



Headspace Gas Analysis – Technology and Solutions

Lugano, November 19th, 2019

Scope

HeadSpace Analysis - HSA

Definition:

- Non-destructive & Non-invasive monitoring of headspace gases

Applications:

- Glass Packages (tubing, molded, clear, amber)
- Plastic Packages optically non-transparent to a NIR laser radiation
- Sterile parenteral products as O₂ sensitive / Lyo under modified atmosphere or vacuum

Target:

- Ensuring sterility and stability of product/package:
- Confirm Container Closure Integrity
- Keep under control the primary packaging process (filling + stoppering)

Scope

HeadSpace Analysis - HSA

Criticality of headspace composition:

- Any modification in the headspace pressure, moisture, oxygen and/or carbon dioxide levels may result in active drug degradation, likewise in the reduction of drug potency and product shelf life
- For products that demand package headspace content preservation, it is appropriate that the integrity test for stability studies verify the continued presence of specific headspace gases or sub-atmospheric pressure over time

Applications:

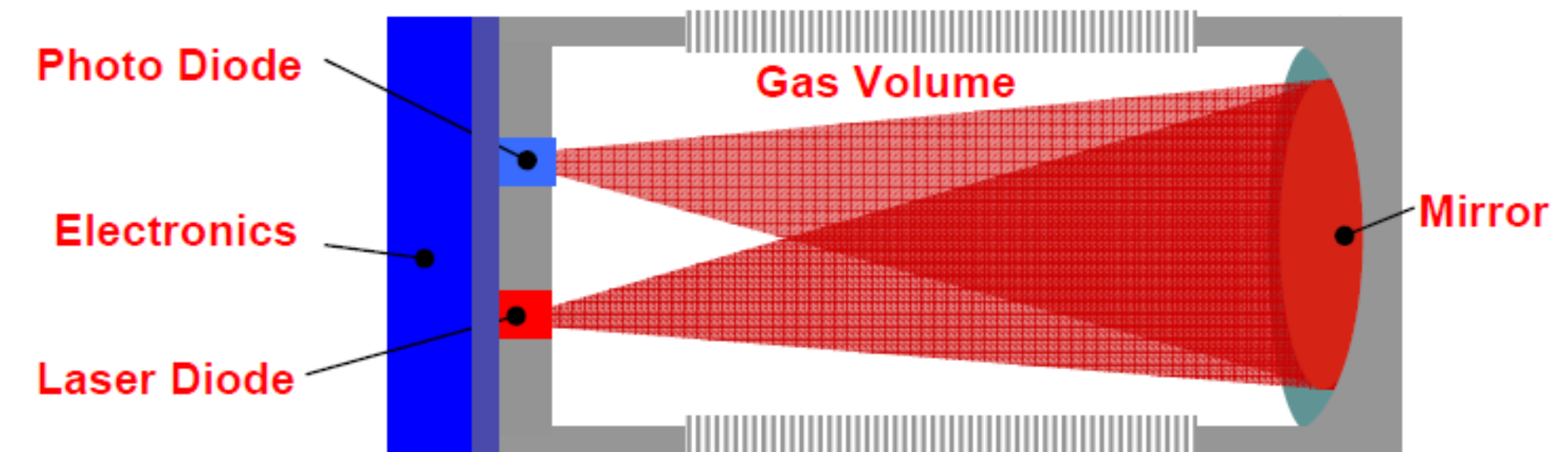
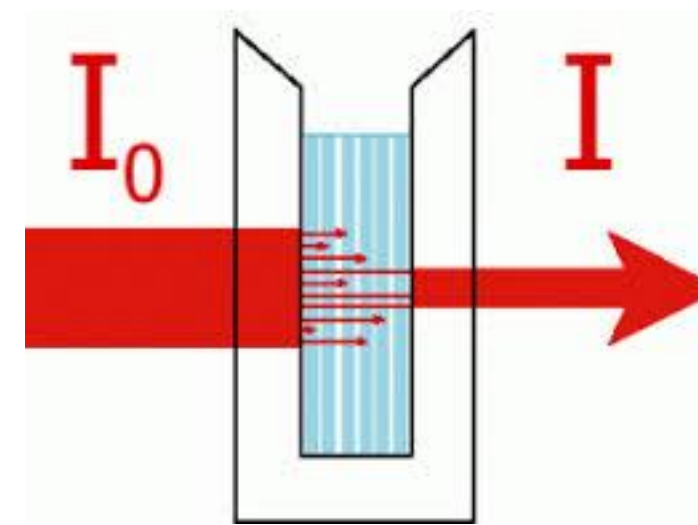
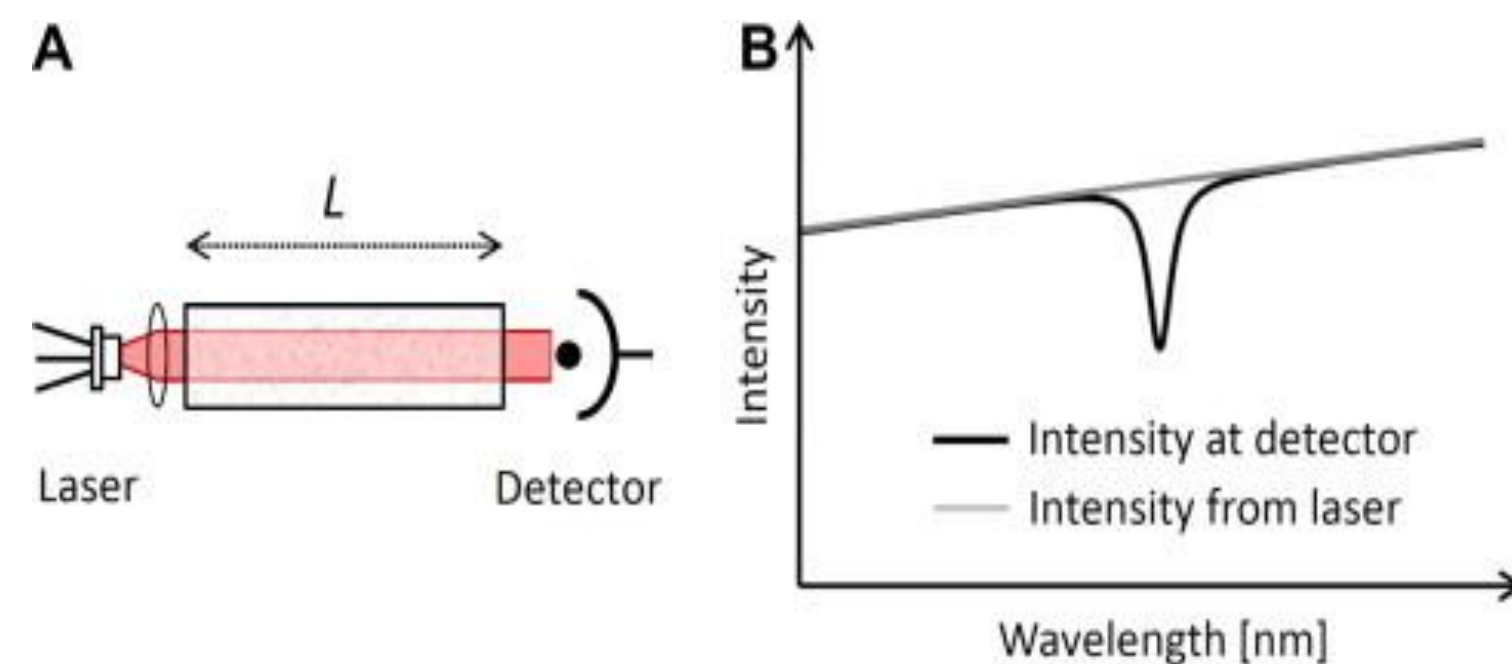
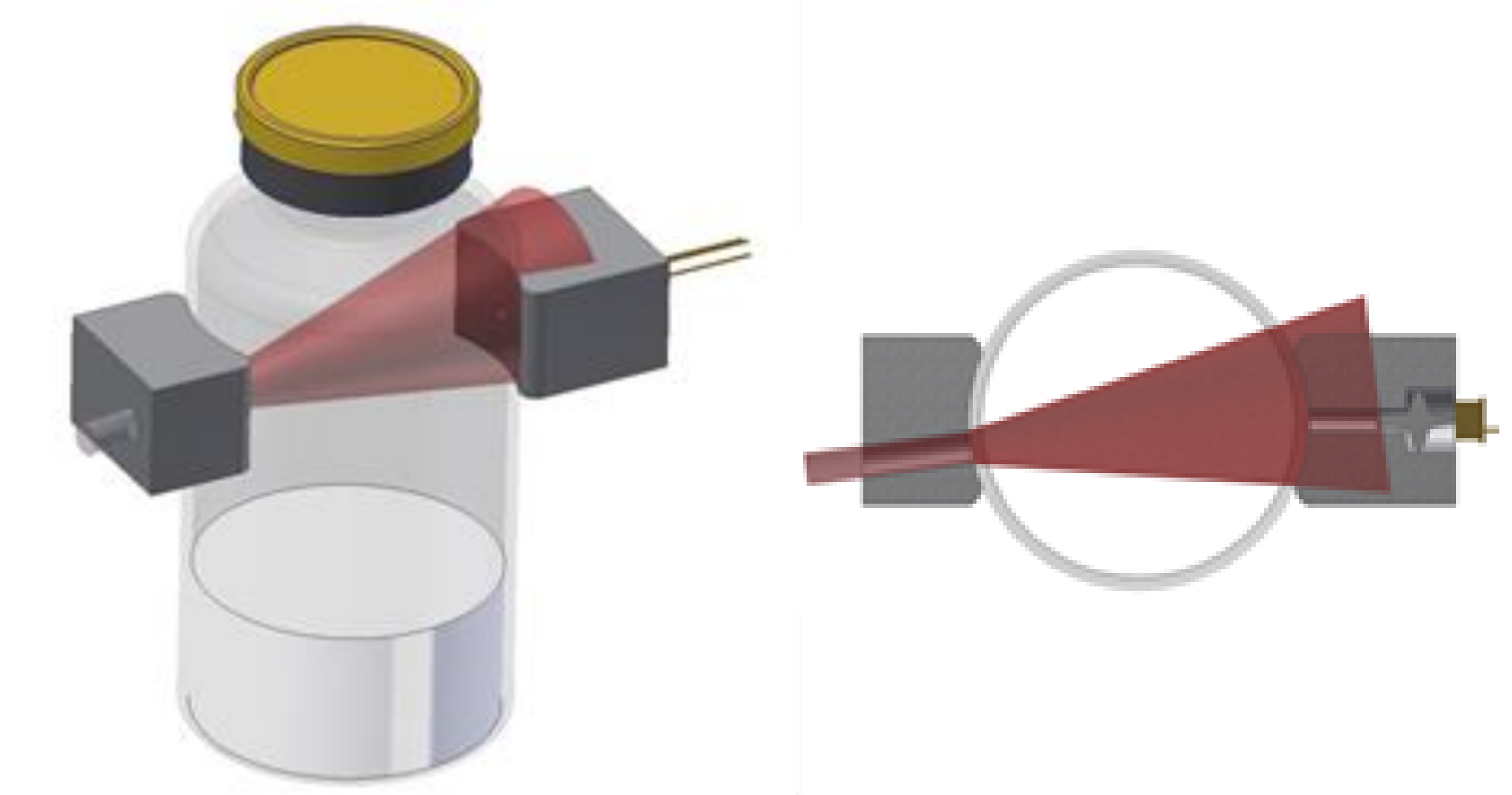
- Headspace critical content verification can be performed through the entire product life cycle, from stability studies to commercial production stage
 - ✓ 100% Online
 - ✓ IPC
 - ✓ Laboratory
 - ✓ R&D
 - ✓ Clinical trials

HeadSpace Analysis - HSA

Technology

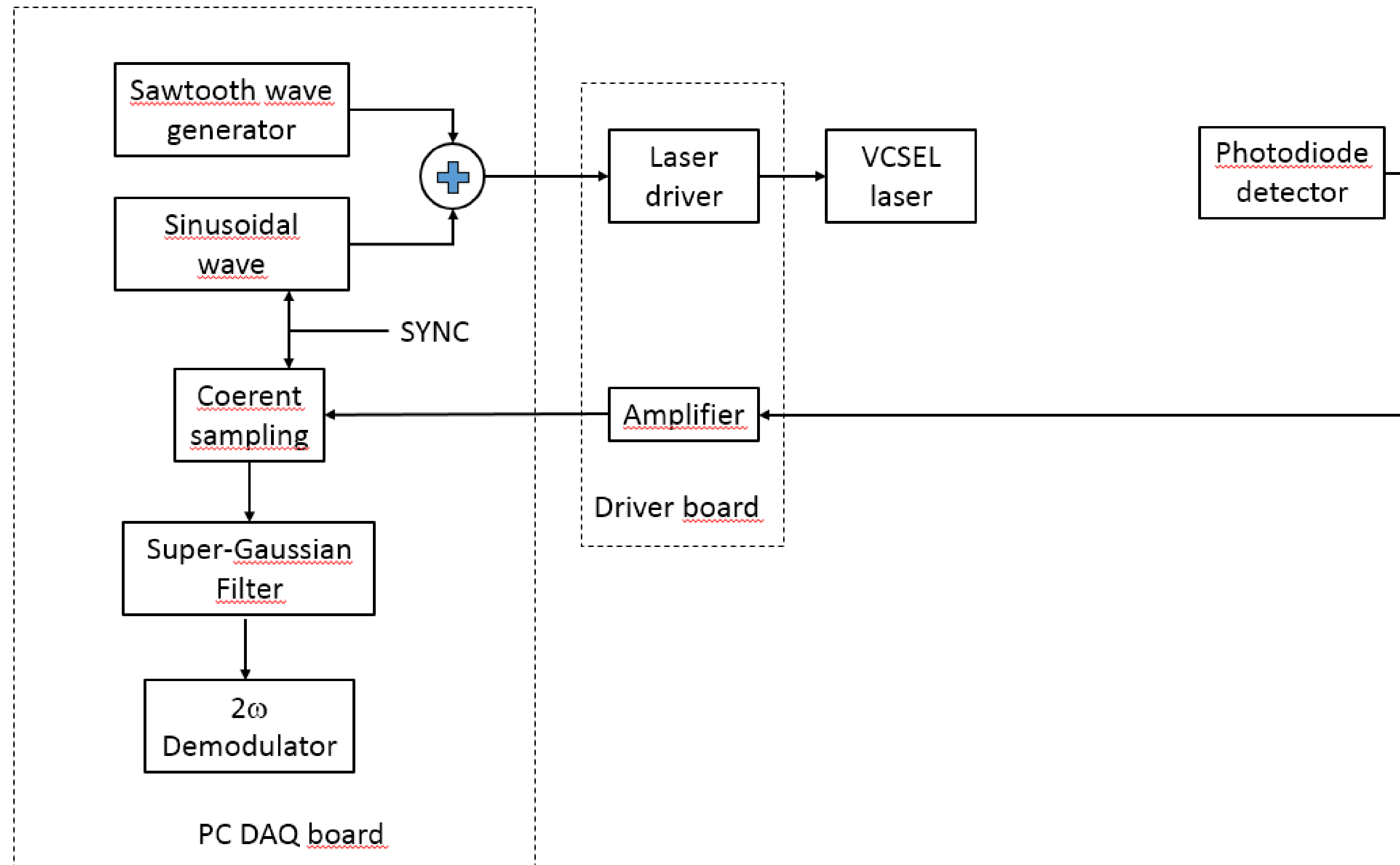
Principle of Operation:

- A diode laser beam is transmitted through the container in the region above the product and below the cap/closure (headspace)
- Laser beam is then received by a detector
- The amount of light absorbed while crossing the headspace is measured and related to the target gas concentration
- The Absorption is a quantitative measurement of the gas concentration
- Absorption $A = \log_{10} (I_0/I)$ (Lambert – Beer law)



HeadSpace Analysis - HSA

Hardware System



HeadSpace Analysis - HSA

Xepics offering

Xepics HSA solutions are ranging between:

- Laboratory unit – batch processing and laboratory inspection
- Production equipment – offering 100% inspection capability
 - ✓ On-line / Off-line
 - ✓ Multiple laser units can be installed

Laboratory Equipment – HSA Lab:

- 1 or optionally 2 laser units can be installed
 - ✓ Oxygen + Moisture measurement – maximum flexibility
 - ✓ Oxygen + Oxygen – higher accuracy and resolution

100% Production Equipment – HSA 120, HSA 400:

- Production speed 120 cpm or 400 cpm
- On-line (Conveyor in-out) / Off-line (Tray in-out) configuration
- Multiple laser units can be installed

HSA Lab

Equipment



HSA Lab

Specifications

Nominal Specifications

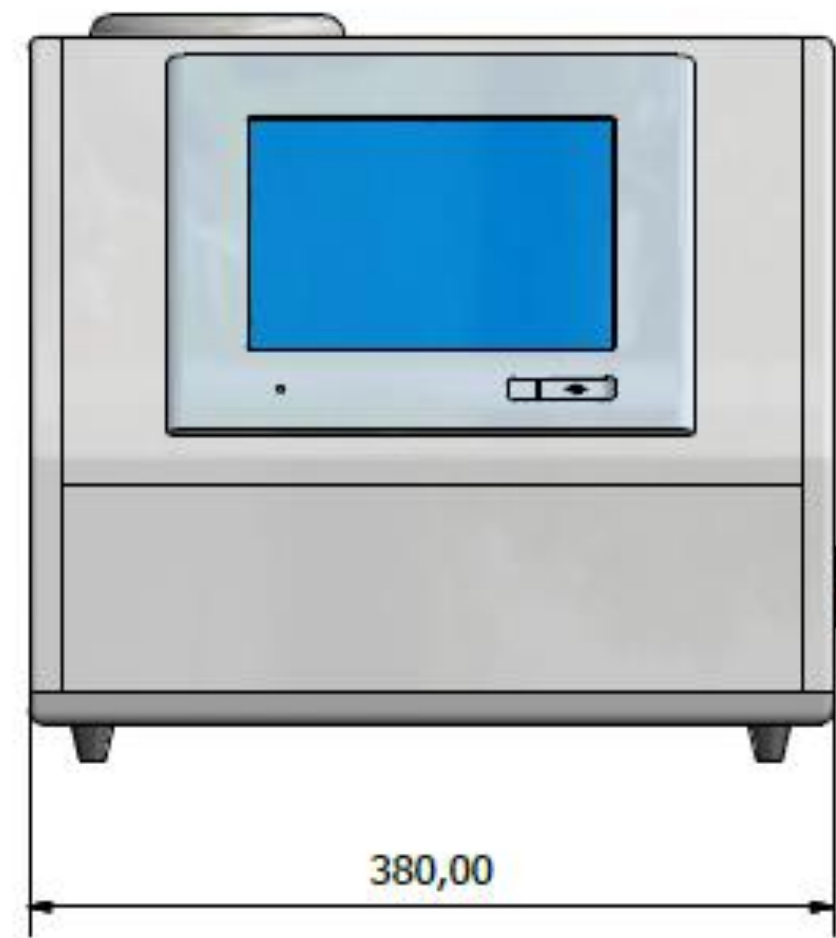
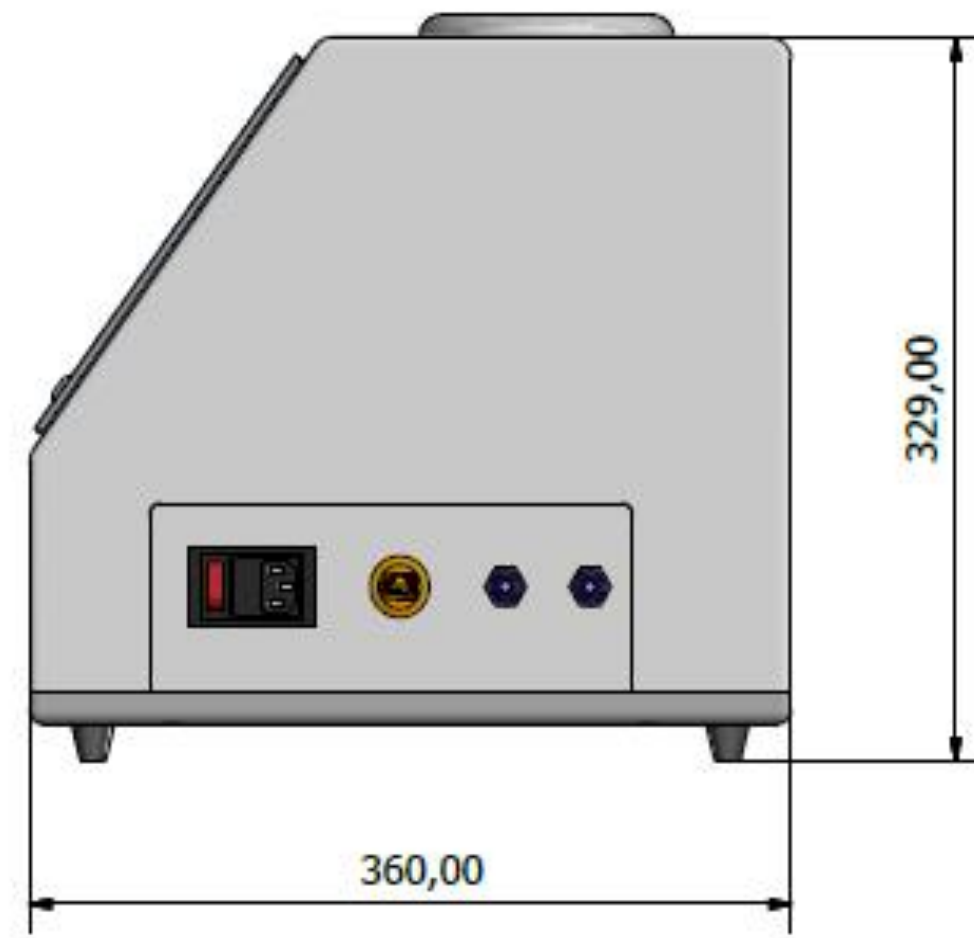
Containers to be processed	Ampoule, Vial, Cartridge, Bottle, Prefilled Syringe
Container content:	Liquid, Freeze Dried, Powder
Container material	Glass (clear and / or amber)
Container sizes:	8 to 52 mm in diameter
	35 to 110 mm in height
Container type	Tubular, Molded
Fill volume:	1 to 100ml

Technical Specifications

Equipment dimensions (WxDxH)	380 x 360 x 329 mm
Equipment weight	14 kg
Power supply requirements	110-240 VAC, 50-60Hz, 1 kW
Format mechanical components material	White Derlin, self-lubricated
	FDA approved material
Operating system	Windows 10 IOT
HMI	Touch screen 8”
Network communication	Ethernet

HSA Lab

Benefits and Differentiators



Advantages:

- Robust proprietary technology
- Non-destructive, non-invasive inspection of liquid, lyo and powder filled packages
- Lower standard deviation can be achieved by increasing inspection time
- Applicable to vials, ampoules, cartridges, syringes, bottles with different headspace composition
- Suitable for different glass colors (amber, clear) and types (tubular, molded)
- HSA Lab can accommodate up to 2 Laser Units

HSA Lab

System Built



Relevant Features:

- Applicable for R&D, clinical trials and IPC operations
- Motorized vertical lift for package loading and rotation during inspection
- Wide range of package sizes: ϕ [8-52]mm, \updownarrow up to 110mm
- HQ components: all parts ensure long lifespan even with 24/7 use
- Intuitive and designed for super simple operation
- Extremely compact design, superior cleanability, scratch resistance
- The container holder ensures stable placement during inspection and provides for a container rotation on its axis if needed
- Connection to nitrogen or dry air supply for purging the inspection volume is available



How to Get in Touch



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