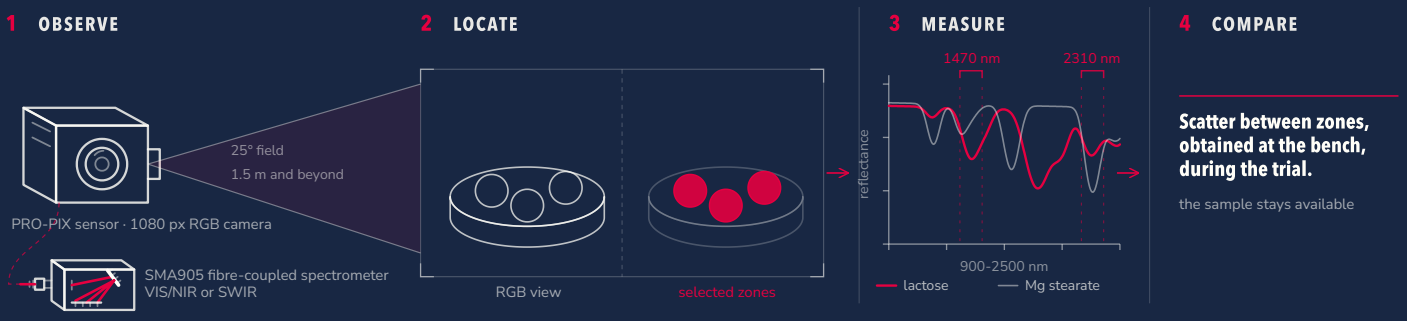
- **Your on-board algorithms remain your property**
- **Method proven on ONE-PIX, transferred to PRO-PIX**
- **OEM white-label integration**
- **Designed and made in France, in Lannion**

## SPECIFICATIONS

| SPECIFICATION | PRO-PIX VIS/NIR | PRO-PIX SWIR |
|---|---|---|
| **Typical spectral range*** | 400-1000 nm<br>*The range is chosen to suit the spectral question.* | 900-2500 nm |
| **Spectral resolution*** | 0.5 nm typical (0.06 to 20 nm depending on configuration)<br>*The finer the resolution, the better the discrimination and the longer the integration time.* | |
| **Built-in RGB camera** | 1080 px, segmentation and colour reference | |
| **Measurement and analysis rate**** | 4 to 10 Hz at best<br>*Segmentation, measurement and analysis included: this is the rate at which usable data leaves the sensor.* | |
| **Typical working distance / FOV** | 1.5 m to infinity / 25° | |
| **Connectivity / Power** | GigE / xVolt battery or PoE | |
| **Dimensions / Weight***** | 125 × 90 × 90 mm / < 700 g | |
| **Regulatory status** | Measuring instrument: neither qualified, validated nor certified | |

* depending on the spectrometer selected. ** depending on the number of clusters and the segmentation and integration times. *** excluding the remote optical head

## OPERATING PRINCIPLE: ADDRESSED MEASUREMENT




1 RGB observation · 2 zone segmentation · 3 addressed spectral measurement · 4 on-board analysis inside the sensor, 4 to 10 Hz

## STATE OF THE ART

**PRO-PIX has no published case study in this sector yet. Near-infrared spectroscopy has, however, established:**

- NIRS is used across the pharmaceutical industry, from raw material identification to finished-product control, including as process analytical technology.
  *Reviews of NIR and chemometric applications in pharmaceutical technology*
- Blend homogeneity monitoring by NIRS has been demonstrated live on a blender, with relative standard deviations of 1.0 to 2.5 % depending on active ingredient concentration.
  *Characterisation of pharmaceutical powder blends by NIR*
- Excipient identification by spectral library (magnesium stearate, mannitol, talc, lactose, starch, microcrystalline cellulose) is an established NIR application.
  *NIR spectra of common pharmaceutical excipients*
- The technique is covered by pharmacopoeial general chapters: Ph. Eur. 2.2.40 and USP <1119>, now <1856>.
  *European Pharmacopoeia and United States Pharmacopeia*

## WHO FOR?

- **Formulation engineers**: compare formulations without destroying the samples.
- **Laboratory and analytical methods**: prepare an NIR method ahead of any qualification.
- **Process and industrial development**: characterise an incoming raw material.

## CONDITIONS AND LIMITS OF USE

- **PRO-PIX is an instrument for characterisation and development.** It is neither qualified, validated nor certified against any pharmaceutical or cosmetic standard: its qualification and the validation of any method are yours to carry out.
- **Looking to distribute a qualified version?** Let's work together: we can build the instrument's qualification pathway with you, within your own standard.
- Working distance from 1.5 m; 4 to 10 Hz at best.
- The discrimination available is that of a spectrometer at the chosen resolution: it is established on your own materials.

## SEND US A MATERIAL AND A QUESTION.

Feasibility study on your samples, under a confidentiality agreement. Sensor delivered within three months. Rental is available for an evaluation in real conditions.

### WHAT TO SEND US

→ A representative sample
→ The measurement question being asked
→ The confidentiality terms you require

**Tel.** +33 7 83 41 41 36 · sales@photonics-open-projects.com · **www.photonics-open-projects.com** · 4 rue Louis de Broglie, 22300 Lannion, France
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