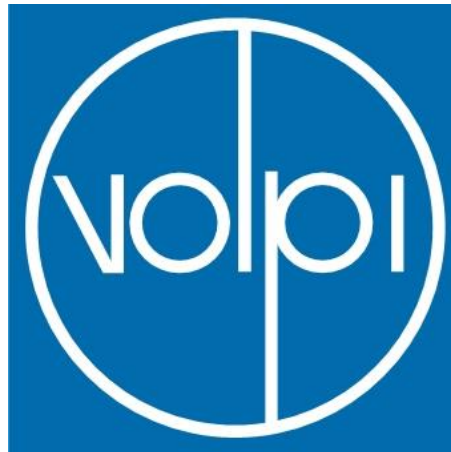
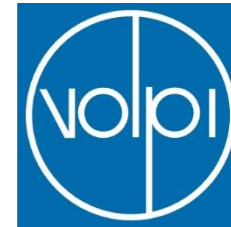


Volpi – Ihr Partner für Lichtsysteme

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Light is Vision



Light is Vision

Life Science Tools and In-Vitro Diagnostics

Challenges for industrialization of OEM-solutions

Volpi – The Optical Key to Your Application

Set-up:

- Development and production in Switzerland and the USA
- About 100 employees, hereof 15% in development and engineering
- Certified against ISO 9001 and ISO 13485

Key capabilities:

- Systems engineering and manufacturing of optical modules and instruments
- Light emission – light transmission – light detection – data pre-processing
- Glass fiber drawing, mixing and assembly



Volpi USA, Auburn, NY



Volpi AG, Zurich, CH

Trends in IVD-instrumentation

Megatrends:

- Diagnostic result generation closer to the patient treatment
- Reduction of cost per diagnostic result

Requirements in instrumentation:

- Higher sample throughput
- Higher functional integration in modules
- Price reduction

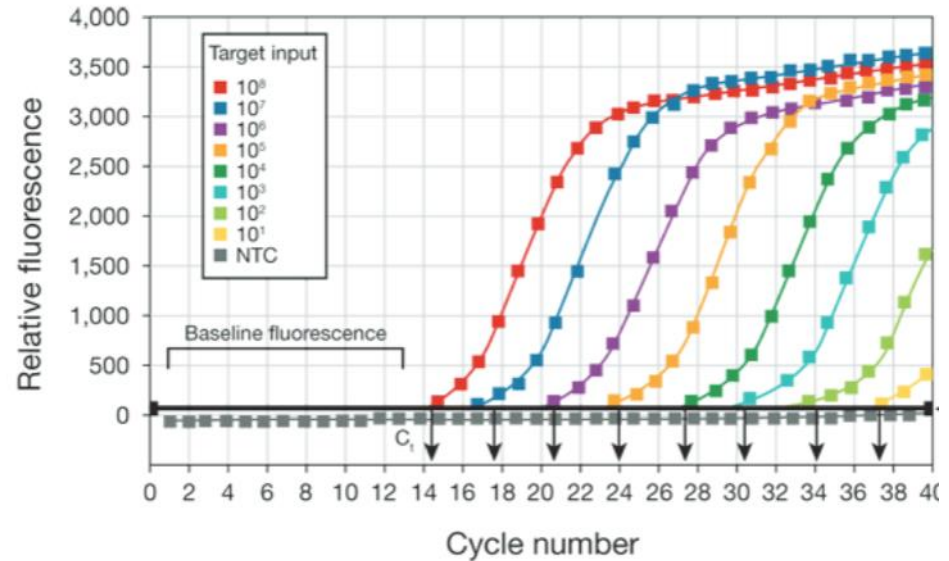
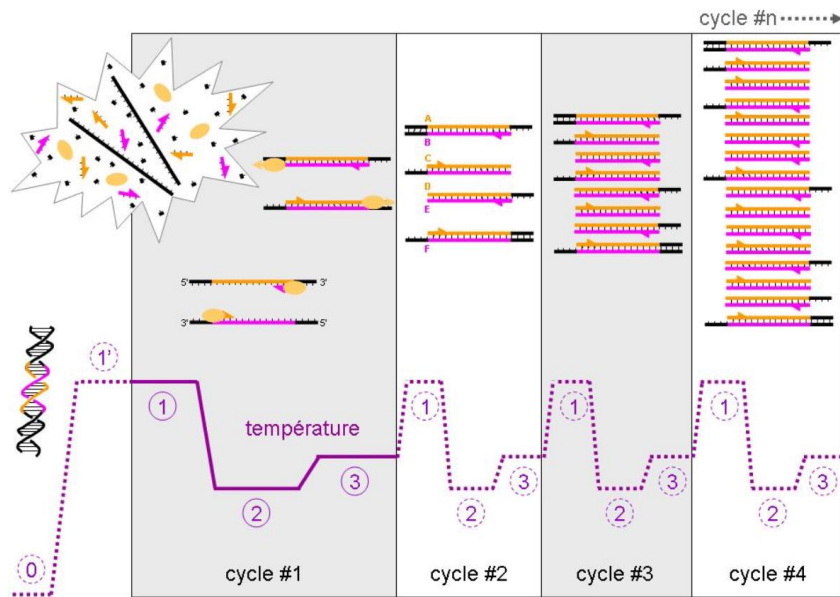
Optical throughput as a consequence for optical systems:

- Use of high NA systems
- Fast moving measurement heads or multiplexed solutions
- Good suppression of parasitic signals

Cost reduction as a consequence for modules:

- Use of Off-the shelf components (using scale effects in manufacturing & sourcing)
- Focus on efficiency in assembly processes (LEAN workflows)
- Plastic parts & housings (injection molded or 3D-printed)

qPCR-instrumentation as an example for demanding local environmental conditions in IVD.

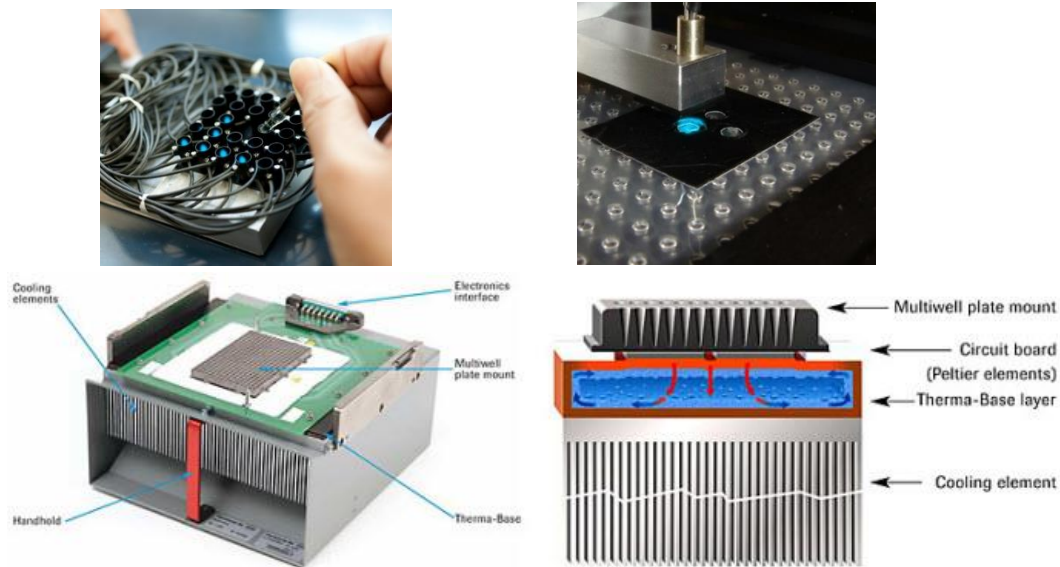


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Key constrains from methodology:

- For each sample the fluorescence intensity has to be read within every process cycle.
- A high reproducibility of measurement results is mandatory for the diagnostic application.
- A system performance validation has to be integrates in the measurement protocol.

The local environment of the optical measurement head contains strong varying heat sources.

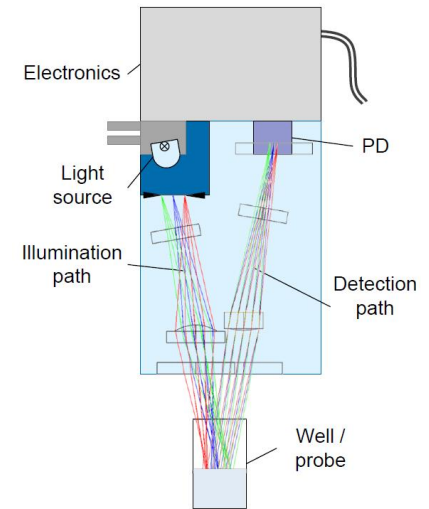
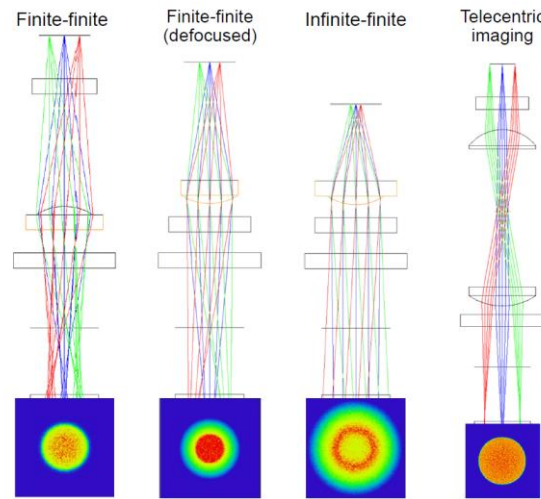
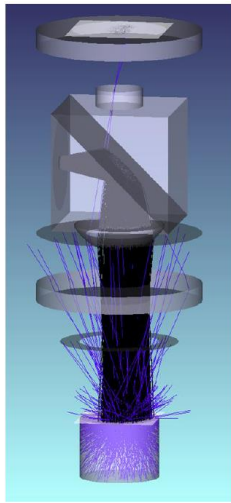


<http://lifescience.roche.com/shop/PrintView?langId=-1&storeId=15016&articleId=67502>

Key environmental constraints for measurement head:

- The sample volumes to be detected are small due to their intrinsic thermal mass.
- The pick-up head must comprise a small envelope defined by the microwell plate spacing.
- The measurement head is exposed to cyclic temperature changes in the vicinity by the active sample heating & cooling system.

Typical optical system concepts are designed for illumination uniformity and pick-up efficiency.



Key sample interaction constrains for measurement head:

- The sample volumes to be detected are small.
- The unquenched fluorophore concentration varies over a large dynamic range and therefore the absorption coefficient of the sample solution varies.
- The pick-up efficiency has to be high due to the low LOD.

Heat and humidity changes are key contributors to signal variations in the system.

Heat induced changes in the system:

- thermal expansion of the mechanical reference frame
- deformation due to induced stress & strain
- emitter & detector characteristic changes

Humidity induced changes:

- Swelling of adhesive layers used for optical element fixing
- injection molded housings / parts
- Changes in the dichroic mirror structure

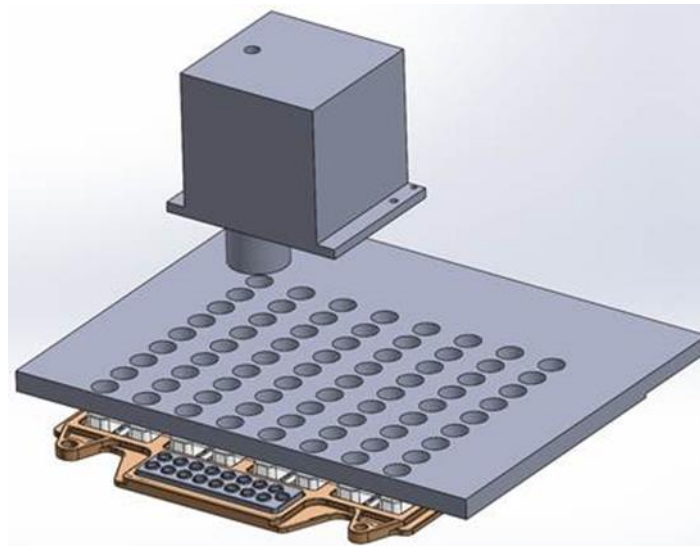
Consequence for optical systems performance:

- Sample respectively measurement head position reproducibility is reduced
- Spectral bandpass of detection channel is altered.
- Channel transmission variation induce signal variations.
- Stray light suppression changes alter inter-channel crosstalk.
- Necessary complex signal-crosstalk compensation algorithms in data analysis show reduced output stability.

Packaging requirements that would support system design of optical measurement head in IVD instrumentation.

Key requirements for packaging solutions:

- Very thin, high transparent, low fluorescent and heated cover glasses
- Cost-efficient, low expansion opto-mechanical mounting material
- Plastic materials suited for optical opaque housings and optical element mounting with
 - low CTEs
 - low heat transfer rates perpendicular to walls
 - good humidity sealing



Thank you for your attention.

