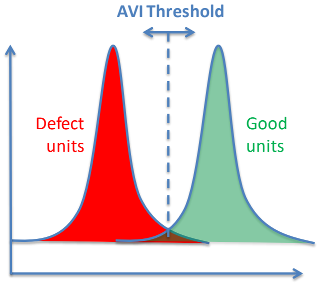
Part2: Introduction to technical principles of automated inspection machines

- Camera systems / light / motion
- Image processing and database system
- Interlinkage of parameters:
  Speed, Rotation speed, Inspection parameters,
  Detection probability, False reject rate
- Properties, capabilities and limitations of automated inspection systems
- Scope of Automated Visual Inspection
- Critical design elements

Mastering Automated Visual Inspection

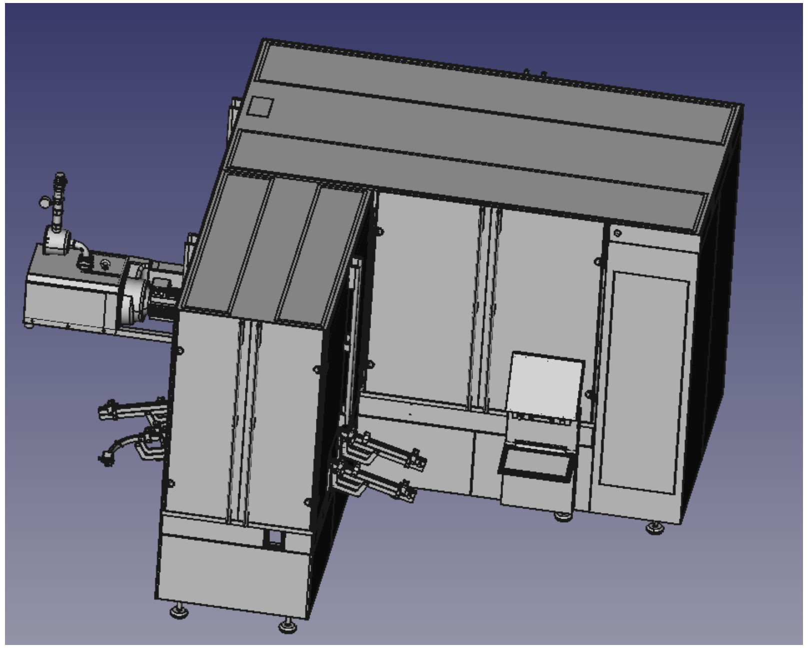
Part 2: Introduction to technical principles of automated inspection machines

- Process / People to master AVI
- Functionality of automated inspection machines
- Camera systems / light / motion
- Image processing and database system
- Interlink age of parameters
    - Speed
    - Rotation speed
    - Inspection parameters
    - Detection probability
    - False reject rate
- Properties, capabilities and limitations of automated inspection systems
- Scope of Automated Visual Inspection

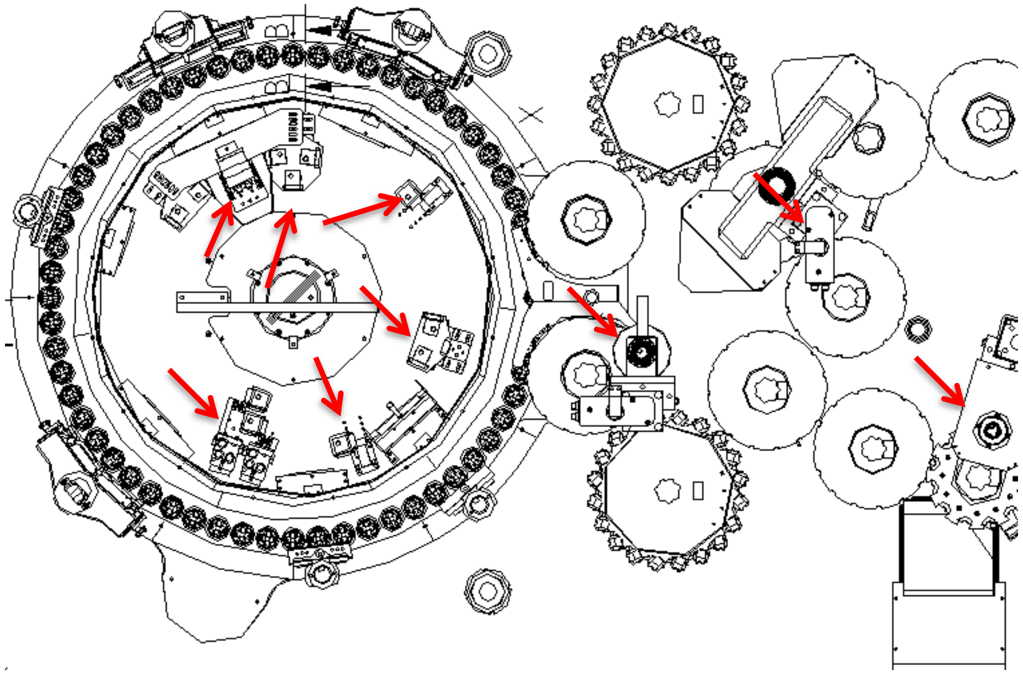


General intro

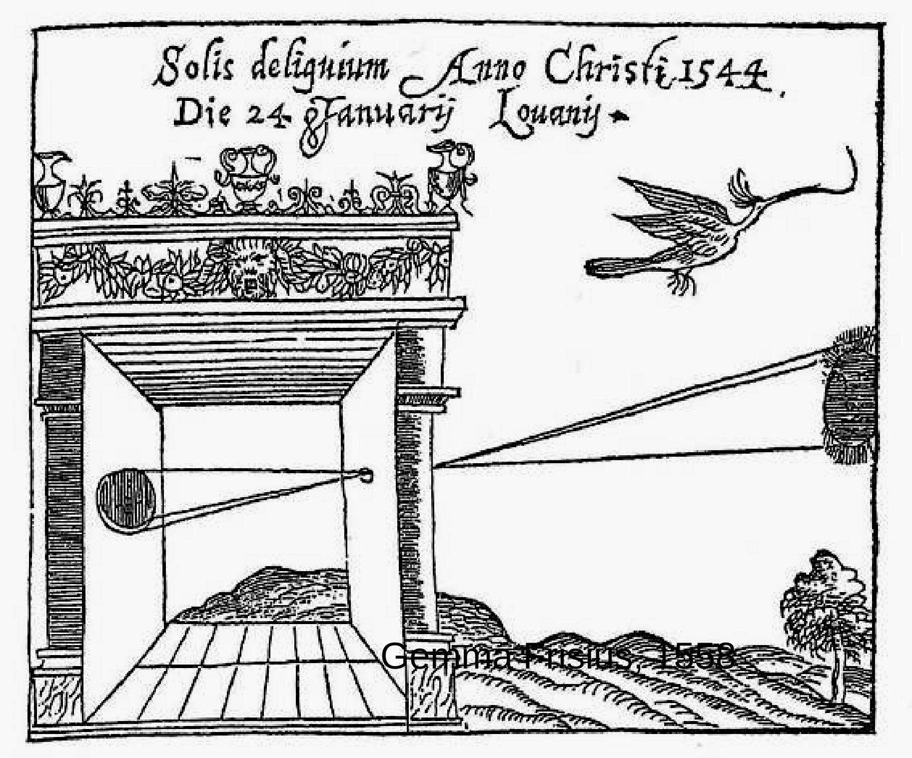
Is it just a black box ?
Need for transparency / explain ability



Certainly, no more!!



inspection machines Some milestones



Gemma Frisius, 1558

"…and we call invisible, either what is absolutely – as we consider impossible in other cases -,
Or what is visible by its inherent nature, but in fact it may only be hardly visible or invisible »
Aristotle, De Anima, Book 2, 10

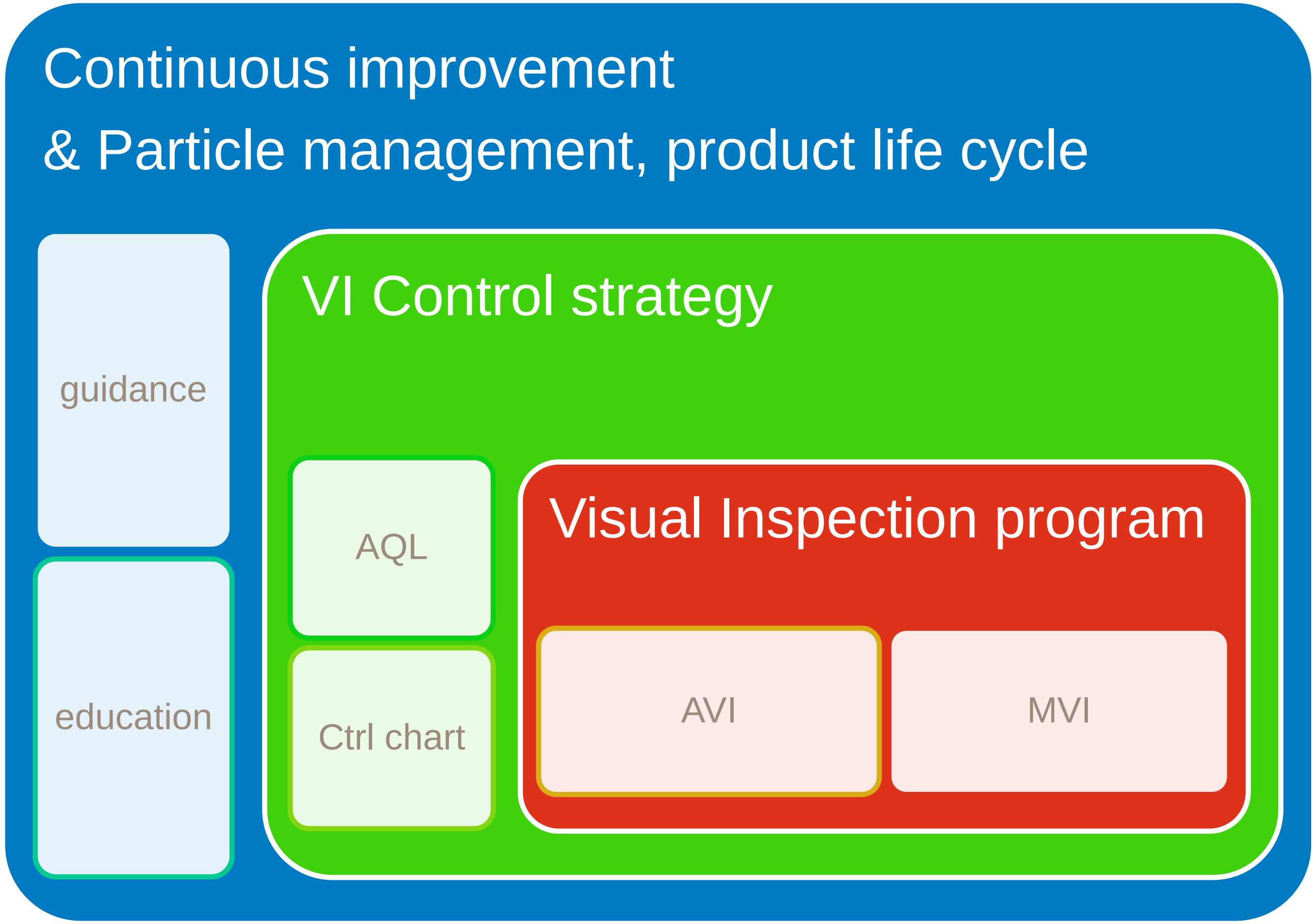
Camera Obscura

- Basic principle Aristotle (384-322 BCE)
- Drawing aid for artists: described by Leonardo da Vinci (1452-1519)
- …..first industrial CCD camera 1975
- 2022 AVI

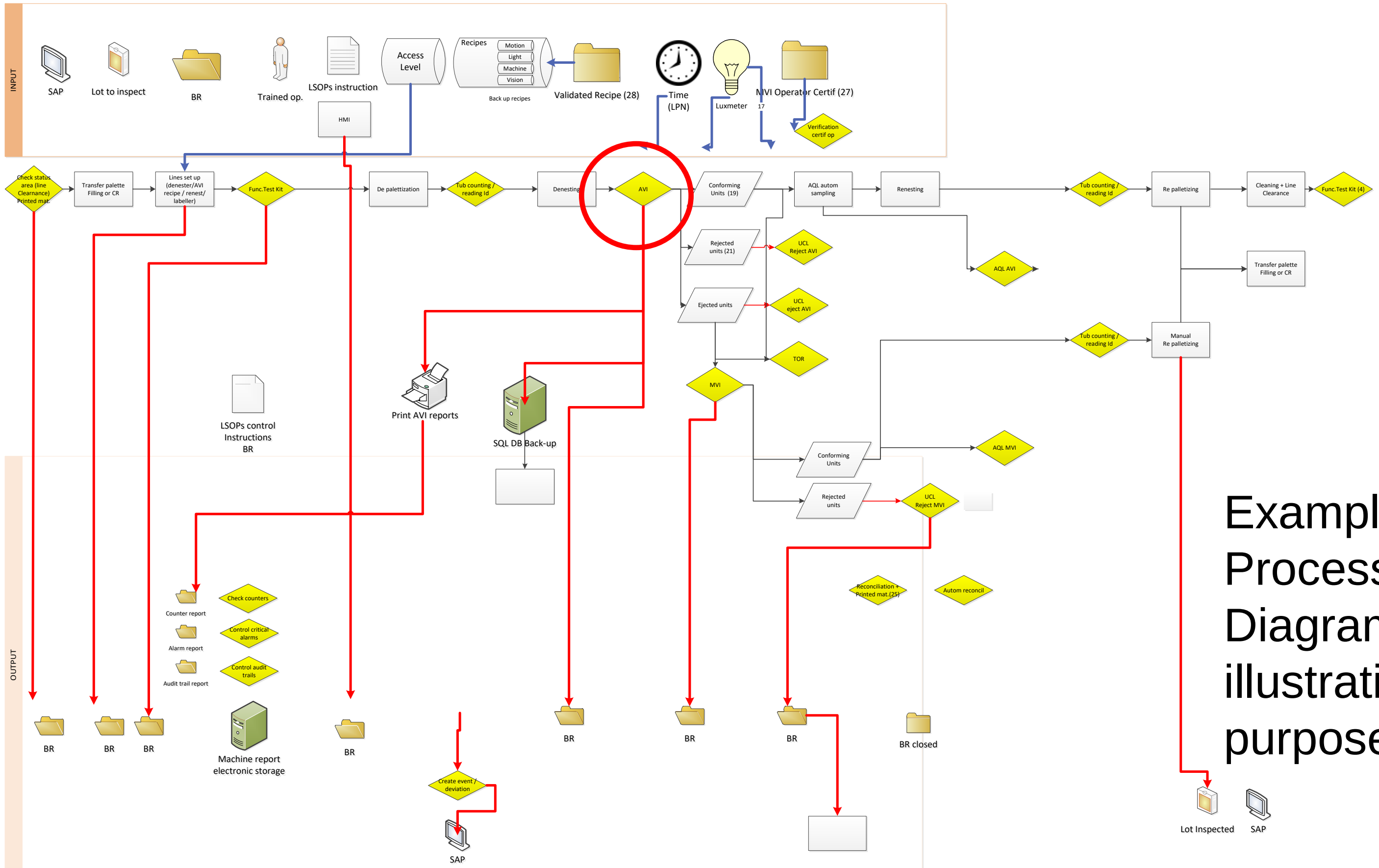
AVI just a Quality control / Or more a quality assurance activity ?

Visual inspection program in 3 layers:

- ❑ -The Core is AVI/MVI program, with strategy for DML / standard work / certification / validation
- ❑ -The control strategy with ctrl chart and AQL guarantees that VI is kept under control
- ❑ -Continuous improvement is the goal of all VI activities with CAPA management. The Particle management guidance is a key to success with particle control and associated WOW & education, product life cycle approach



AVI is just a small part of the process



Example of a Process Flow Diagram for illustration purpose

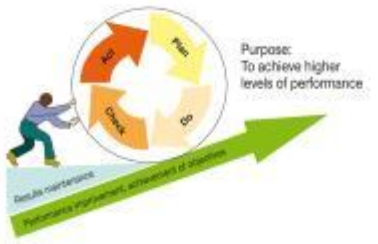
For AVI mastery ….People mgnt is a key !
Need to have landing conditions for equipment / Process

Best in class organisation for VI (People mngt)
Transformation is not only buy a machine, but build a team/organization for VI
- develop operators / supervisors
- develop maintenance (calib./mech./vision)
- develop automation support
- opportunity to develop vision experts / Ext.
- develop a team to supply kits or externalize
- develop AQL quality team
- develop control chart tools & SPC team
- develop defect id. / externalize

CAPABILITY MNGT IS KEY

And change mindset by generating a feedback loop and involve the filling & Quality department

Loop with USP<1790> ultimate goal of VI
is continuous improvement



Let's reflect of Quality attributes ?

CDEs

CPPs

CQAs

- what are your CQAs / CPPs for VI process ?

Some CQAs may be proposed:

Can you list some of them ?

- CQAs: Critical quality attributes

=> think about USP<1790>....

- CPPs: Critical process parameters
- CDEs: Critical Design elements
- PA Performance Attribute

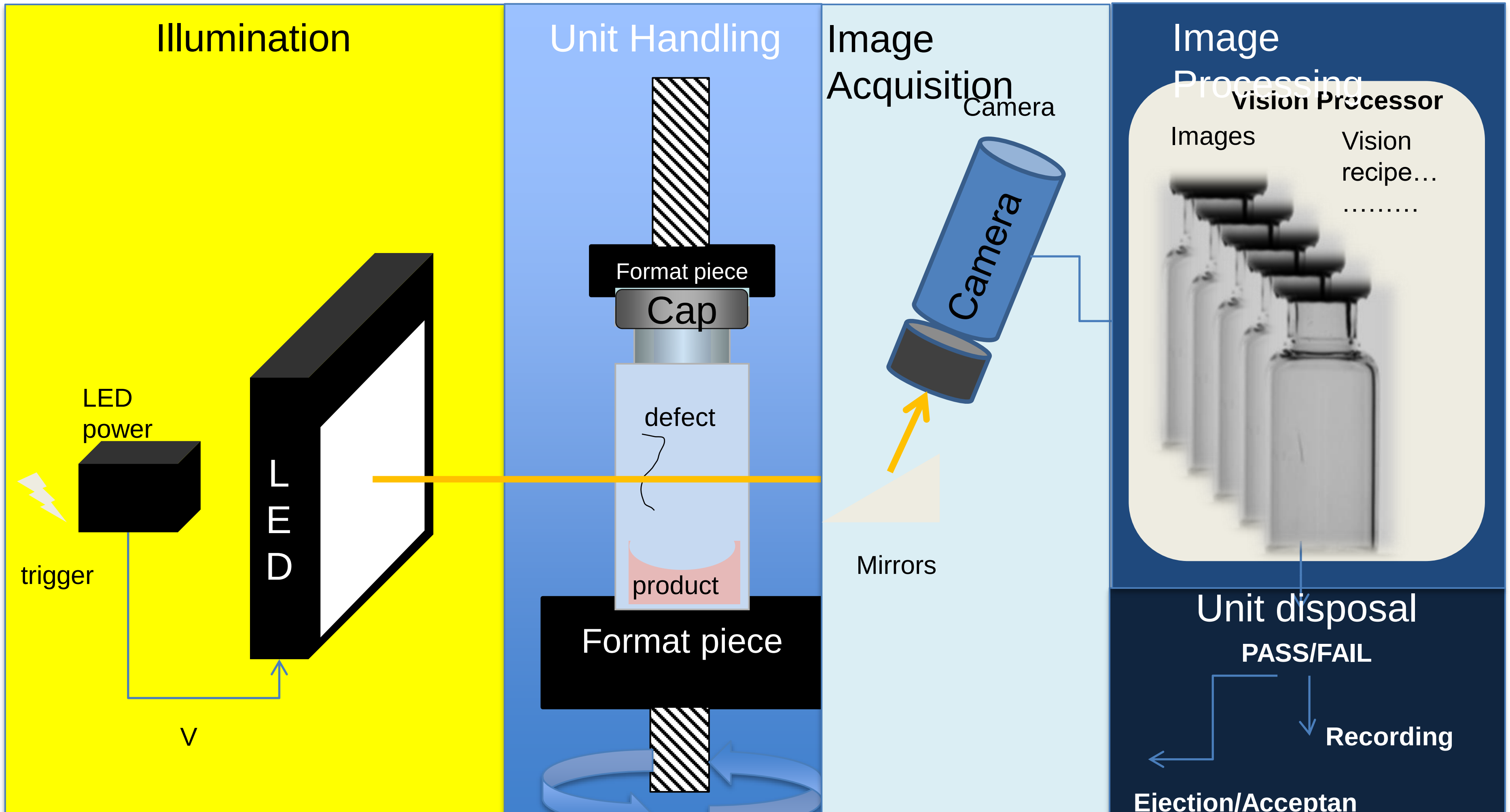
Attributes						
CQA	CQA	CQA	CQA	CQA	CQA	PA
Identity	Essentialy free of glass Defect/Particles/Stopper defect/Closure defec. fill level/Empty/Lyo defect	Leak absence	Container Integrity	Stength, Potency	Potency (sheer stress)	Equipment Performance

Core parts of AVI

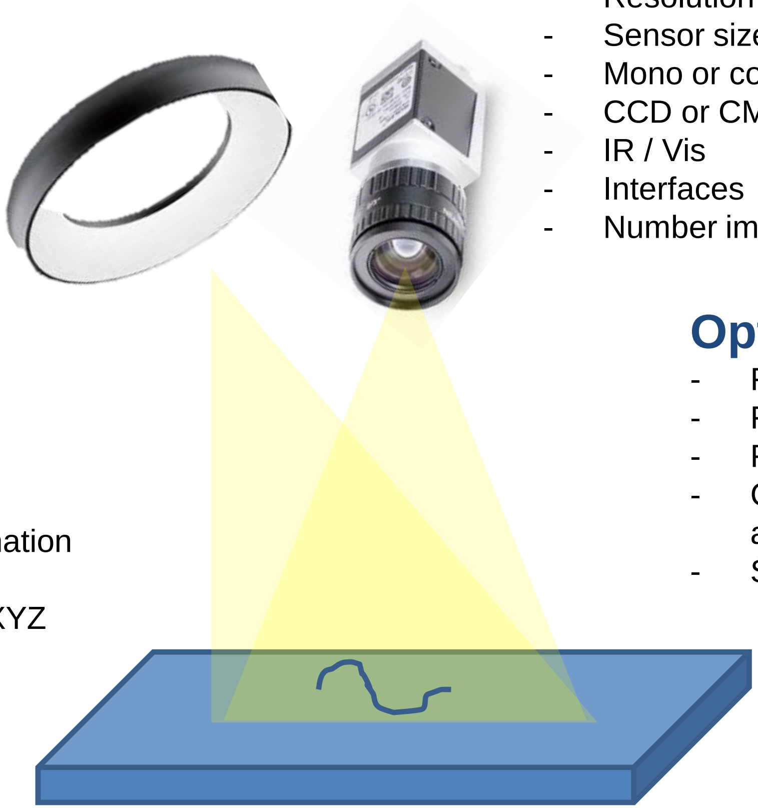
Why classifying AVI Main block functions ?

- **Motion of units**
- **Light illumination**
- **Digital image processing**

AVI Main functions



Vision System critical design elements



Camera Sensor
- Resolution
- Sensor size
- Mono or color
- CCD or CMOS
- IR / Vis
- Interfaces
- Number image

Machine vision
- Digital image processing
- Speed
- Software
- Vision processing
- Learning type
- Access level
- Image archiving

Lightning
- Shape
- Distance
- Color
- Type illumination
- Intensity
- Alignment XYZ

Optics
- Focus
- Focal length
- Field of view
- Chromatic aberration
- Stability of tuning

AVI machine
- Automation
- Fail safe design
- Enviroment (dust, temperature….)
- Holding time
- Vials/syringe
- Closure design
- Glass suppliers

Object to inspect
- Size
- Geometry
- Surface
- Material
- Color / transparency
- rheology

AVI by block of critical function, proposed approach:

1. Unit presentation to camera by mechanical handling
2. Unit presentation to camera with product rotation
3. Unit presentation to camera with glass & product dependent parameters
4. Refeed transport mode
5. Lightning to camera
6. Image acquisition
7. Digital Image Processing
8. Result transfer to shift register
9. Physical unit ejection
10. Inspection result archiving (ex SQL)
11. Batch closure and local report creation
12. Central reporting & archiving

Object presentation to camera

Unit presentation to camera in many ways

Different ways of conveying:

Intermittent rotary CMP : https://www.youtube.com/watch?v=H55CQj1JsNI
Linear Continuous Heuft: https://www.youtube.com/watch?v=5BCChqQZFac
Bottom gripper Rotary continuous: https://www.youtube.com/watch?v=xC2ed0Tu2NU
handling syringes: https://www.youtube.com/watch?v=GlojLwZeX0o
Side clip conveyor Innoscan: https://www.youtube.com/watch?v=_5oueC3ilxY
Top gripper ATS Lyo : https://www.youtube.com/watch?v=opscAQFk1sM
Brevetti Continous mvt + up and go moving arm: https://www.youtube.com/watch?v=XkiKzsL-bfw
Innoscan continuous mvt + fixed VI + oscillating mirror piezo:
https://www.youtube.com/watch?v=mw3UU9wPwKo
Vacuum wheels suckers Seideander: https://www.youtube.com/watch?v=2g4RABopl1k
Pre Spin turret Syntegon: https://www.youtube.com/watch?v=s31mC8rFwZk
Wilco mechanical conveyor: https://www.youtube.com/watch?v=7MiQVALsRCo

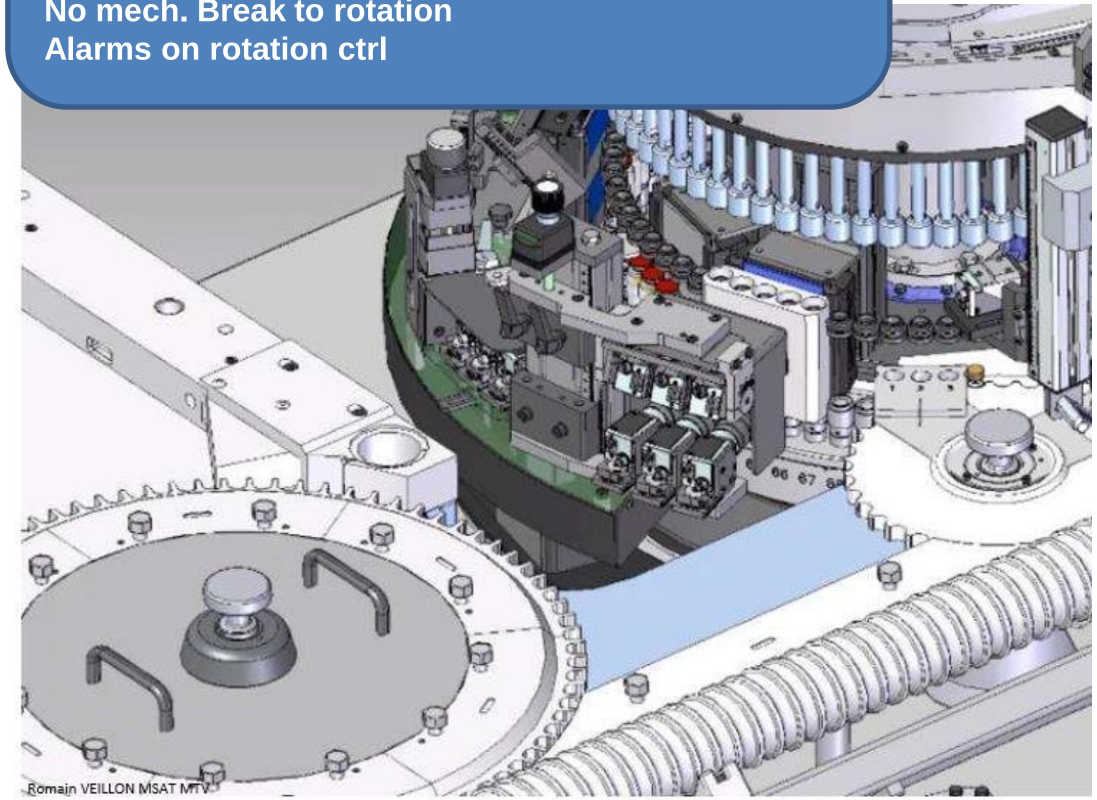
Base holder / Gripper / sucker
Those are pieces with ageing / regular checks / changes

Critical Design Element:
Mechanical stability of AVI
Axial Rotation no cavitation
Aging parts maintenance

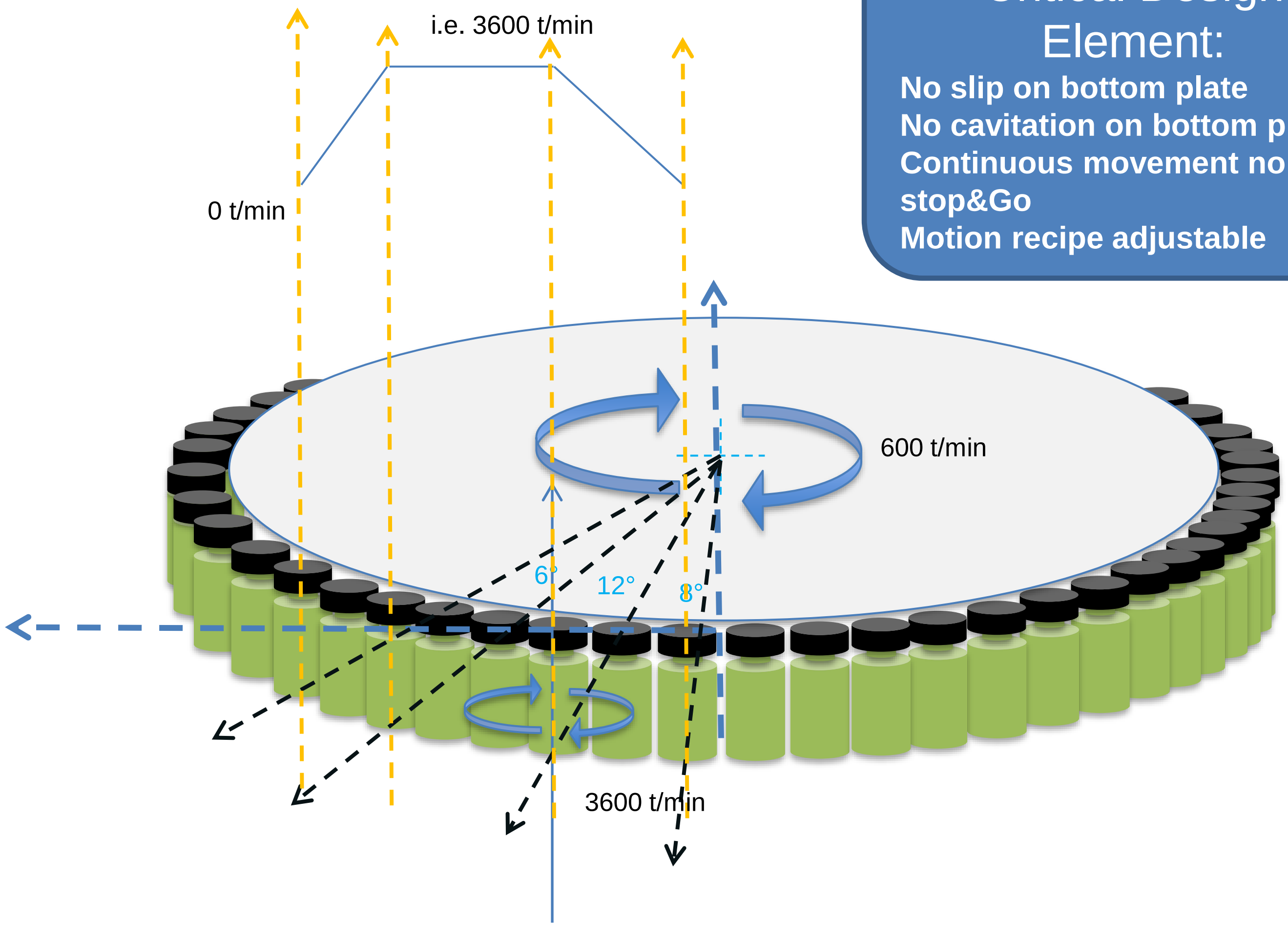
Unit presentation to camera

Critical Design Element:

- Bottom and top carousel aligned
- Pressure top caroussel
- Mechanical fitting bottom ring
- No loose in X Y
- No mech. Break to rotation
- Alarms on rotation ctrl



Unit presentation to camera



Critical Design Element:

No slip on bottom plate
No cavitation on bottom plate
Continuous movement no stop&Go
Motion recipe adjustable

<u>Key learning:</u> Modern AVI machine is very complex in term of unit motion;
Double motion main
- **carousel rotation**
- **each unit individual fast rotation**

+ all synchronized to image acquisition every few ms

Unit presentation to camera => Fast spin rotation


0 t/min


600 t/min

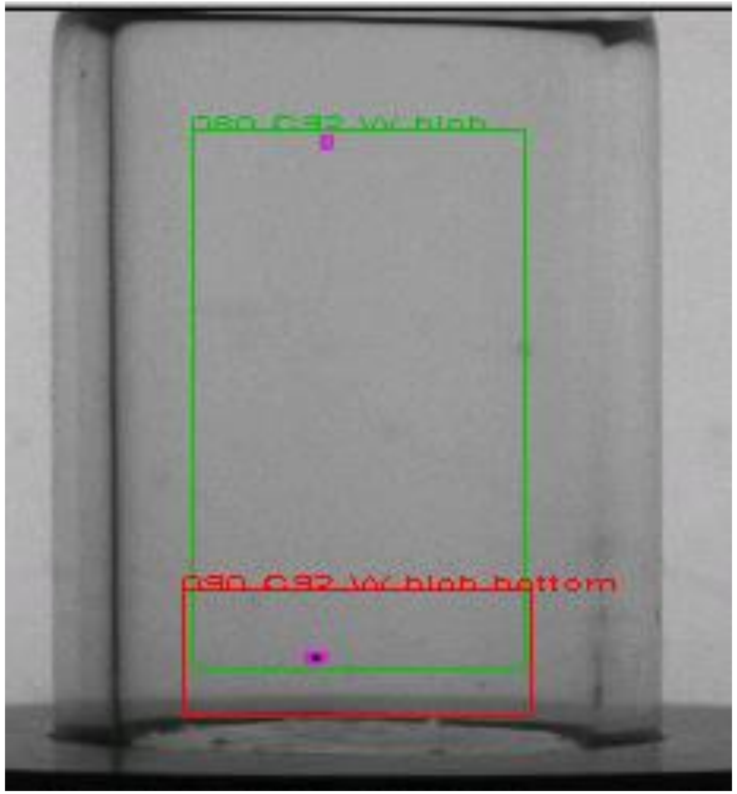

1800 t/min


3600 t/min

How to inspect Automatically a suspension that has a high optical density + scattering?

= Fast rotation To present liquid in thin layer

- ⇒ Lower optical path (density beer lambert)
- ⇒ Minimized scattering effect



Unit presentation to camera => Fast spin rotation

1000 images Conform overlayed

1000 Crack image overlayed

Conform images are clearly shifted to the left and more shaky

Crack images are more stable

Critical Design Element:

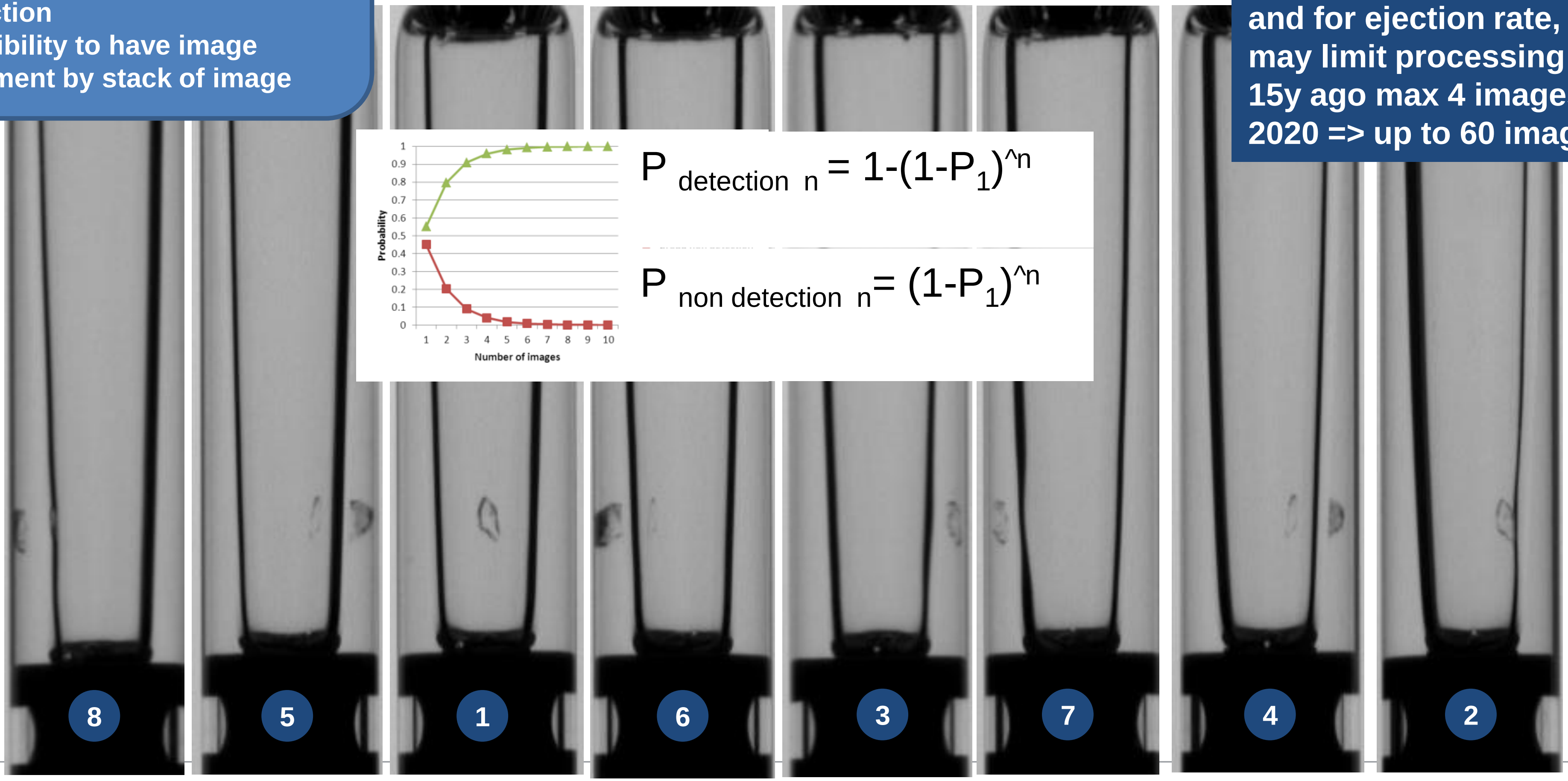
Fast spin requires strict mechanical alignment
Need to have some periodic control of axial rotation with no cavitation

Unit presentation to camera, why multiple images ?

Critical Design Element:

More image increase defect detection
Possibility to have image treatment by stack of image

Key learning: more images per unit is better for detection rate and for ejection rate, but this may limit processing time
15y ago max 4 images
2020 => up to 60 images/unit



$$P_{\text{detection}\ n} = 1-(1-P_1)^{\wedge n}$$

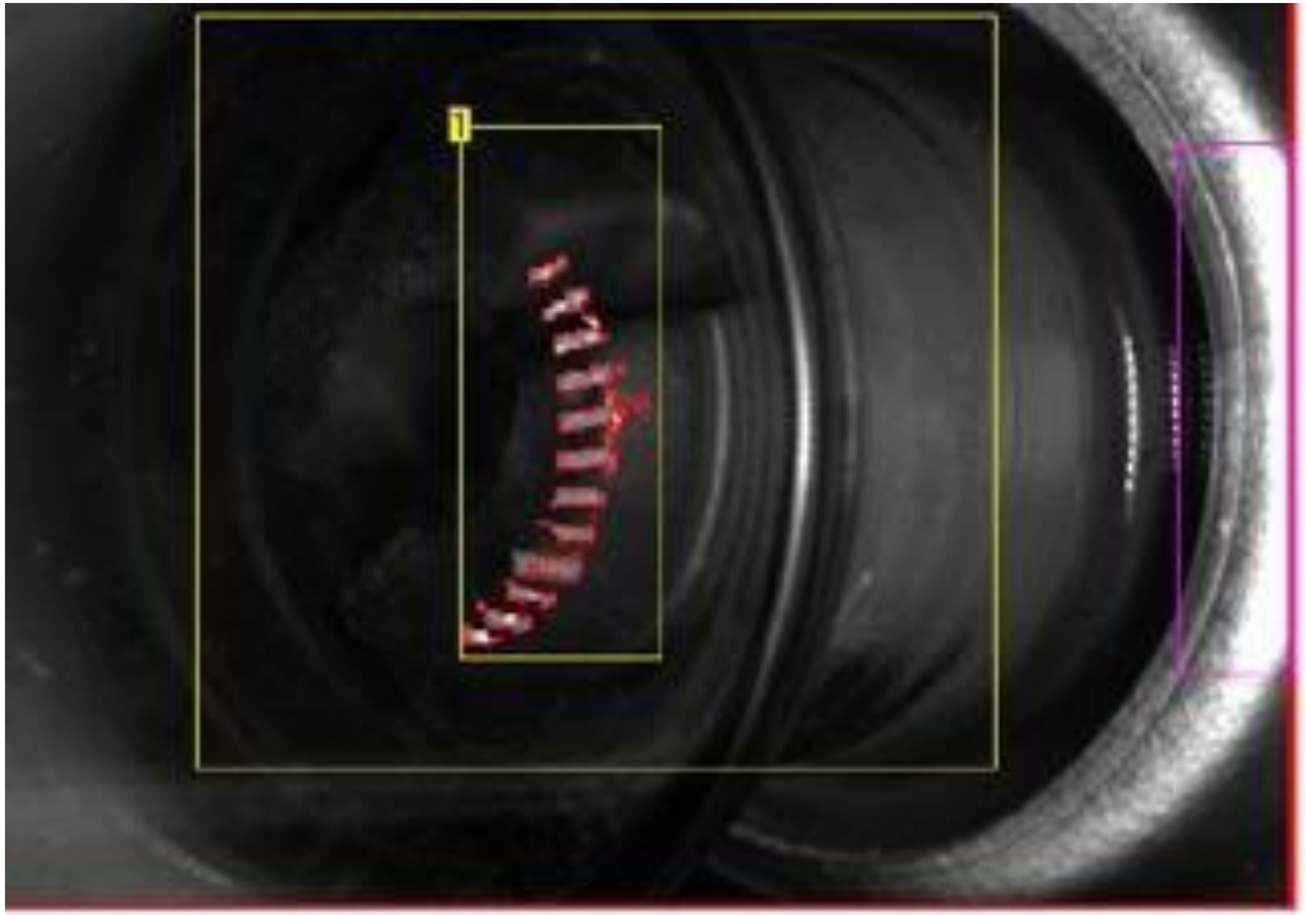
$$P_{\text{non detection}\ n} = (1-P_1)^{\wedge n}$$

Unit presentation to camera, why multiple images ?

Critical Design Element:

More image increase defect detectionand lower false reject

Possibility to have image treatment by stack of image



Unit presentation to camera, different methods

1 Central moving Mirror

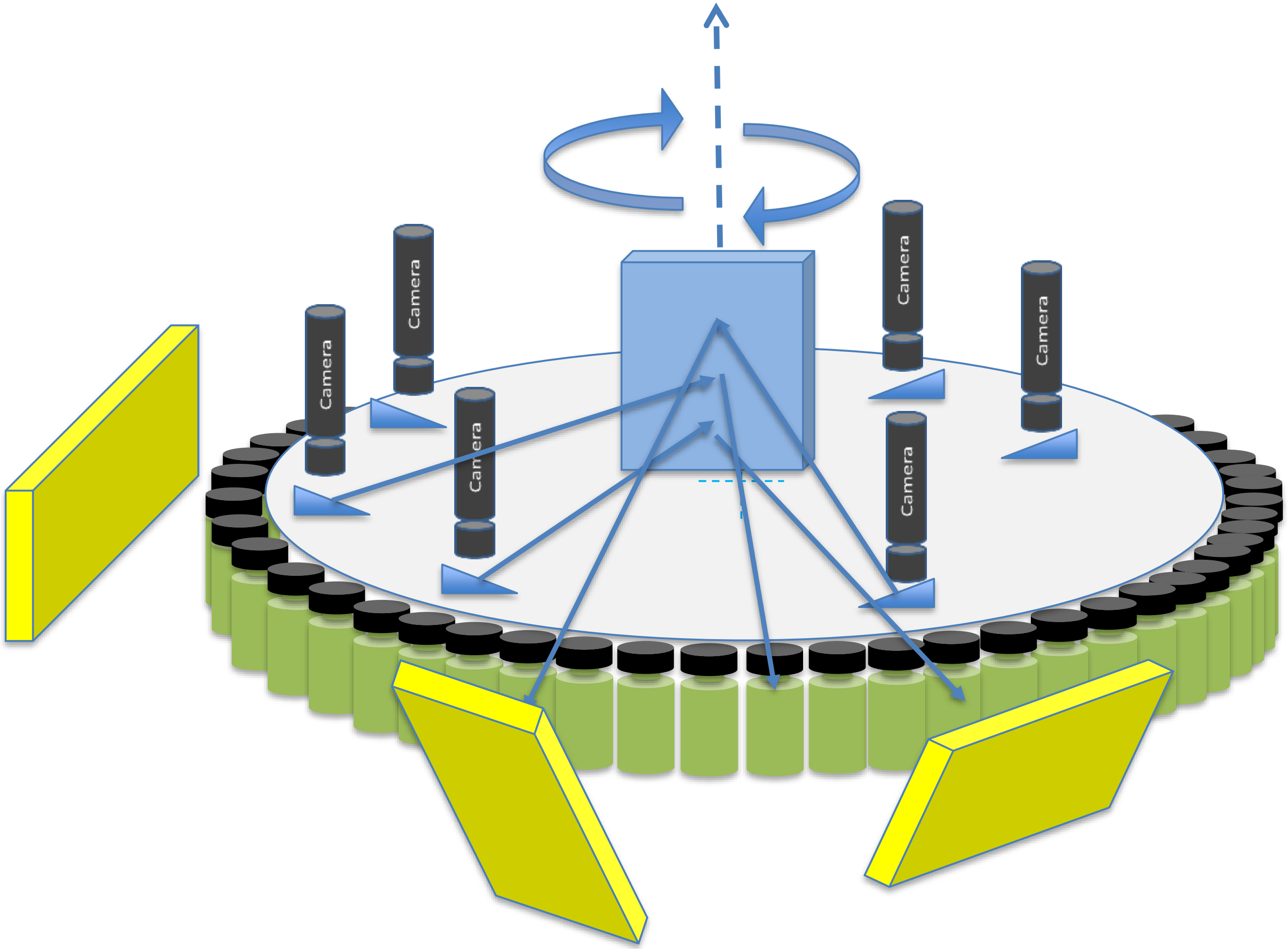
1 torque moving arm for LED / cameras

1 piezo oscillating mirror on each camera station

Fixed camera larger filed of view

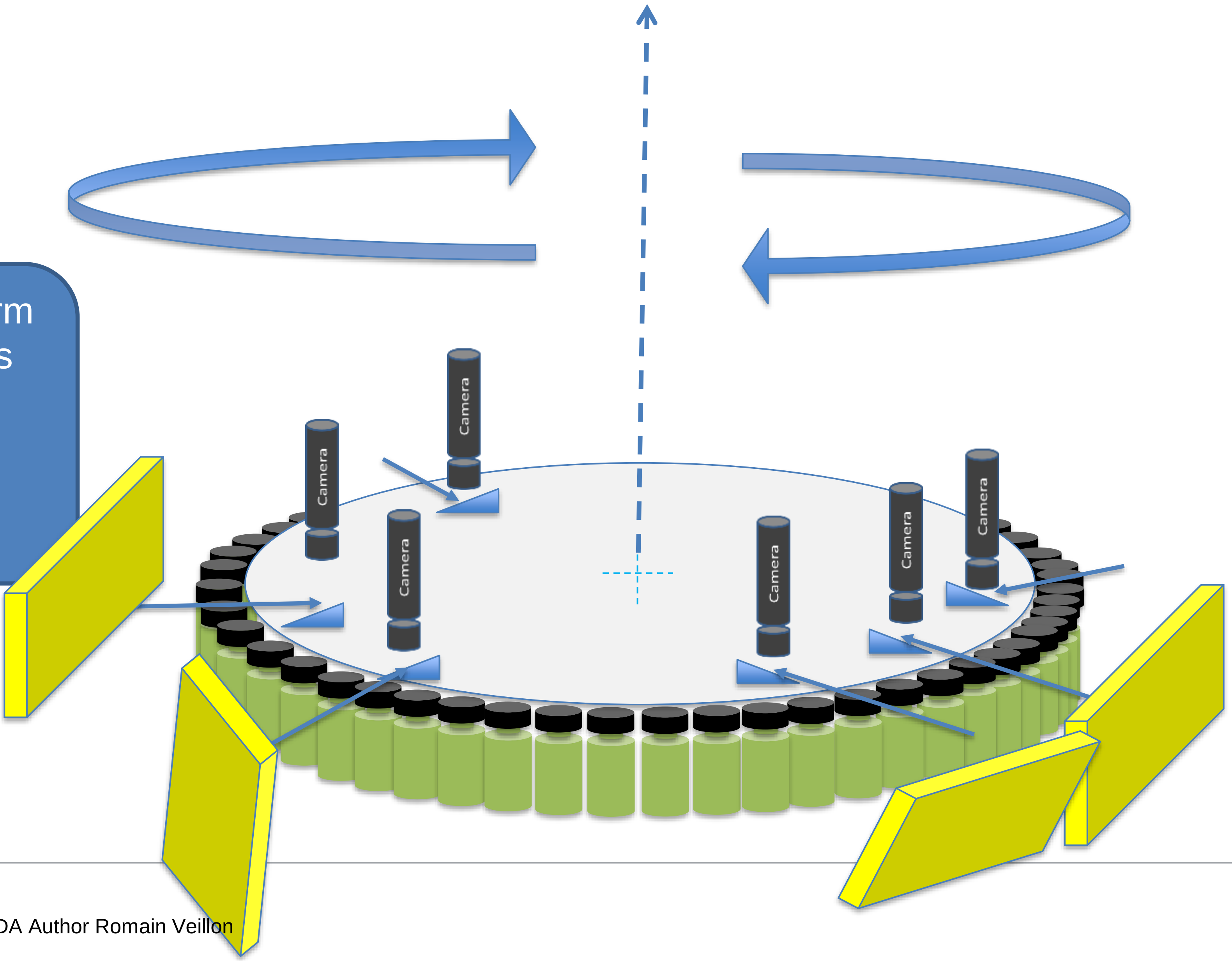
Unit presentation to camera, different methods

1 Central moving Mirror



Unit presentation to camera, different methods

1 torque moving arm
for LED / cameras



Camera and image acquisition

Camera is converting Photons is digital signal

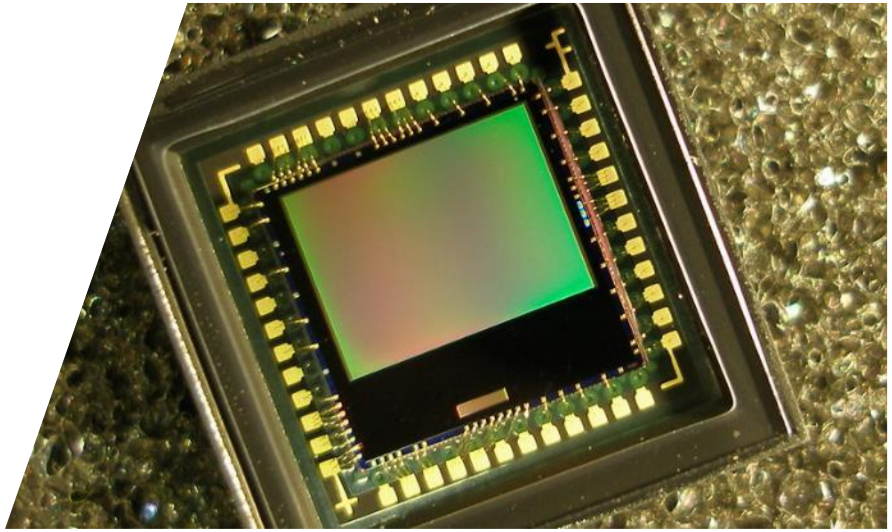
Photon → Photosite → Electron

- Integration
- Transfert
- Amplification

Further Deep Dive: https://www.baslerweb.com/en/vision-campus/

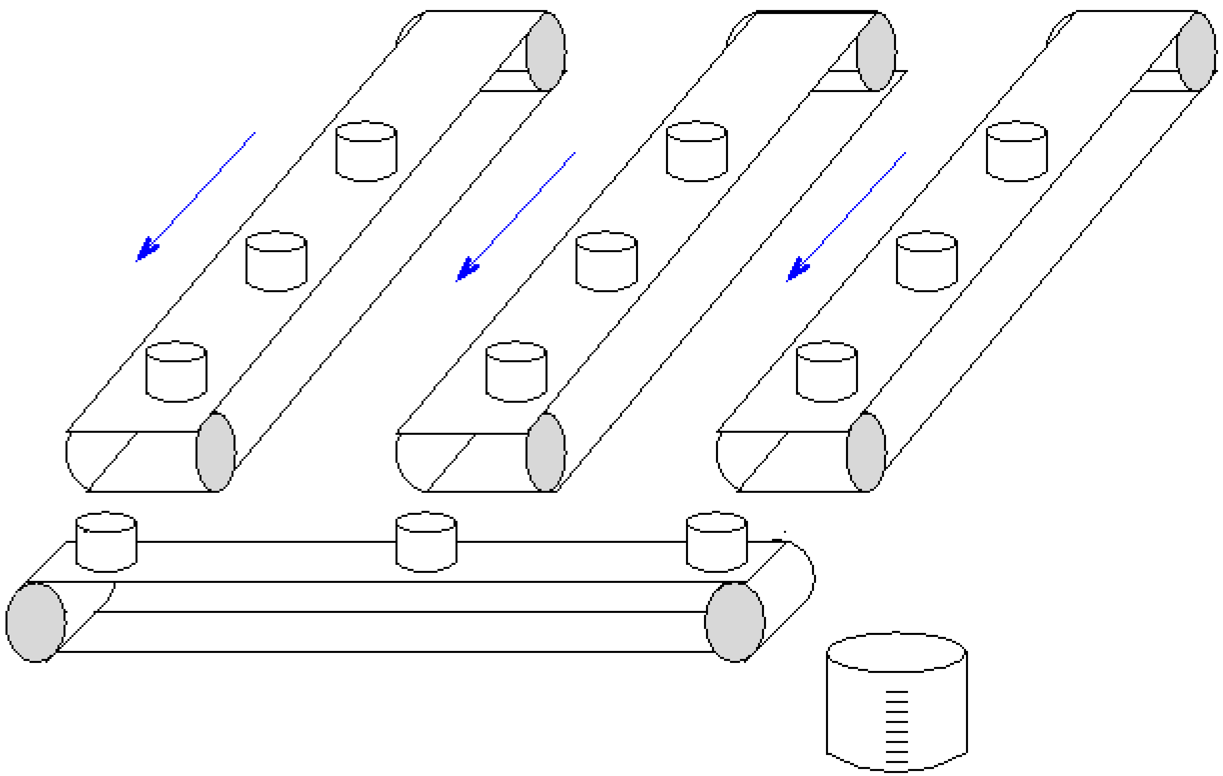
Camera

- Matrixial Sensor : X and Y image



- Linear Sensor = Line Scan

Transfer of electron on a CCD

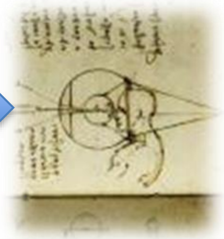


https://youtu.be/ZwN0DT_4FhY

AVI improvement last 2 decades, soon matching Human Eyes

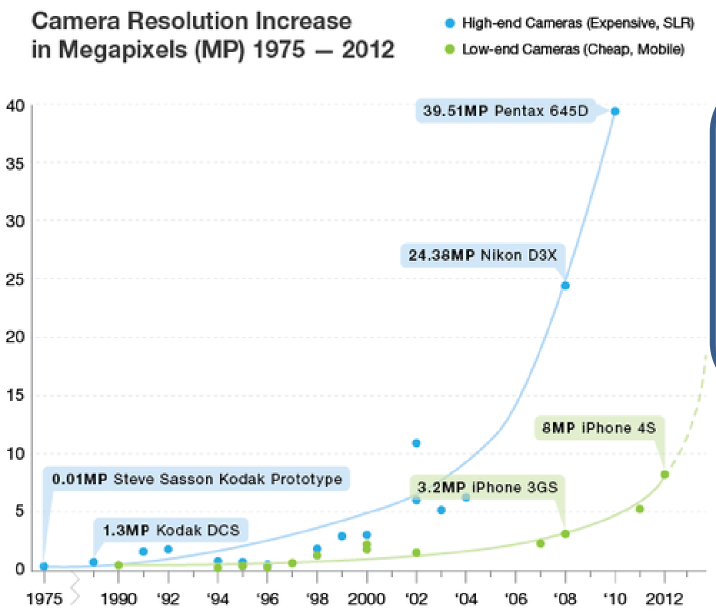
MVI

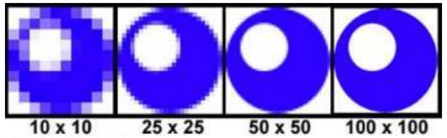
11µm per cone/6^{E6} Cones/ LOD 50-150µm particle



2022
2-5 MP
6µm / pixel
48 images /unit
128FPS

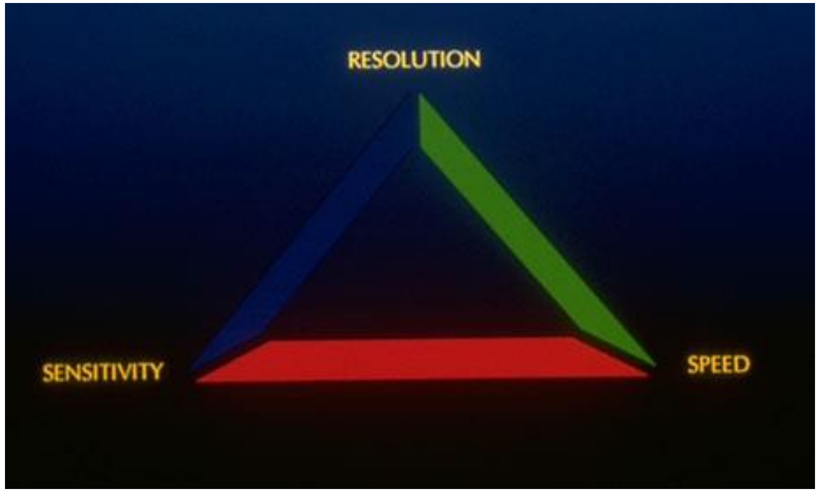
AVI



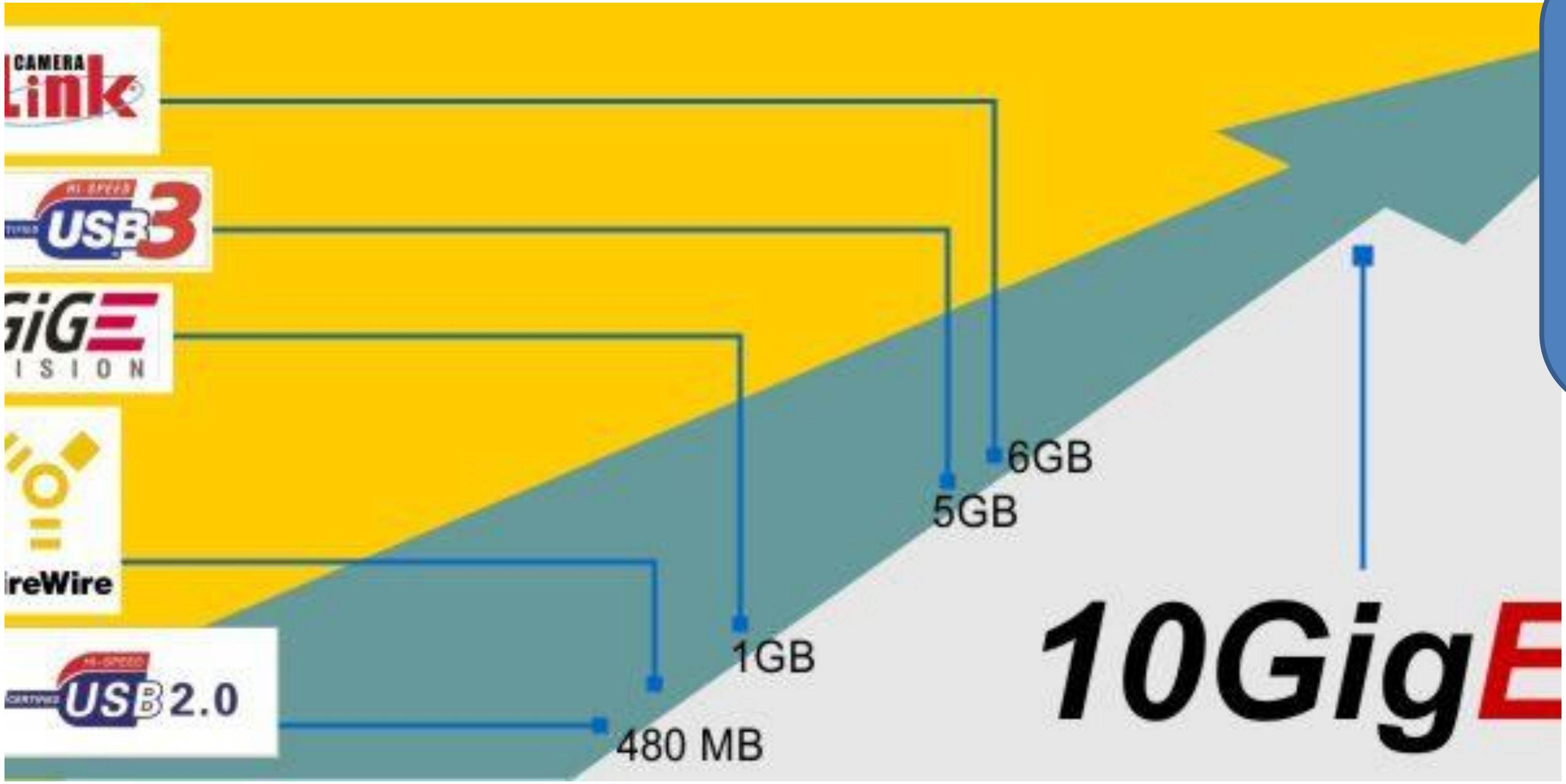


Critical Design Element:

Today compromise between performance / speed
Availability on the market
sustainability



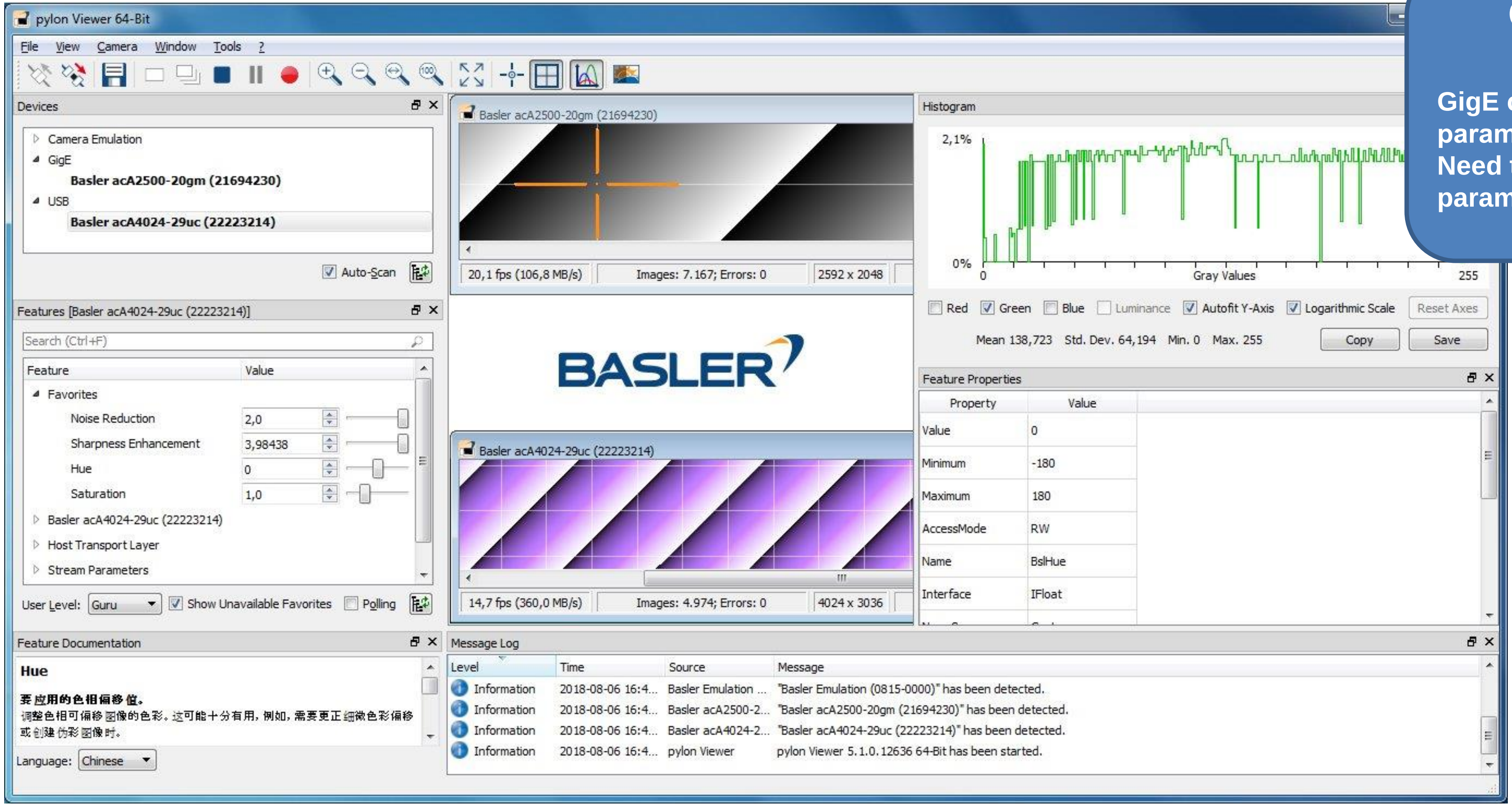
Camera transfer protocols



Critical Design Element:

1 GigE bus on a vision computer is limiting for 3 or 4 camera
The design of com card is critical to handle a fast transfer mode
Some camera have now more than 100 FPS

GigE camera have hundreds of parameters



Critical Design Element:

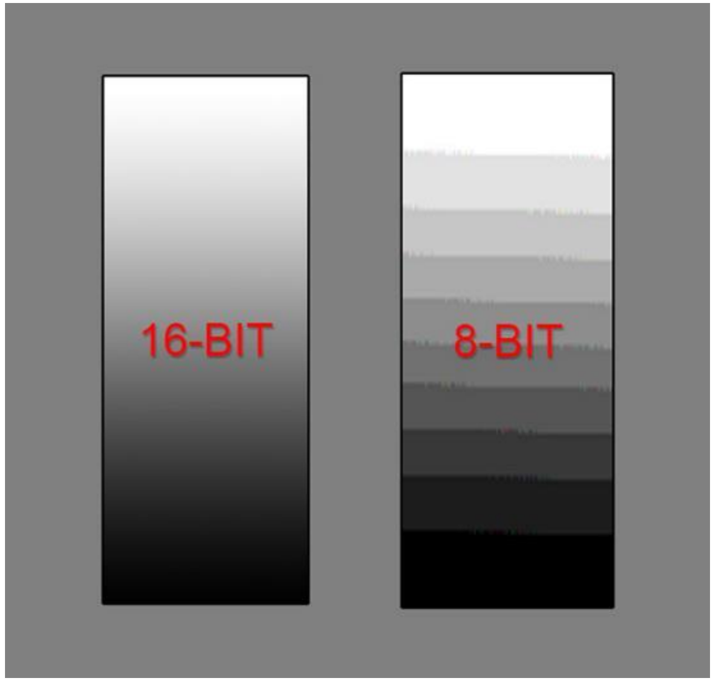
GigE camera have tones of parameters….
Need to control those parameters with access ctrl

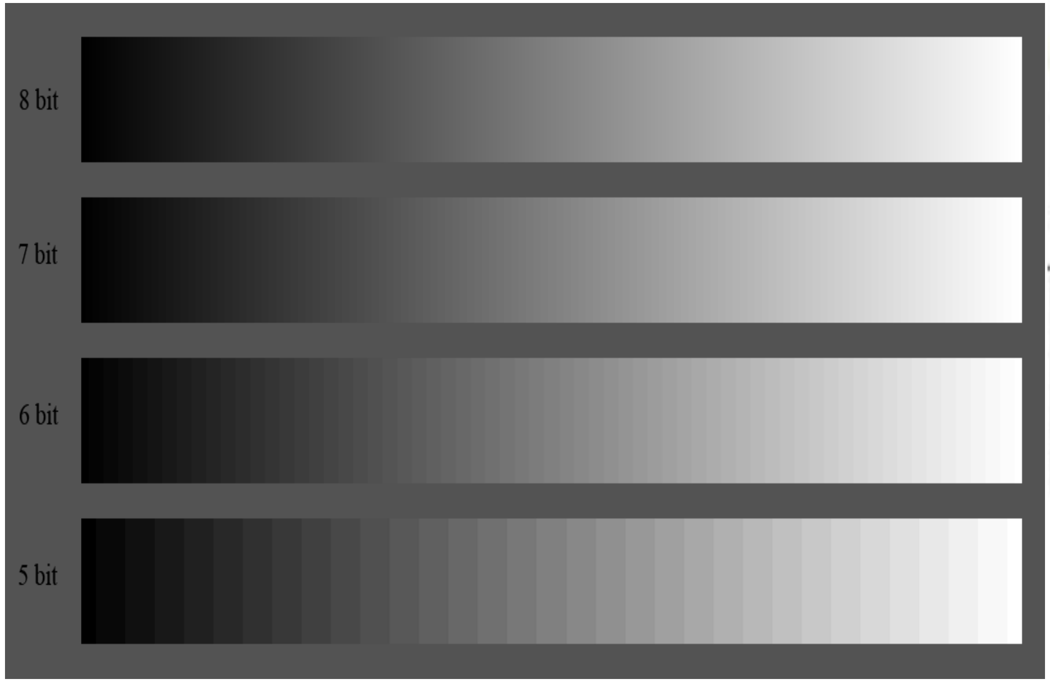
What is Image resolution ?

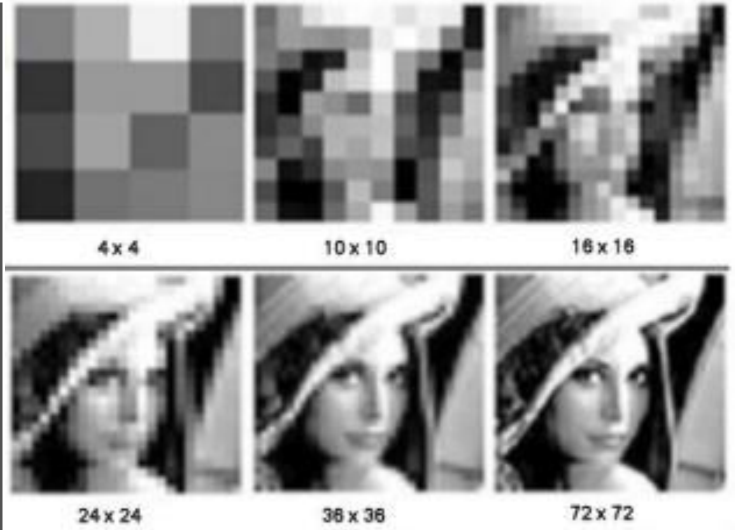
Key learning:
Tonal resolution in bit
Spatial resolution in pixel

tonal resolution in bit

Spatial resolution



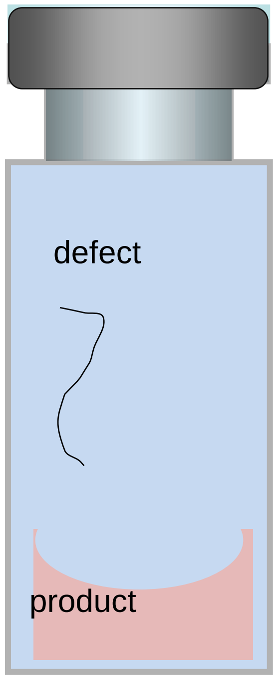


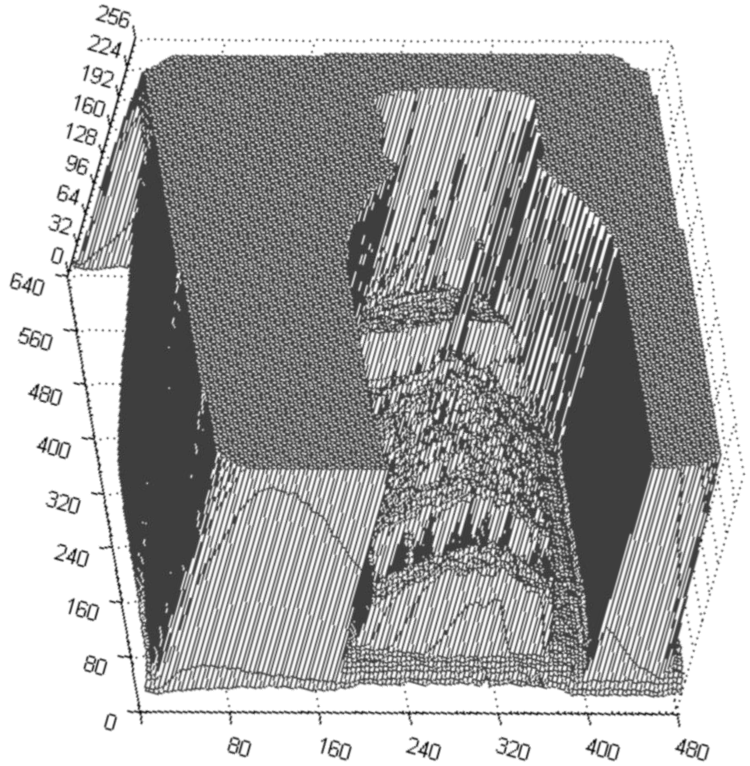


What a machine really sees?

Variable:

- discrete spatially
- discrete quantitatively





<u>Key learning:</u> AVI sees only a matrices of discrete information in X Y and Z for grey levels

Optic Fundamentals

Image Acquisition = > optic parameters

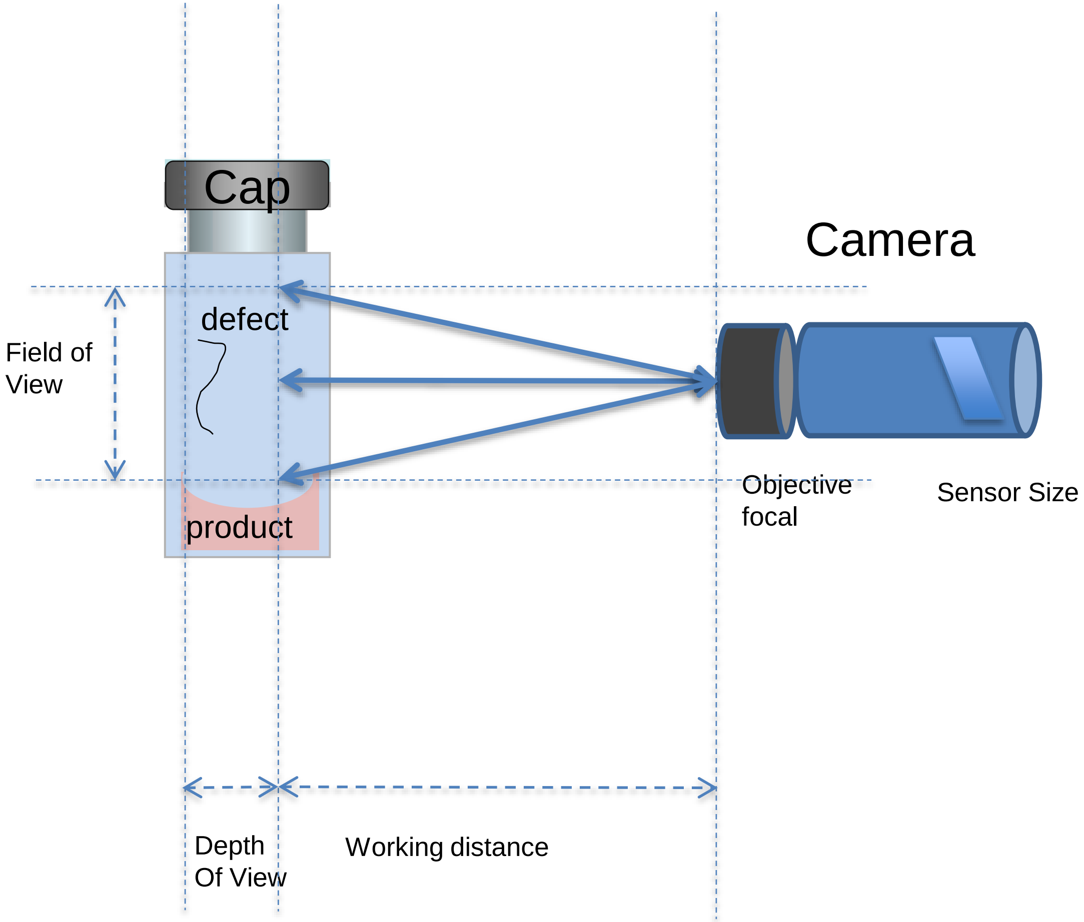
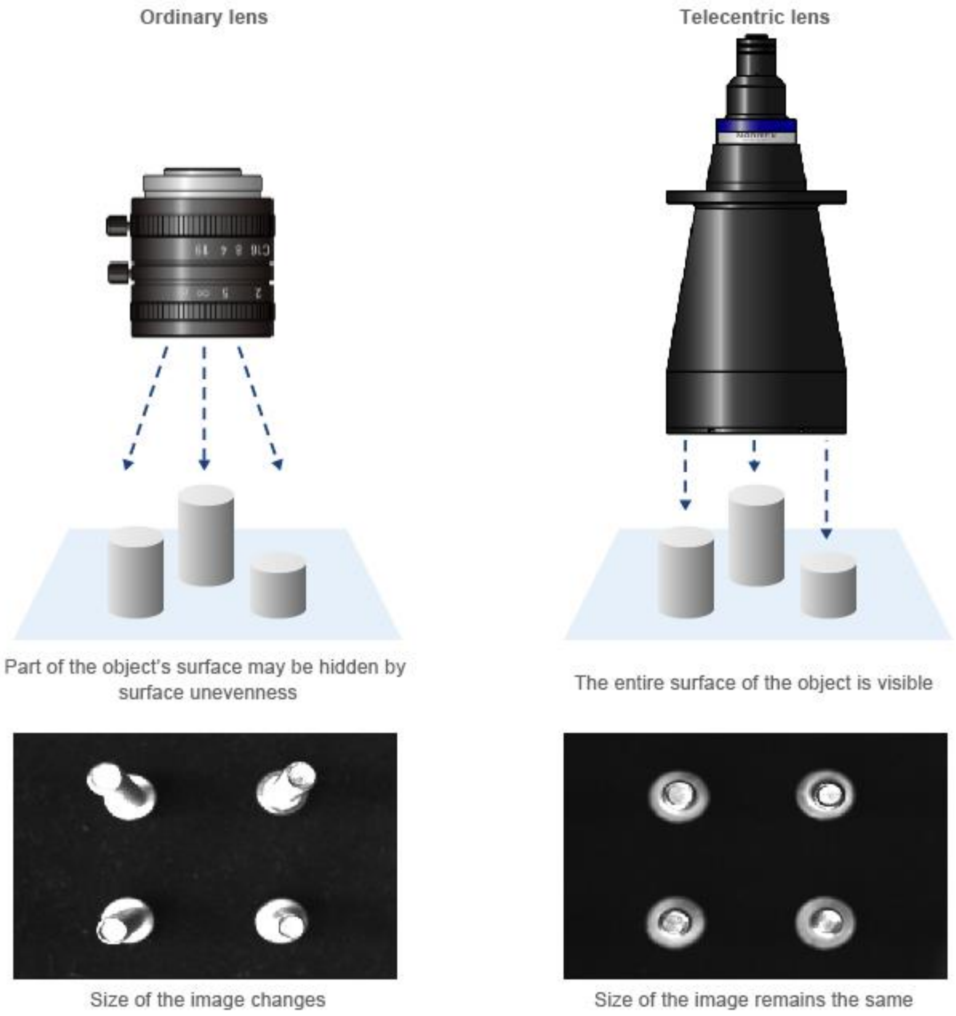


Image Acquisition

Critical Design Element:

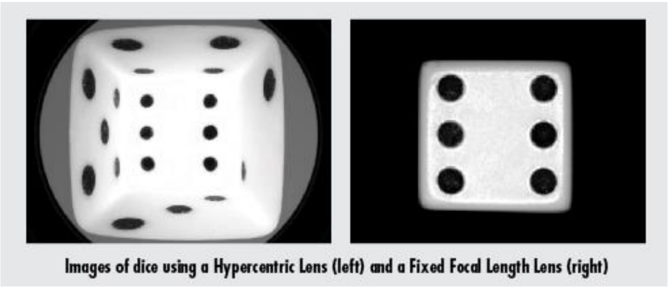
Optical setup must be masked and locked
In case of change possible to come back to pre existing image before validation

Innovation in optics



macro

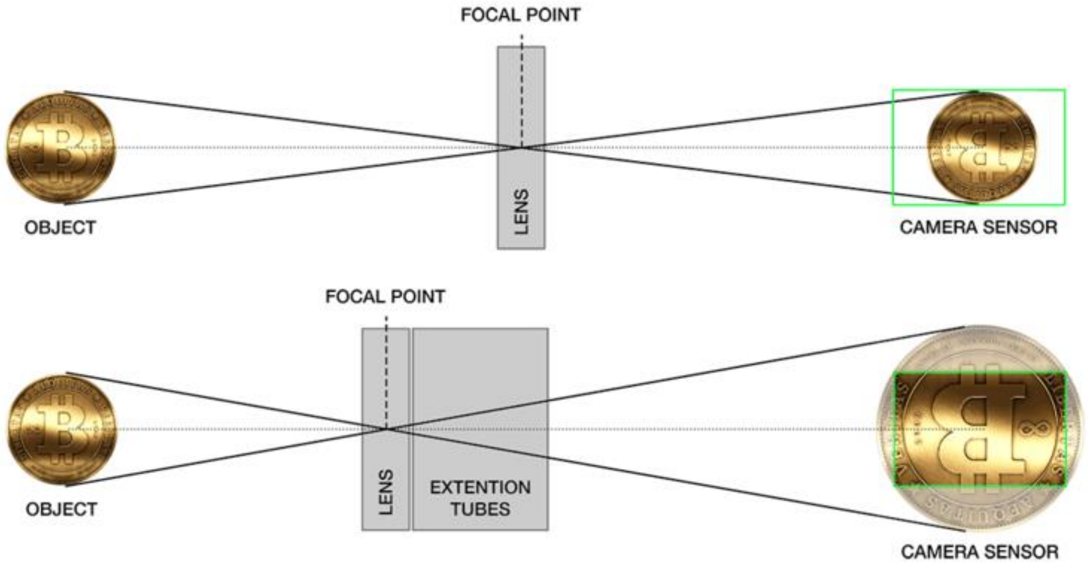
hypercentric



Critical Design Element:

Innovation in optic goes with larger size optics that are difficult to integrate in some AVI design

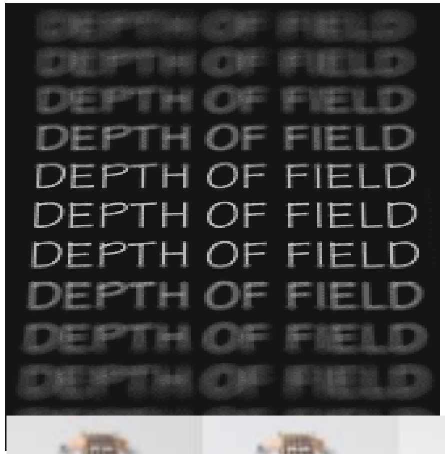
Optical Rings to reduce focal distance

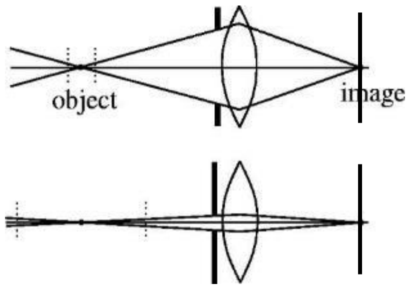


Critical Design Element:

Extension tubes and mirrors are used to cope with lack of space to shorten focal distance
But the depth of view is deeply impacted in some case, to be discussed during design review with suppliers

Depth of field





Critical Design Element:

High Depth of field **can allow to see defect from front and back of unit at same time.**
To do so we close objective aperture but image are darker

Macro objective can allow large field of view like on the lyo cake below:

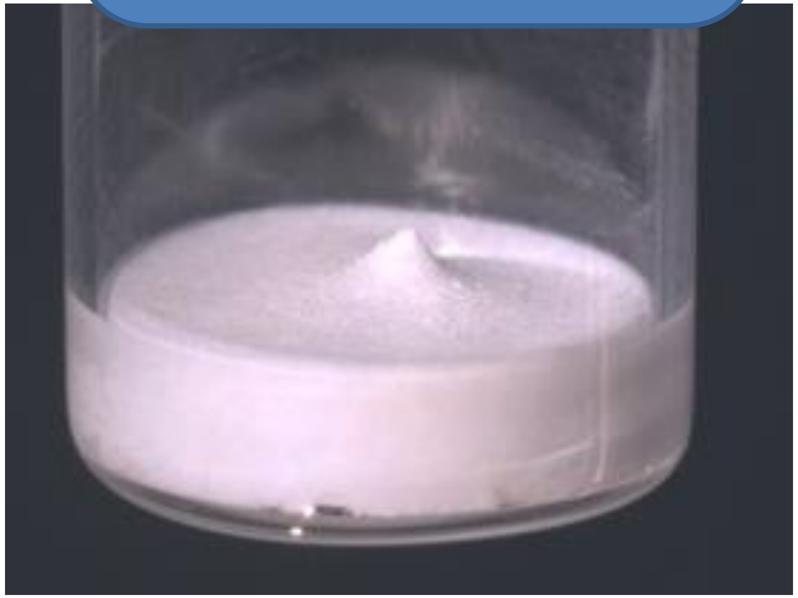
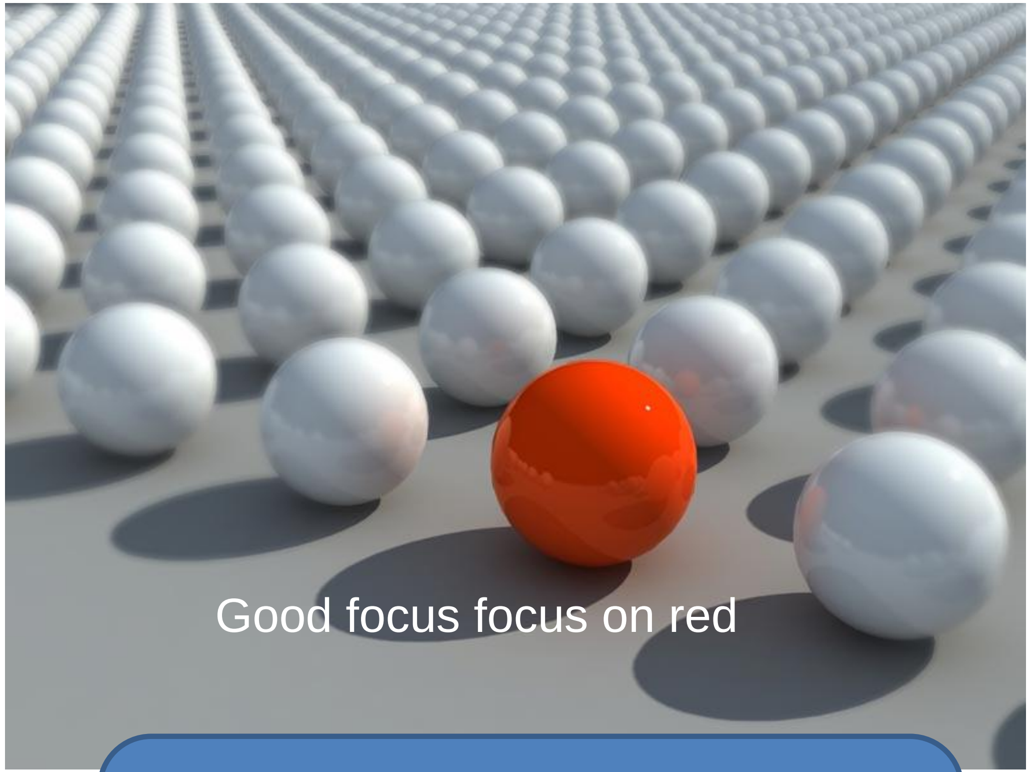


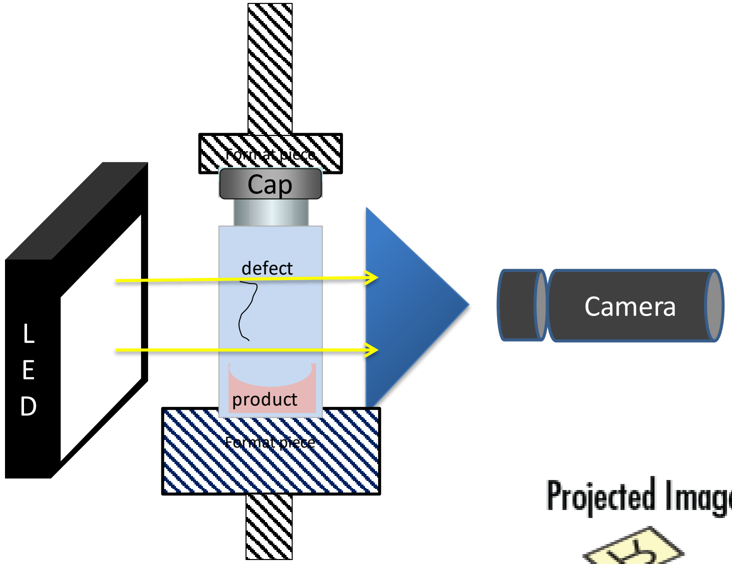
Image Focus

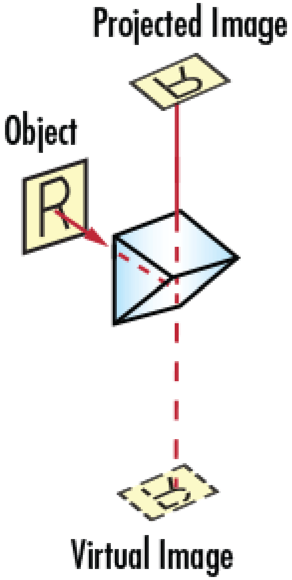


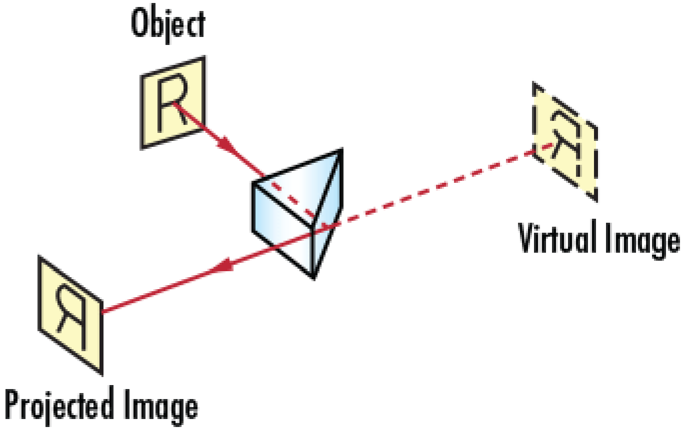
Critical Design Element:
It is critical to have a good focus on the field of view, focus must be locked and graved to be able to come back to pre existing focus

Bad focus
=> poor specificity
=> hard to detect crack vs dust/scratch

Use of Prism





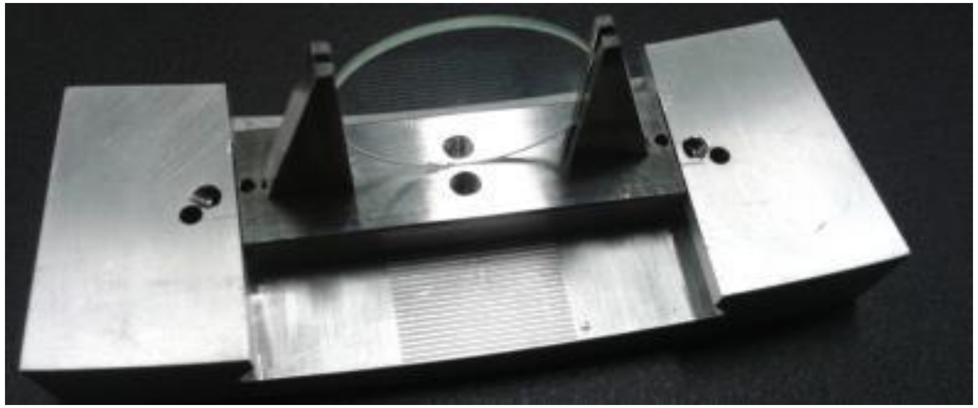


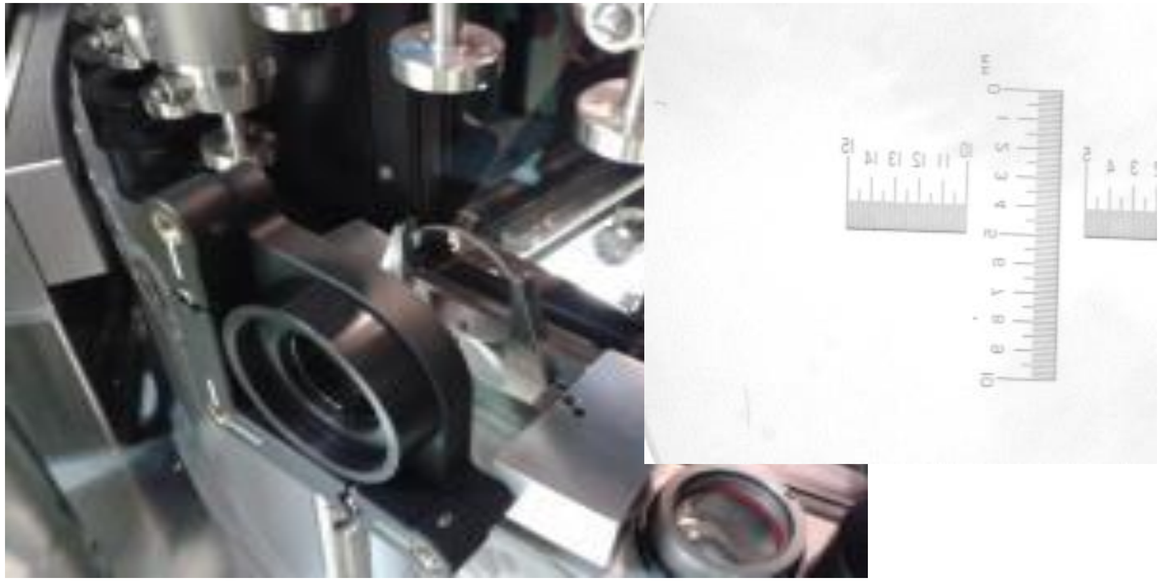
Critical Design Element:

Prism or mirror position and dust may impact image, do periodic check
Can allow to have 2 views with 1 camera

Image Focus control

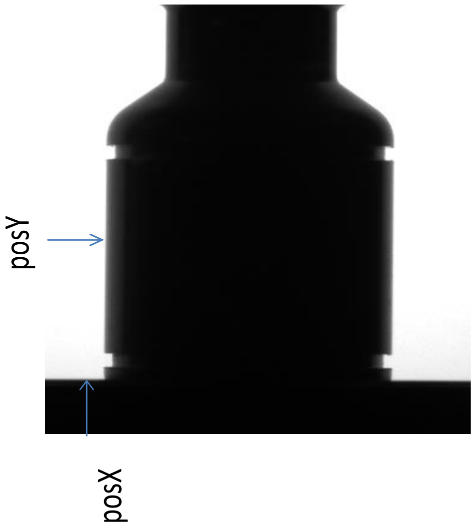
Control focus with reticles





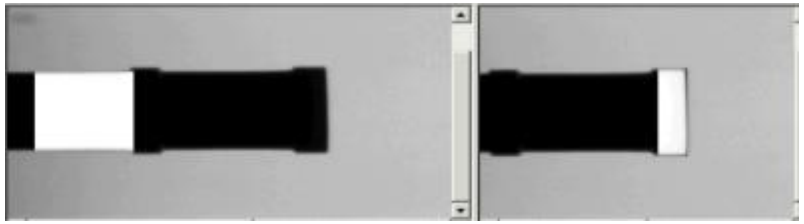
Control focus gauge

How to control Vision mechanical alignment ?



Dummy vial

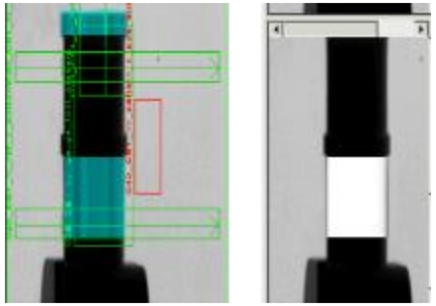
Dummy syringe



Critical Design Element:

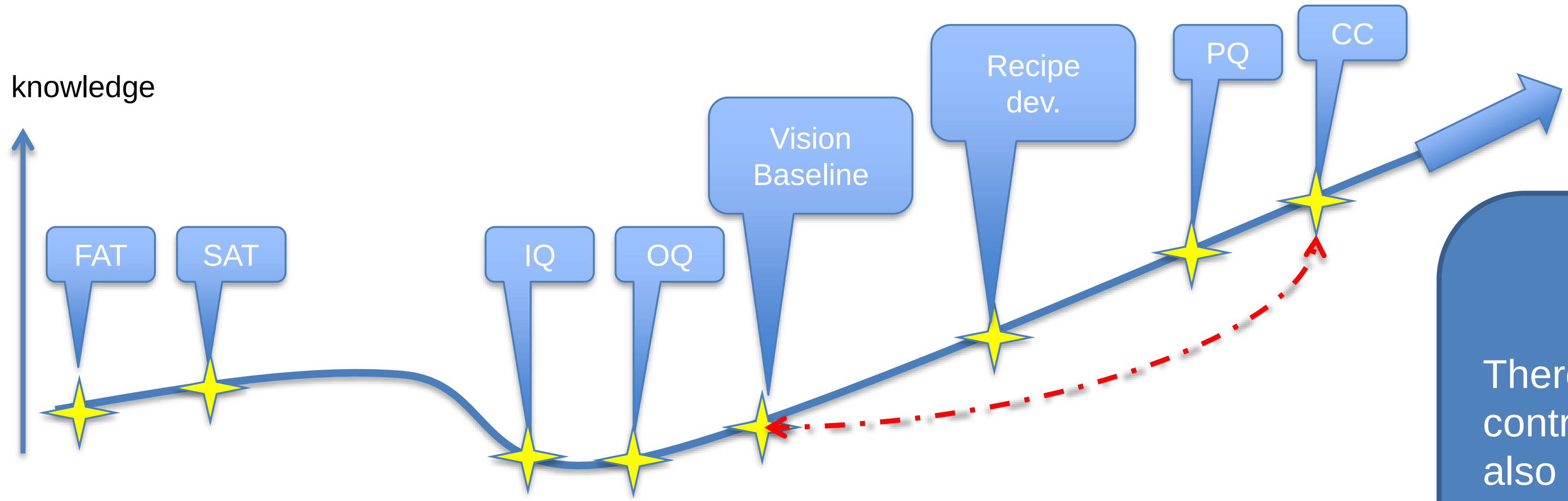
There should be tools to control vision alignment to document that vision tools remains within range from initial baseline corresponding to initial PQ

Special gauges and vision setup



Adjustment recipe

Baseline definition to keep zero alignment



= to comeback to initial state of PQ, what ever appends in life time (big machine breakage, power failure, camera replacement, or CC)

- ❑ **Mechanical Zero piece**
- ❑ **Encoder Zero**
- ❑ **Vision Zero**

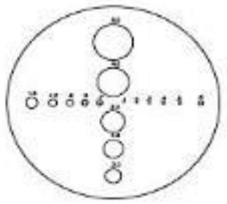
} **all must match**

Critical Design Element:

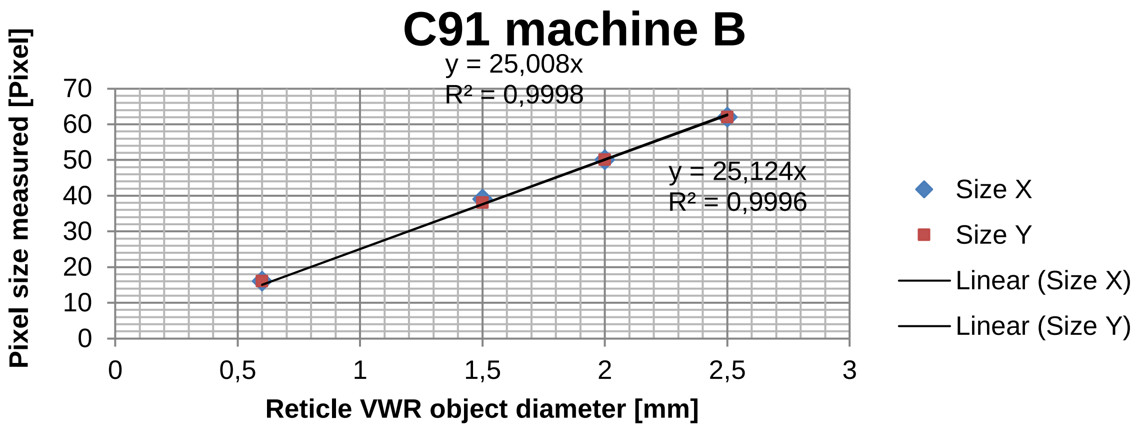
There should be tools to control vision alignment but also the mechanical zero of machine and the zero of encoder

Your AVI is like a swiss watch to handle &maintain with care

Image correlation pixel to size

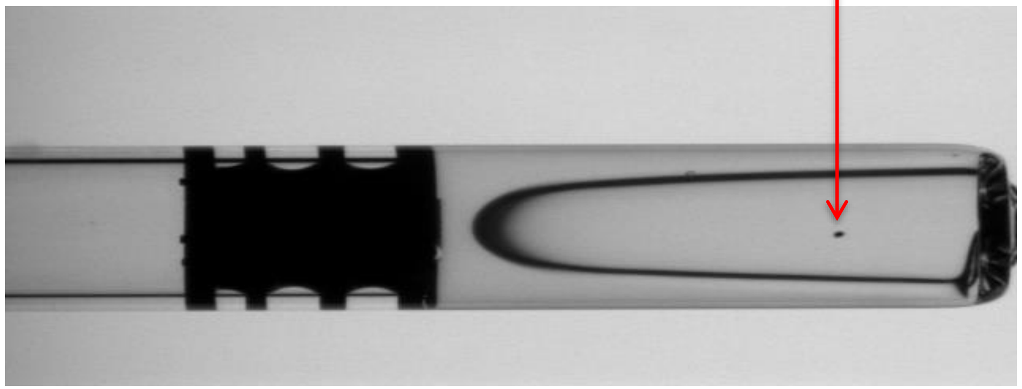


Critical Design Element:
With reticles that are calibrated, you can correlate pixel to size



1.1 mm = 5,3 pixel

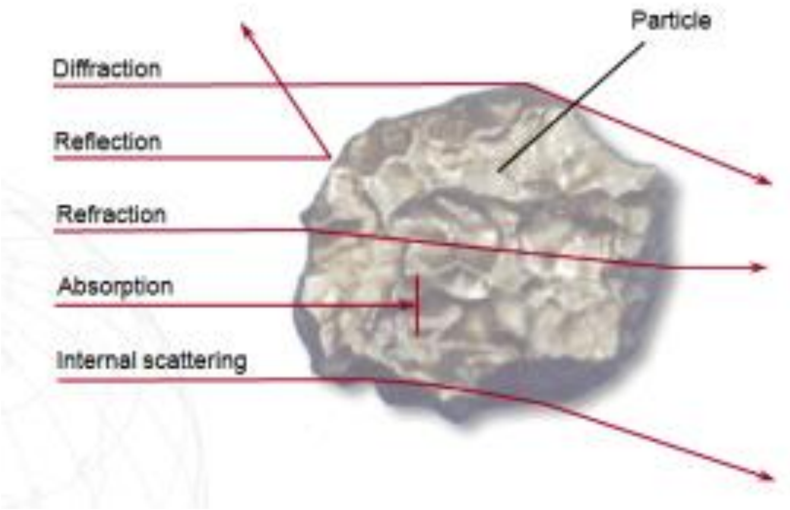
640 pixels = 134 mm (in this picture)



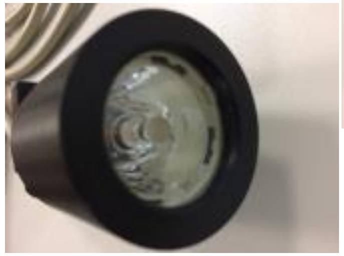
240 pixels =50 mm

Camera C61 resolution: 0.05 mm per pixel or 5,3 pixel = 0,27 mm

Illumination



LED allow to sculpt light in many plan / geometry / orientation ……



Spot LED

Line LED

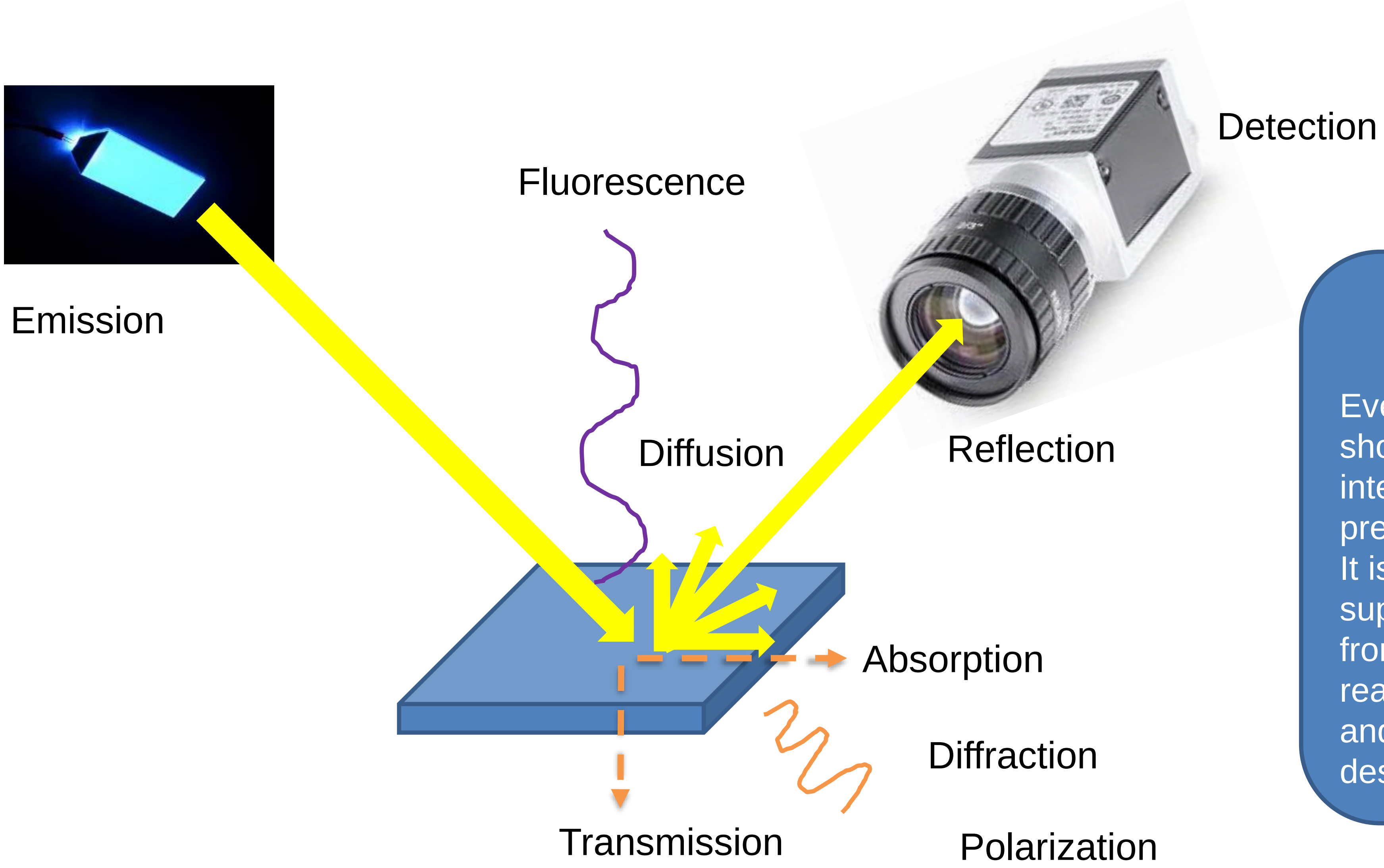
Front Panel LED

NIR LED

Back light LED

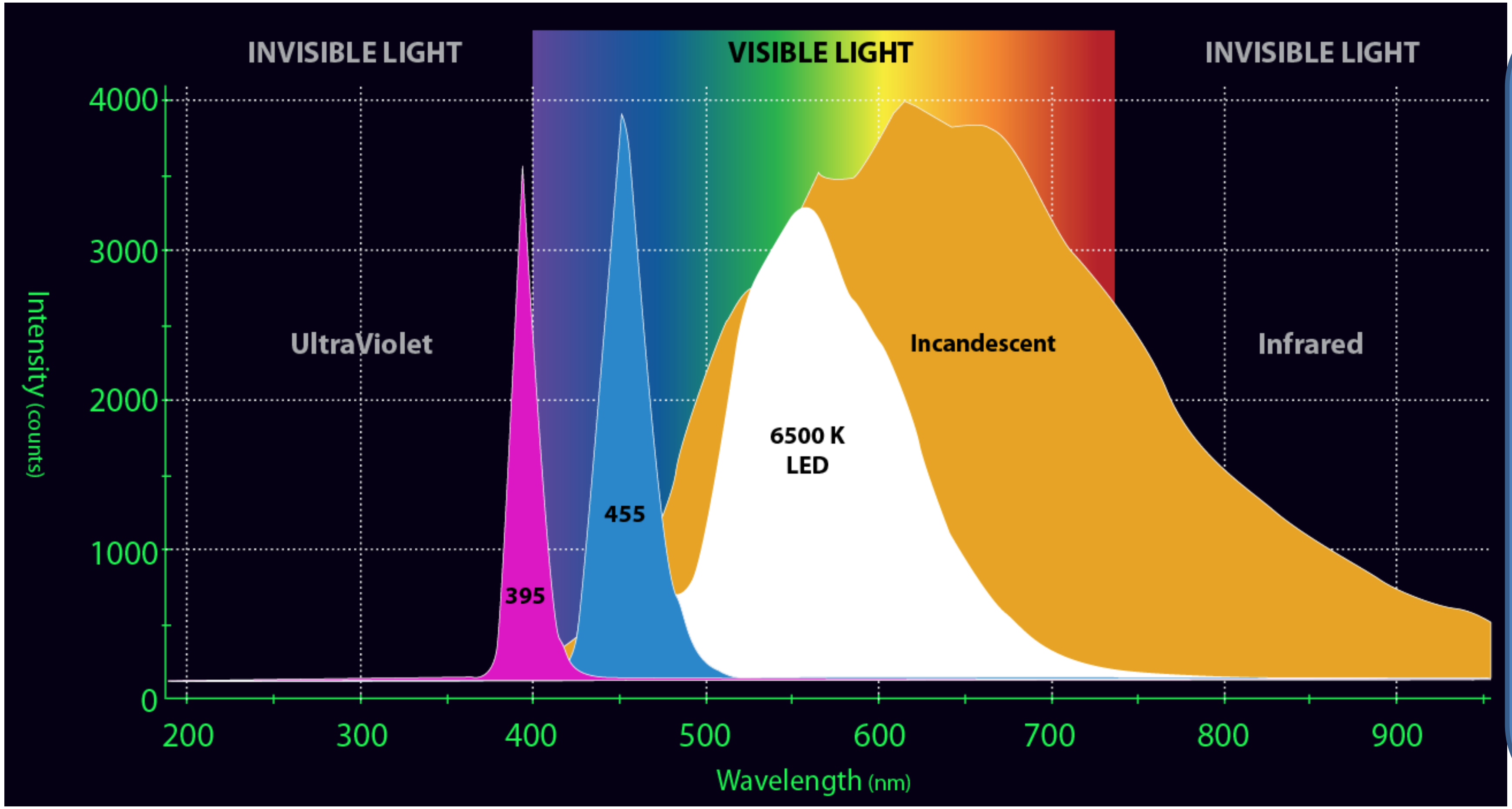
Ring LED

Light interaction paths with an object



Critical Design Element:
Every illumination design should take into account interaction with product presentation,
It is upmost critical to supply product samples from real production with real primary packaging and fill level during AVI design phase

Light source White LED, color LED, or NIR



Critical Design Element:

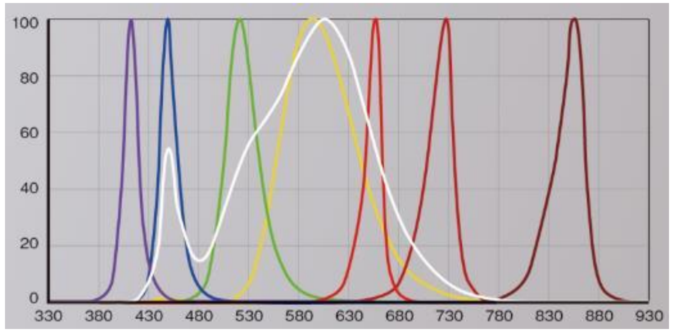
Spectral wavelength is critical to be studied with supplier,

Most of product will use visible range

Color LED may be optimal for some camera setup

Some emulsion scattering product could use NIR range

Multispectral LED are more used in packaging by now



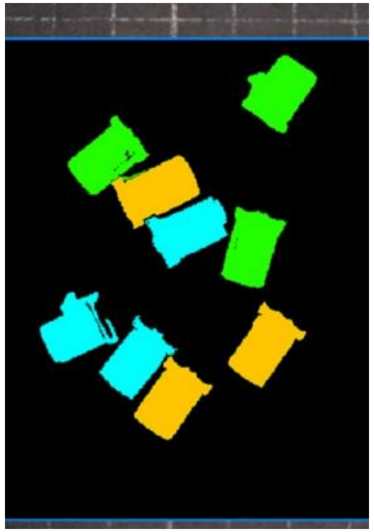
Conventional color camera

With conventional models, distinguishing between similar targets with little noticeable color difference was difficult.

Multi-Spectrum Mode

A different type of cap is extracted virtually as the same color.

Multi-Spectrum Mode : Color picking

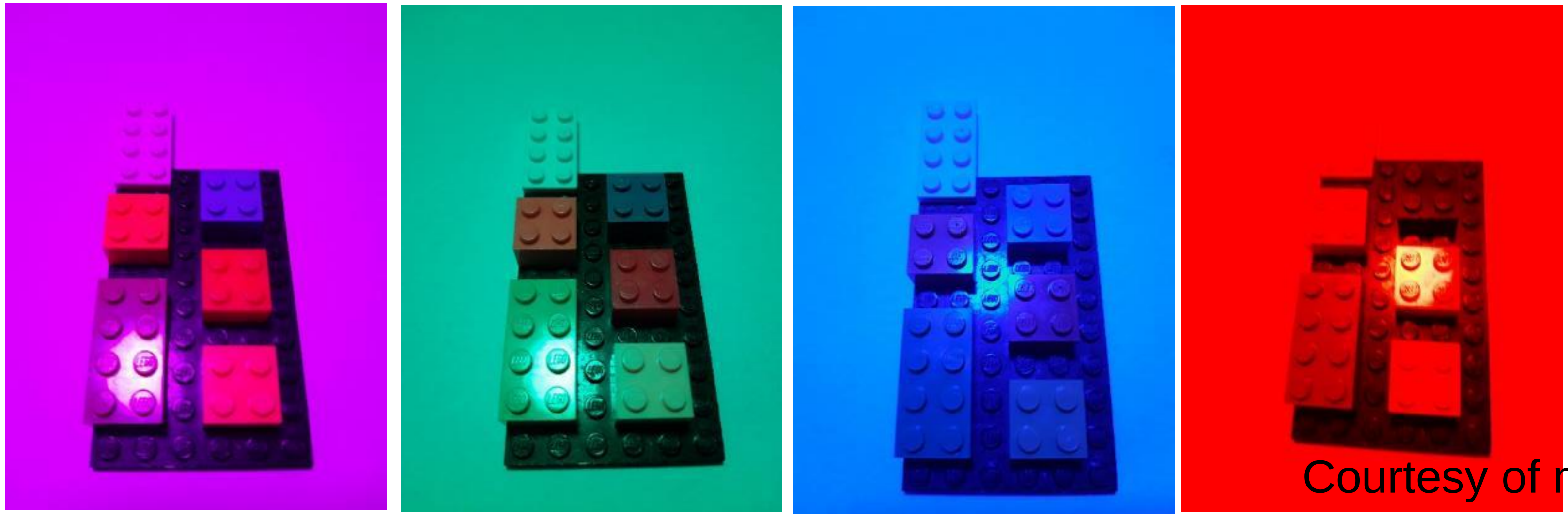


Slight differences in color are clearly defined.

Color perception impacted by light color

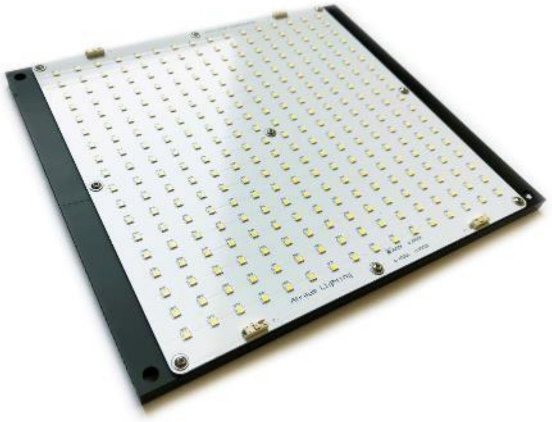
Critical Design Element:

LED color may change defect detection,
like to like change is critical
Color camera calibration is necessary

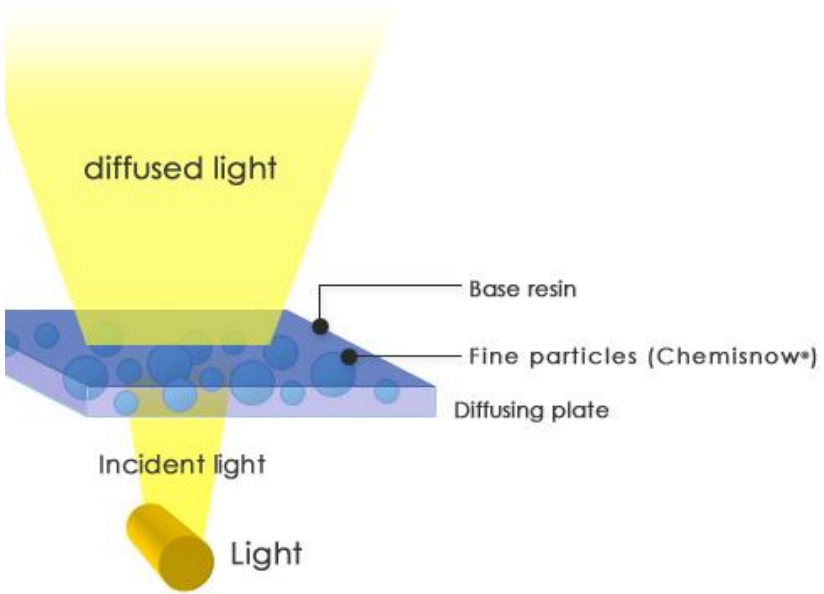


Courtesy of my kids !

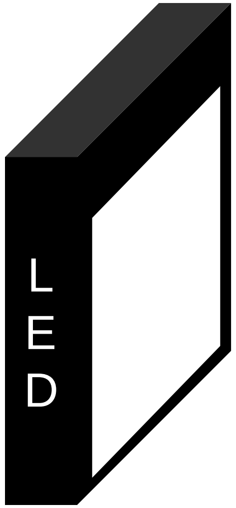
Back Light



Board



High quality diffusor

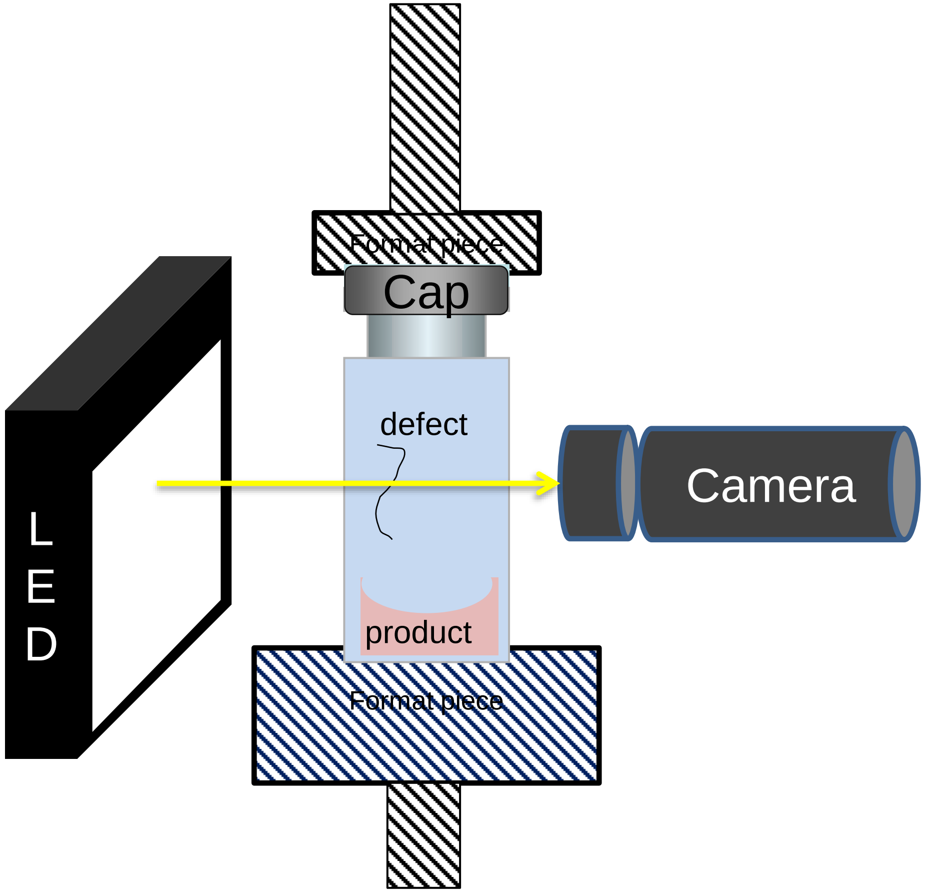


Back Light LED Assembly

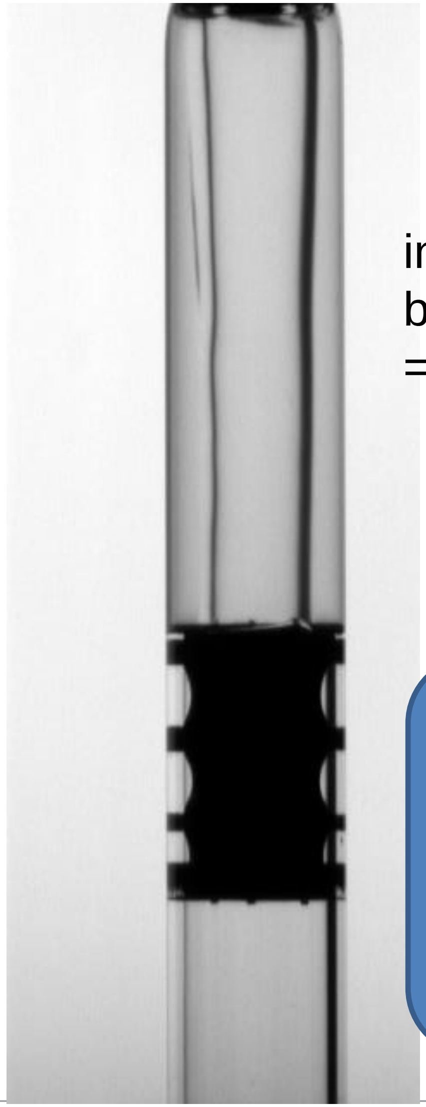
Critical Design Element:

- Back light is easy to place in AVI (very common)
- LED must be replaced like to like or some equivalency studied must be done;
- mind the wire replacement, may impact the luminance

Back Light



Low cost back light = gradient

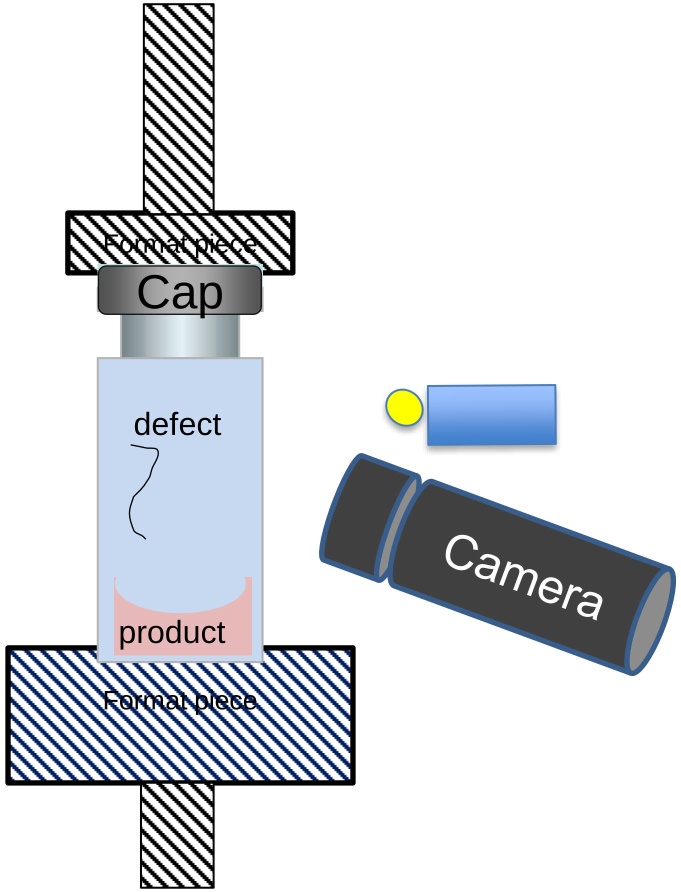


industrial back light = NO gradient

Critical Design Element:

LED distance / position must be fixed, control access level do periodic check

Spot LED Light source

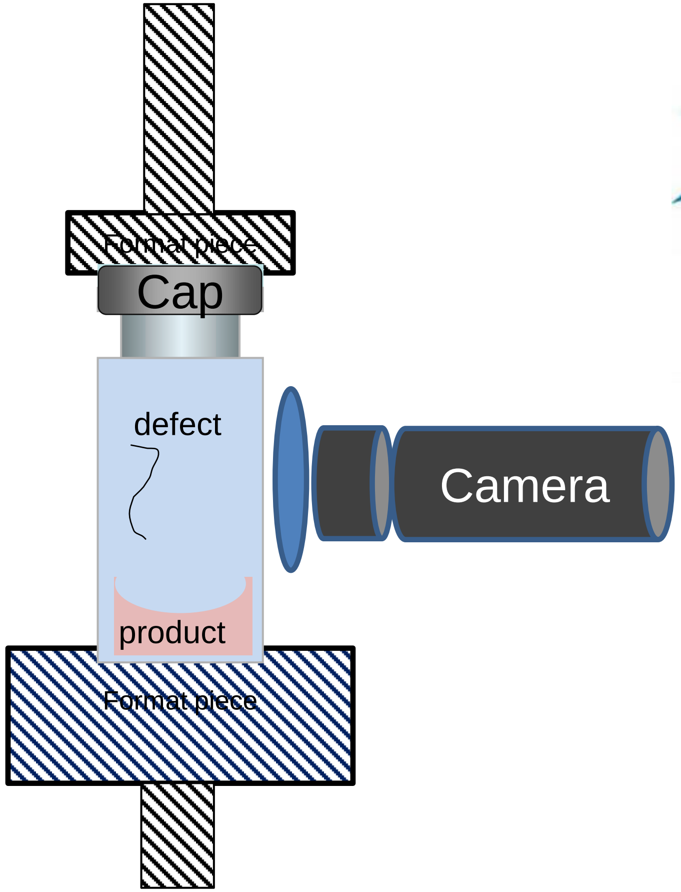


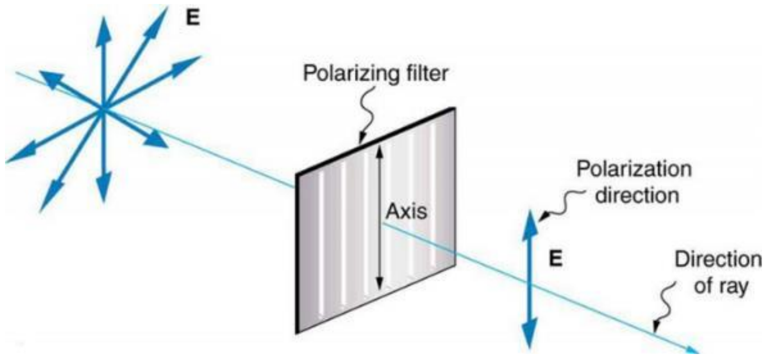
Shiny reflects

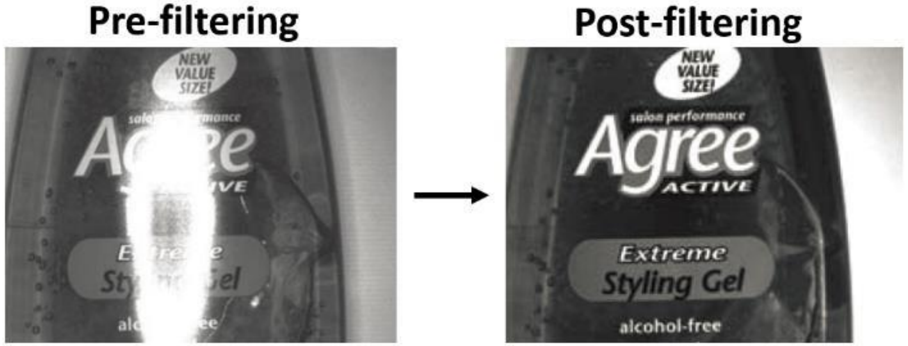
Critical Design Element:

Front spot light may create reflects, control angle position, limit access and do reg check, use pol filters

Light source + Pol filter



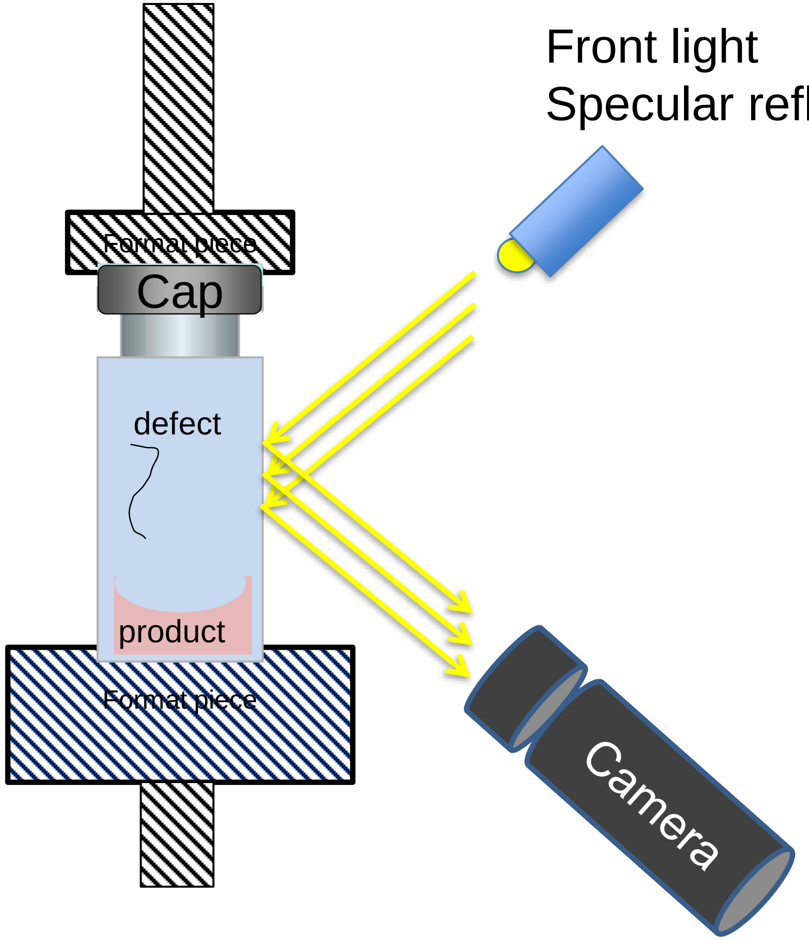




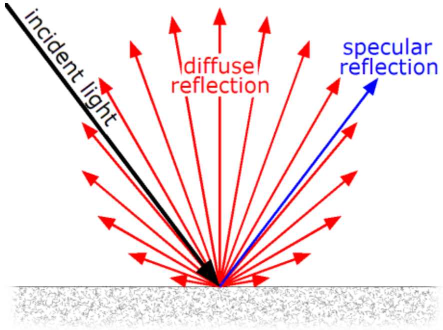
Critical Design Element:

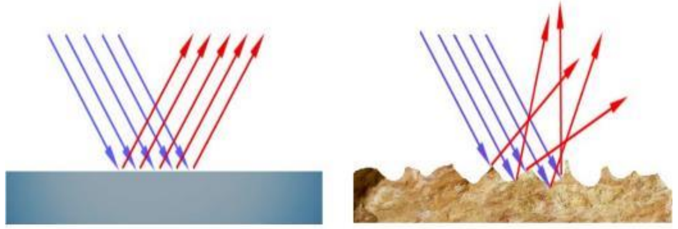
Polarization filter may impact luminance in function to positioning angle, lock and control the angle
Powerful to block some glass reflects

Specular reflectance



Front light
Specular reflectance

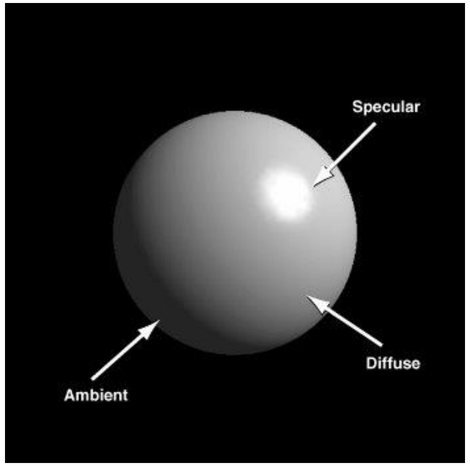




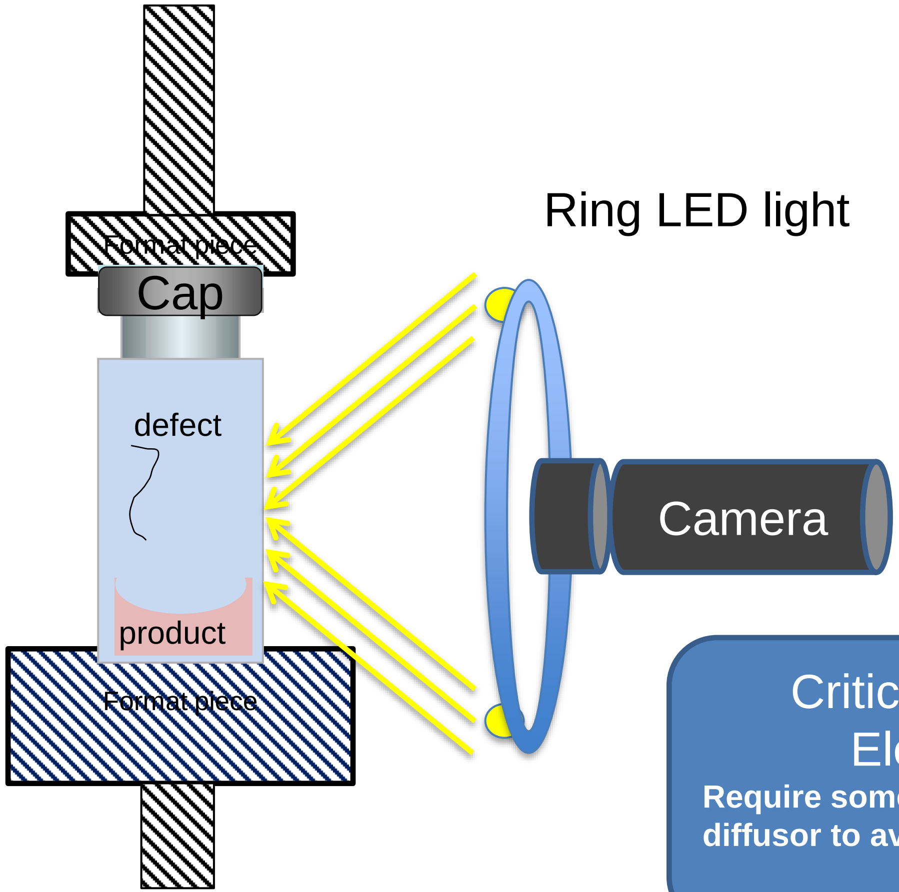
Specular Reflection   Diffuse Reflection

Critical Design Element:

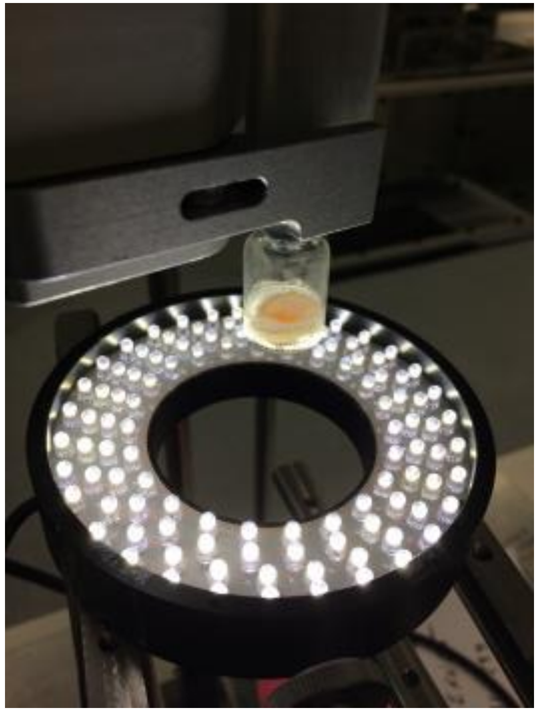
Light position and Angle is upmost critical in term of stability,
control access level and do regular check



Reflectance ring LED light



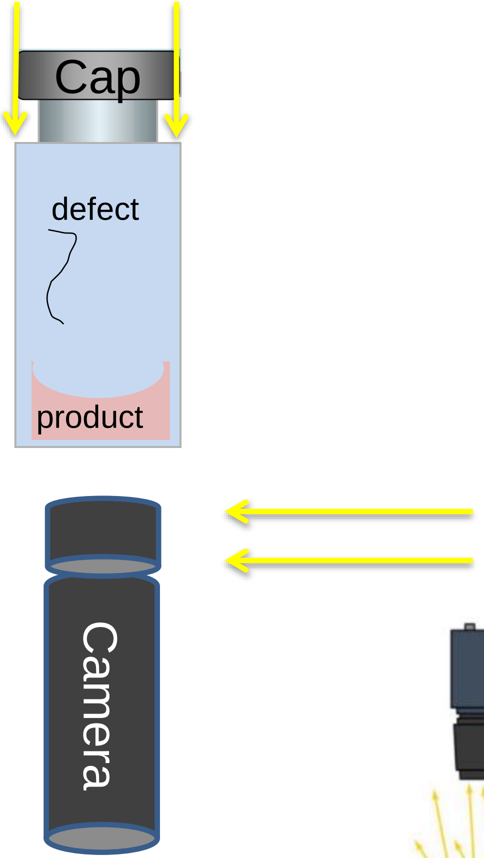
Critical Design Element:
Require some dispersive diffusor to avoid reflects



No dispersive filter = Reflect on glass

Reflect on glass

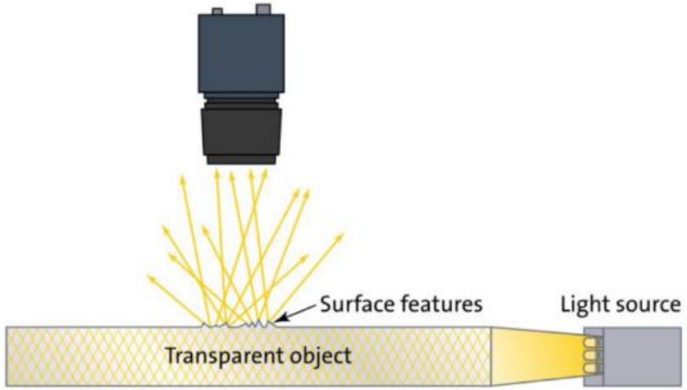
Transmissive illumination LED channeled via glass walls

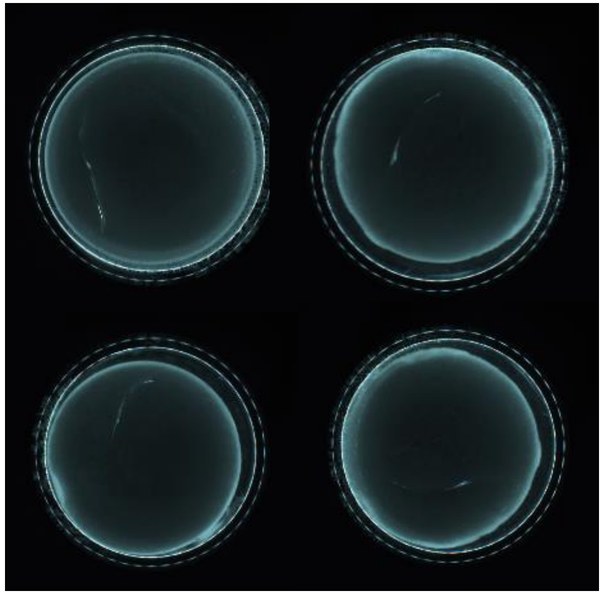


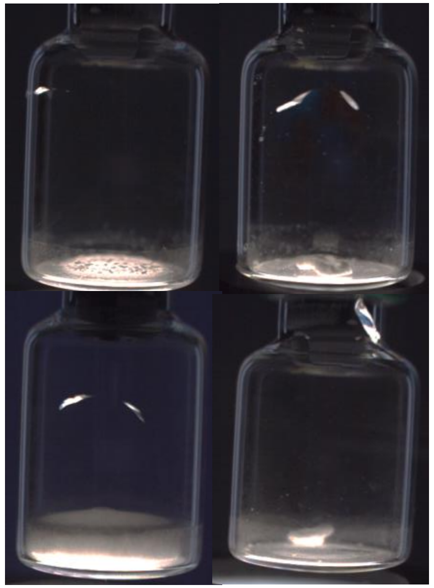
Critical Design Element:

Control glass specifications and mech stability to avoid cavitation from base holder

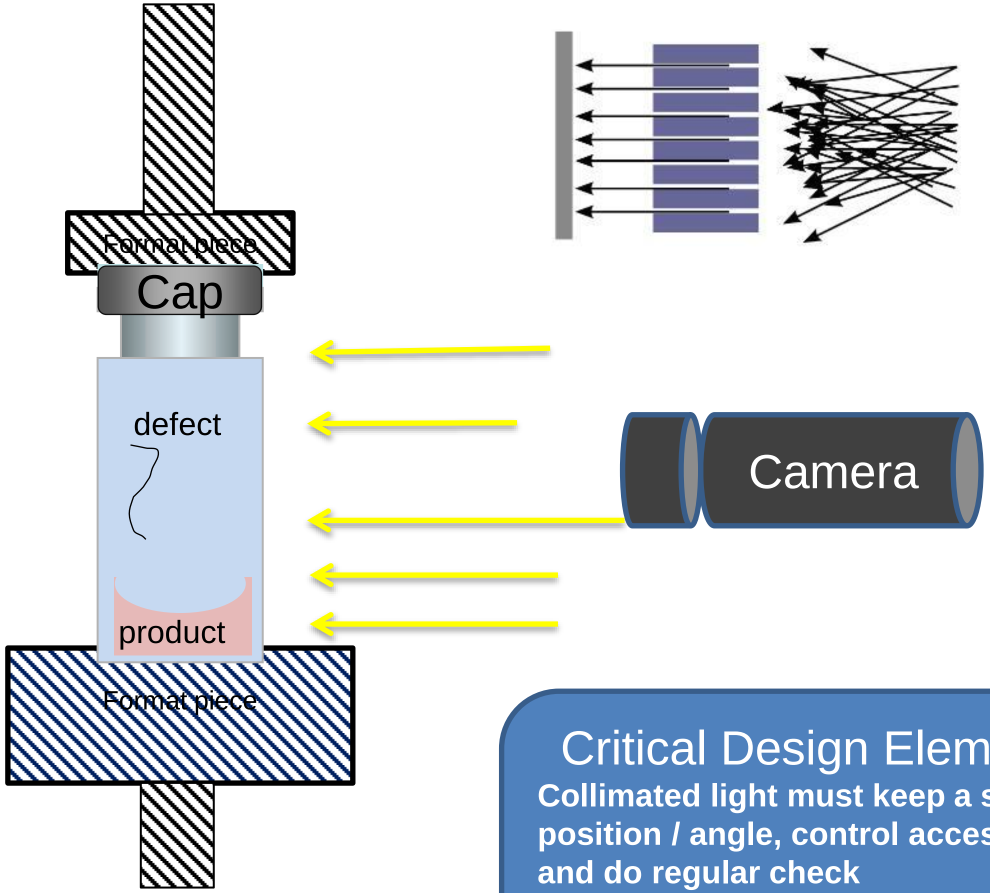
Very powerful for glass defect detection





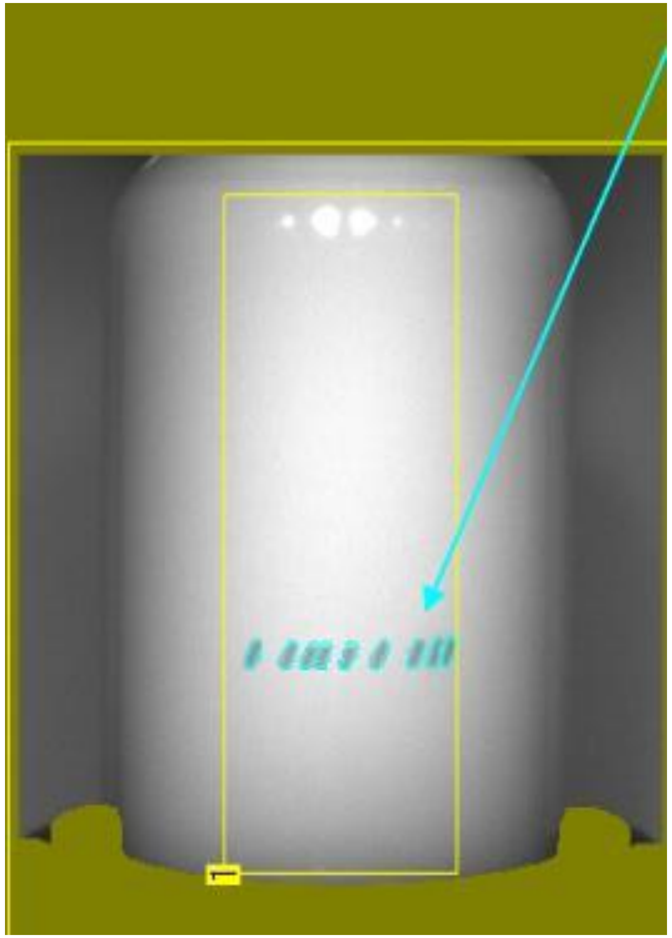


Collimated light

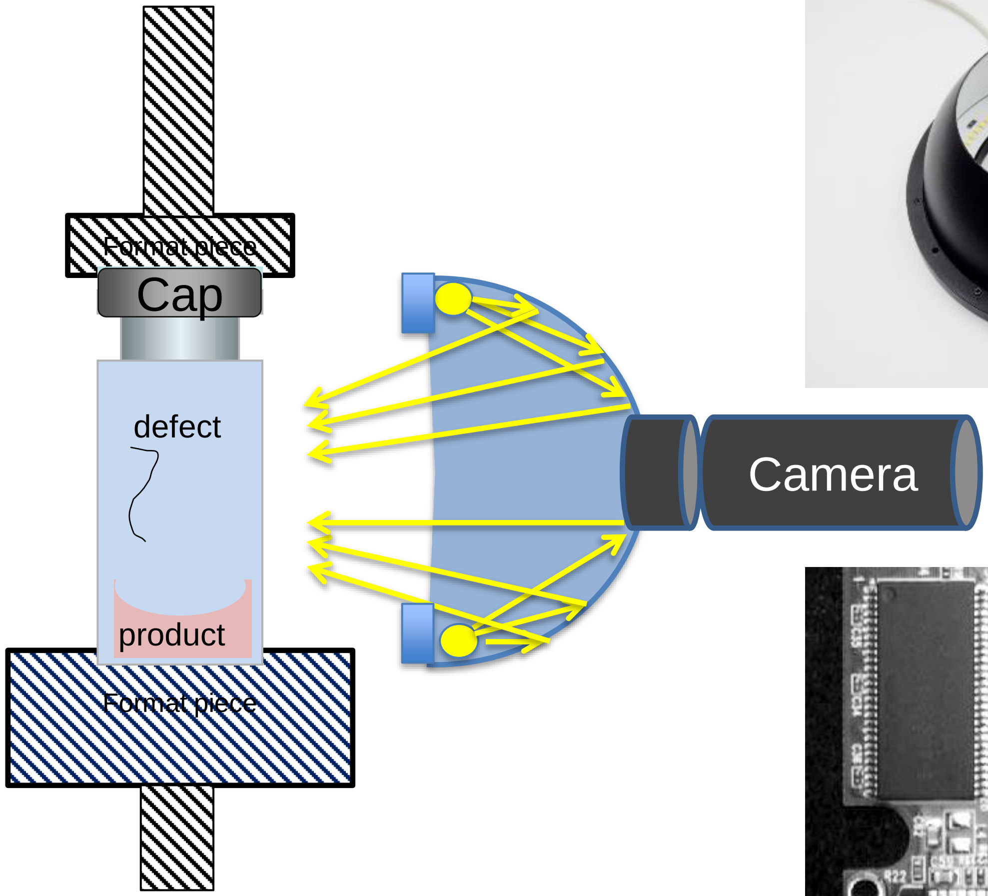


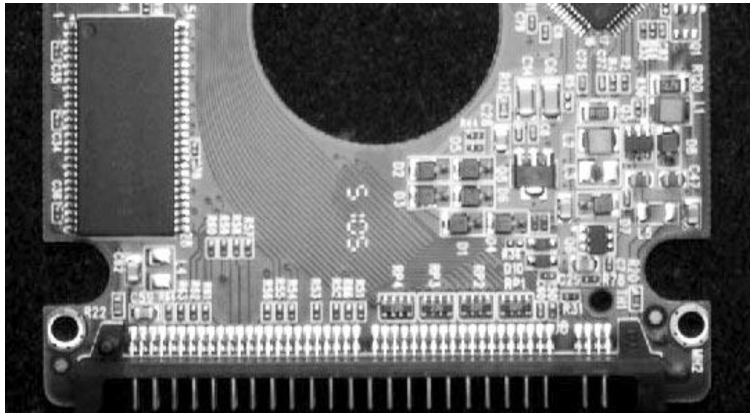
Critical Design Element:

Collimated light must keep a strict position / angle, control access level and do regular check
Interest for scattering product like emulsions



Dome Light

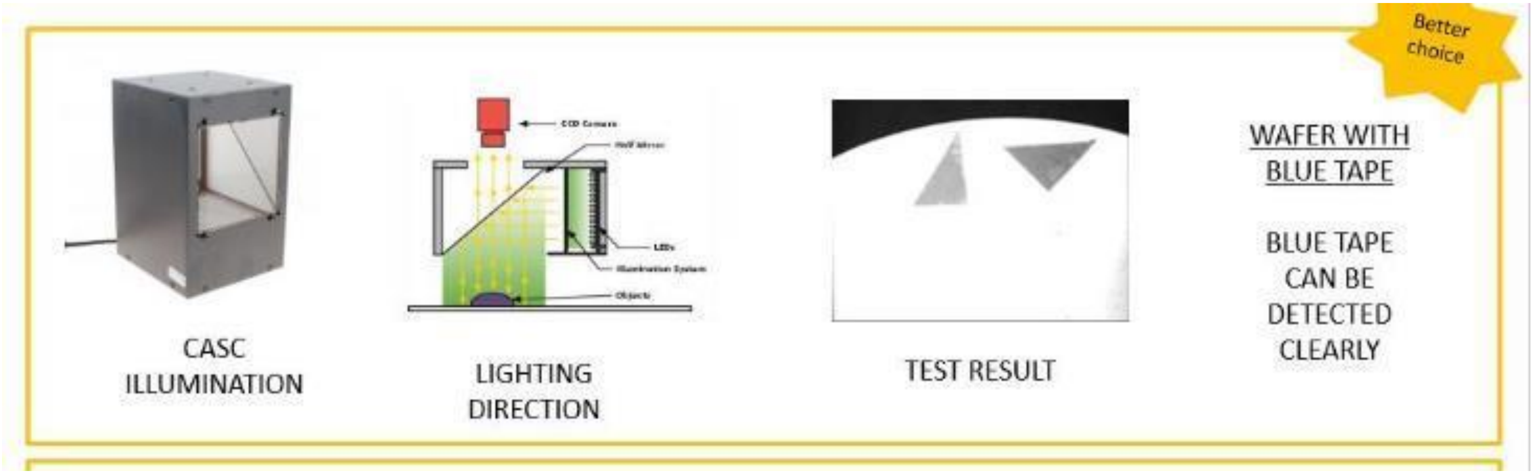


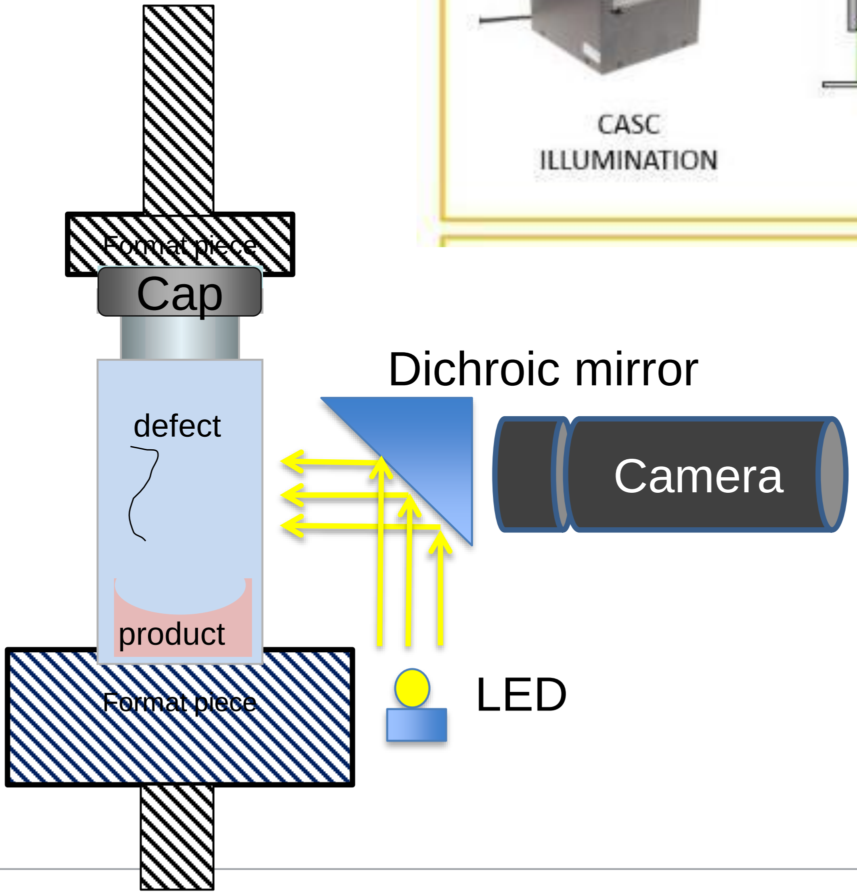


Critical Design Element:

Dome takes some space => mind stability of angle / position fixing
Multiple angle light, interest for glass defect detection

On axial light

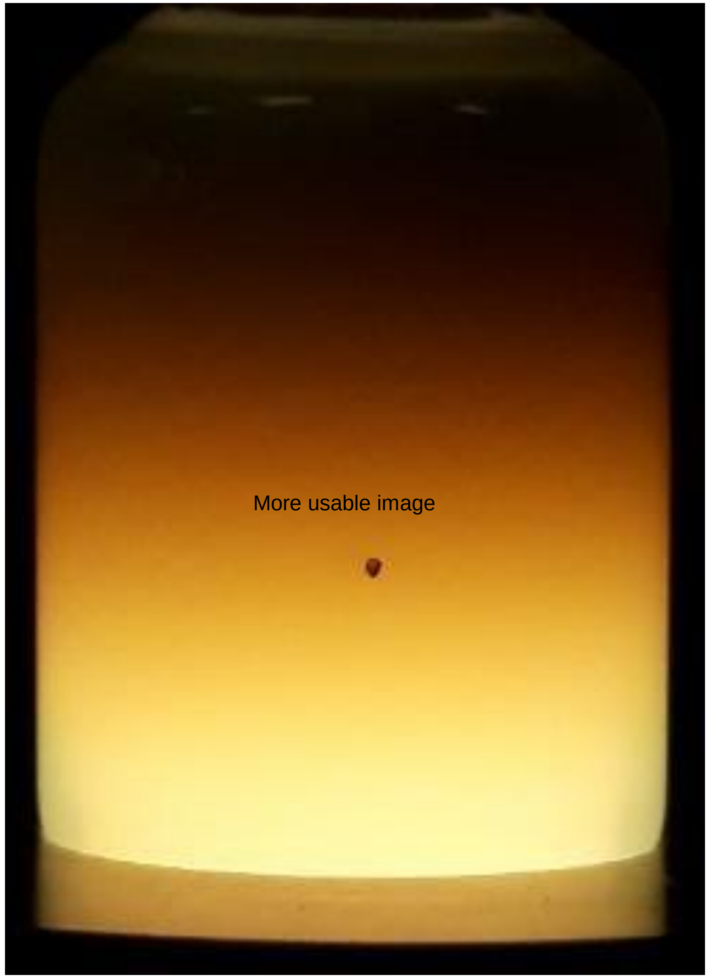




Critical Design Element:

- Can avoid reflect of glass
- Take more space
- The mirror may be obstructed by dust => regular cleaning

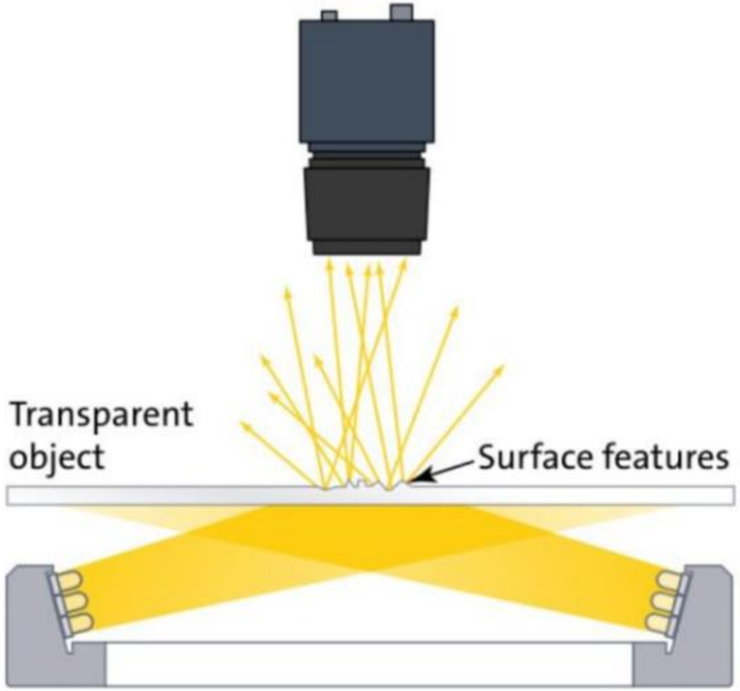
Light source with product as illuminator

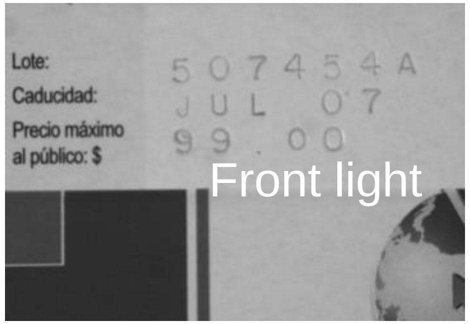


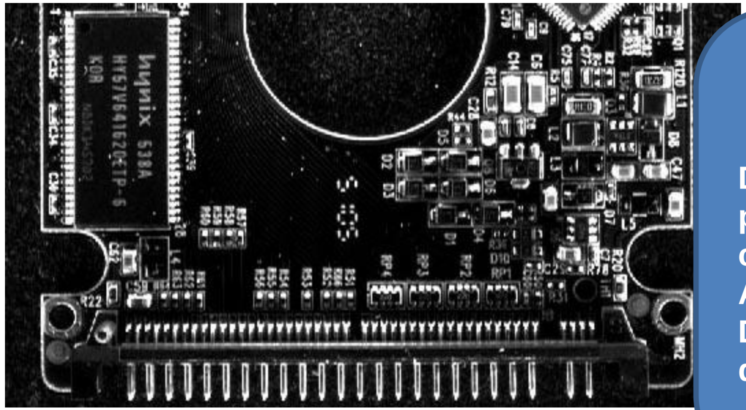
Critical Design Element:

Light from bottom vial may diffract light and burn the image, need to have a small diameter beam light

Dark field



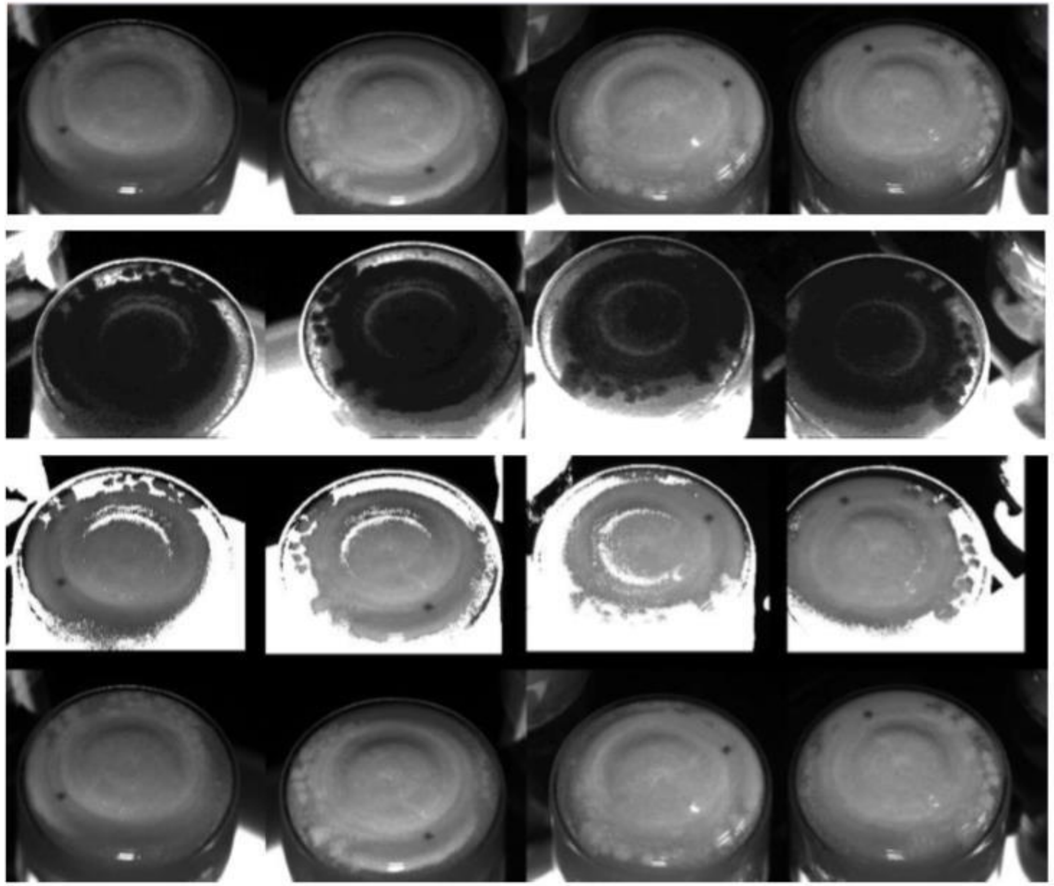




Critical Design Element:

Dark field is very sensitive to powder on side walls => extra care in vial handling before AVI
Darkfield can enhance surface defects

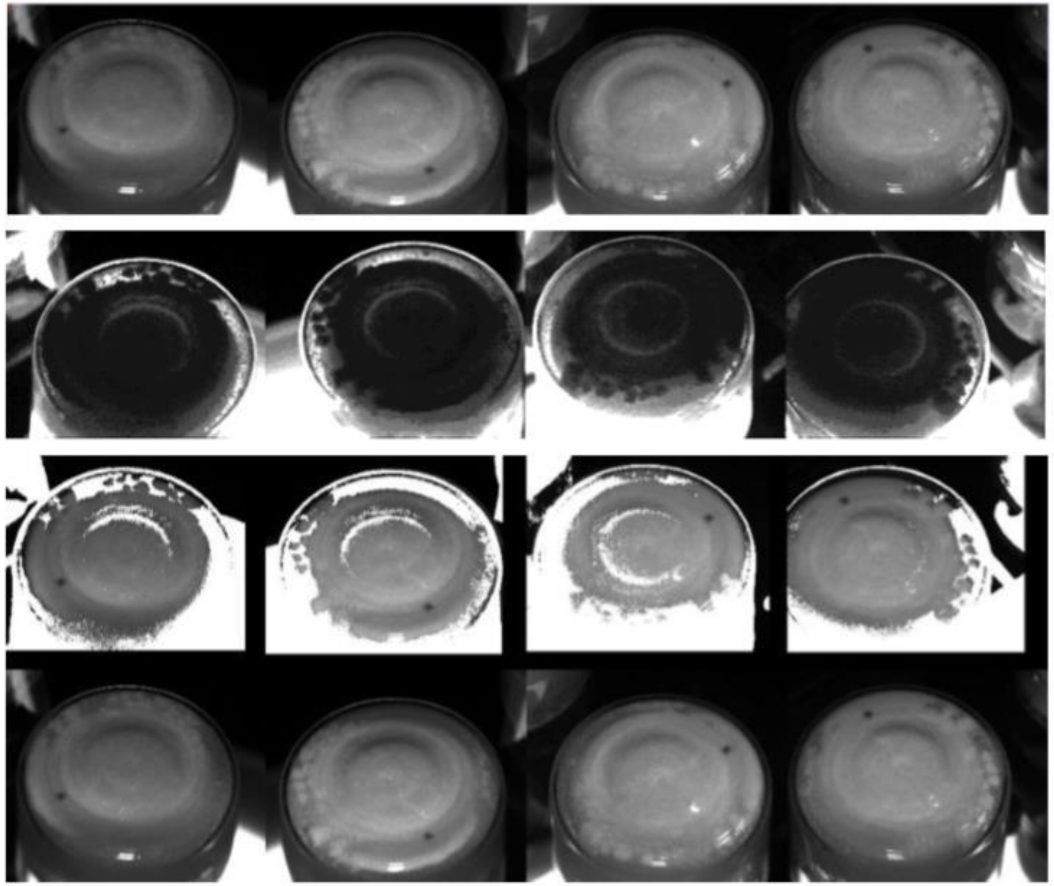
Combination of lightLight source



Critical Design Element:

Check no interference of LED from 1 station to other
Sequential strobing

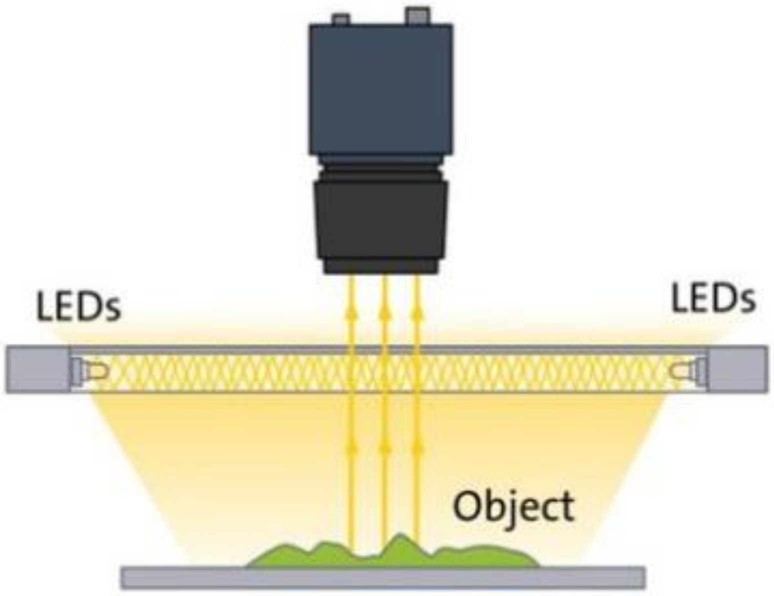
Combination of lightLight source



Critical Design Element:

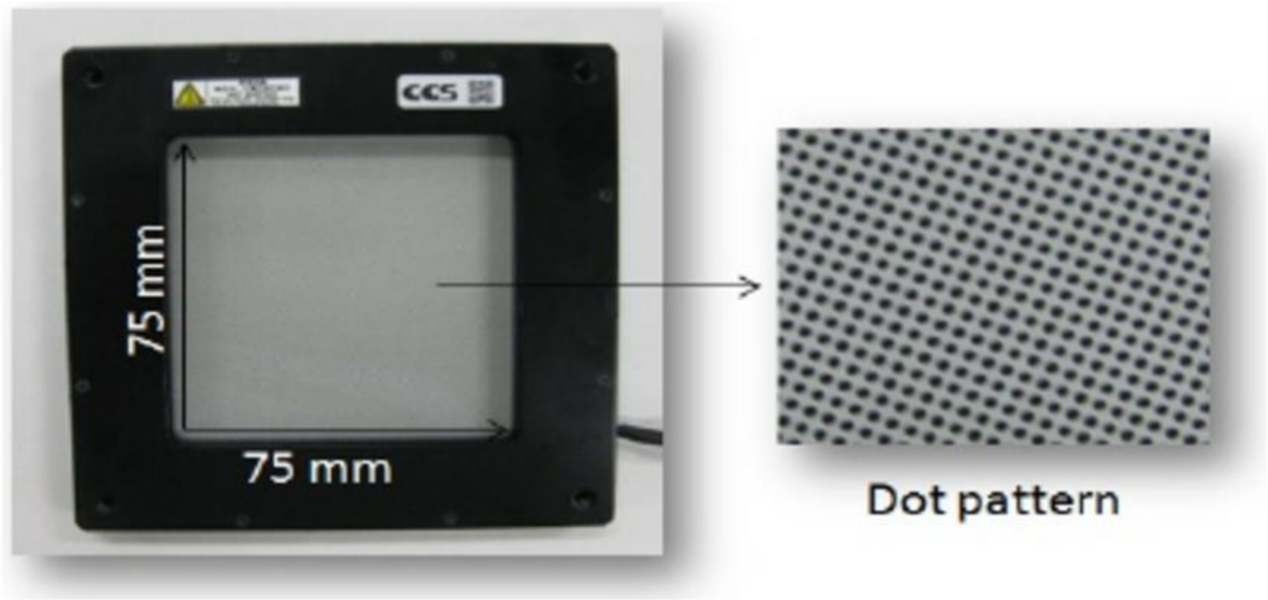
Check no interference of LED from 1 station to other
Sequential strobing

Flat Dome a new type of LED

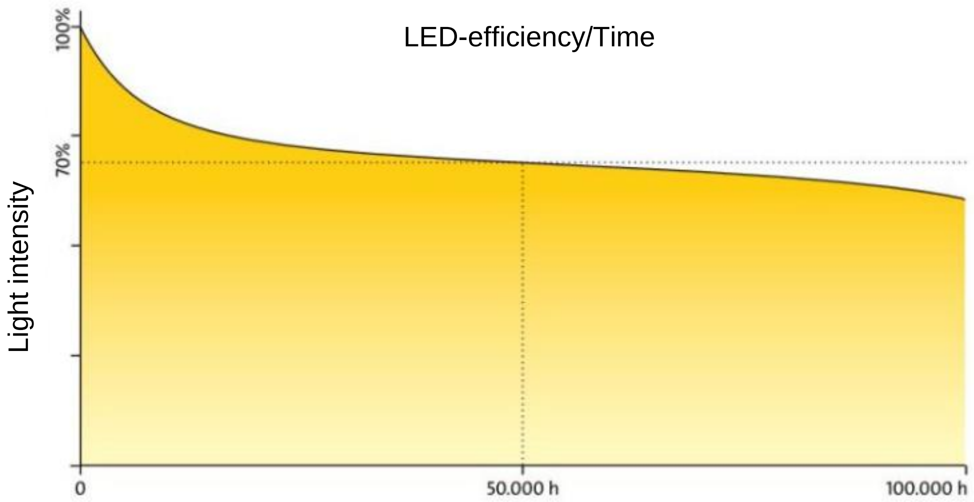


Critical Design Element:

Very powerful with on axial light to avoid reflects
Fragile surface with microscopic dots on glass

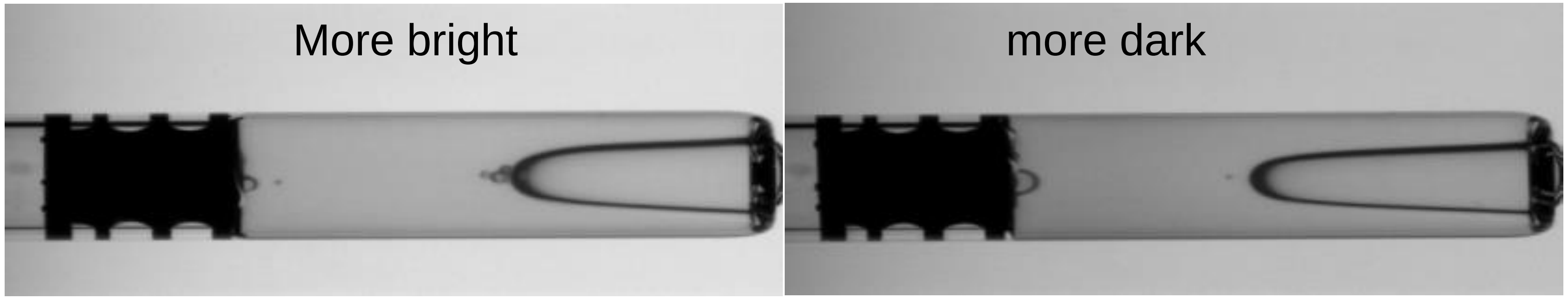


LED risks

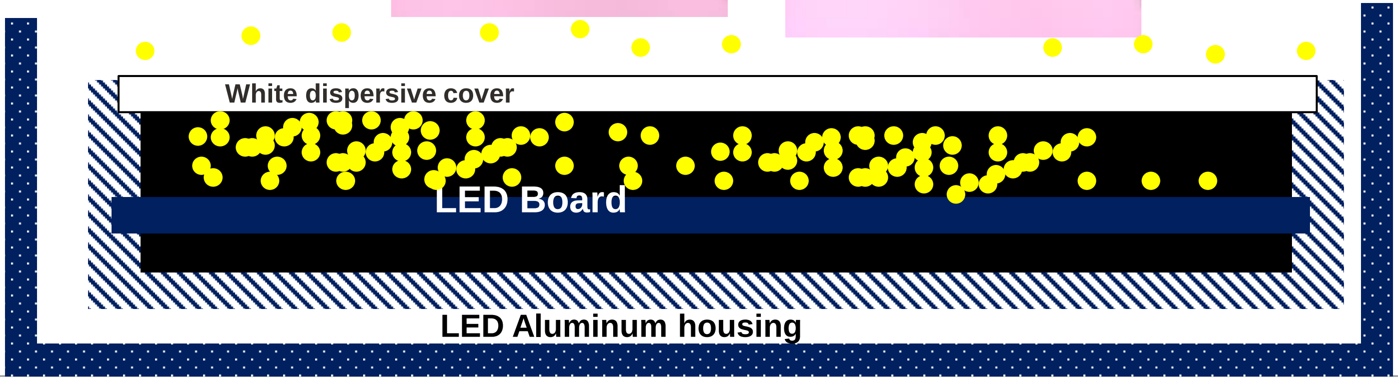

LED-efficiency/Time
Light intensity
100%
70%
0
50.000 h
100.000 h

LED Heat Dissipation Risks

LED are more stable but …….beware of heat dissipation

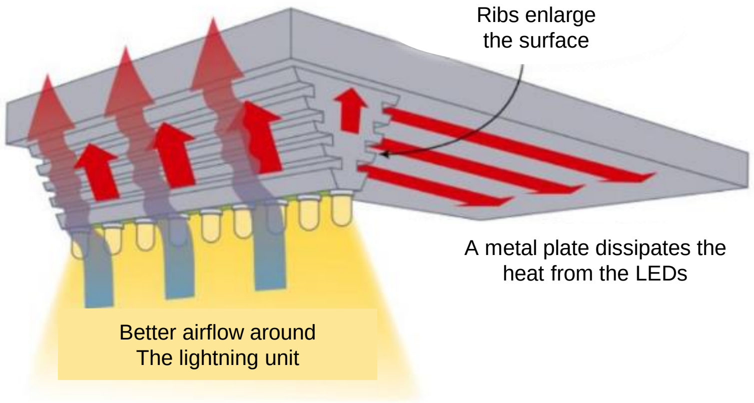


Conform Crack



Critical Design Element:

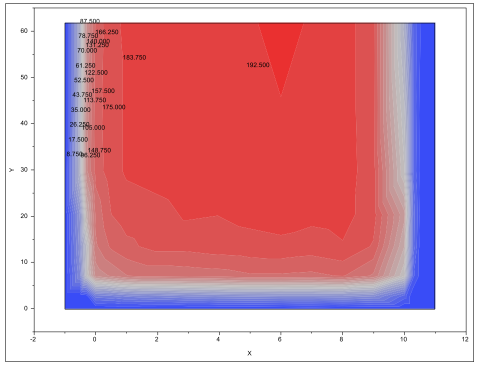
- **LED are not stable if no good heat dissipation**
- **Need a periodic ctrl or permanent**
- **Good heat dissipation by design**



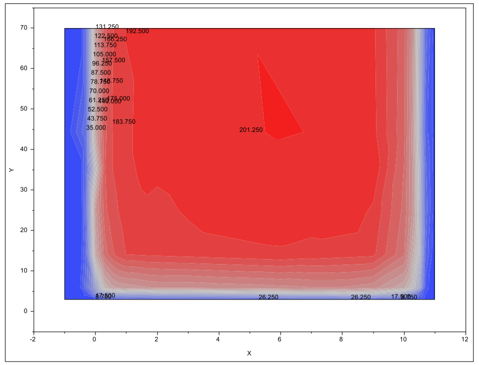
LED are more stable but …….beware of boarder effect

Mapping of Luminance Level in X and Y position
And Z position

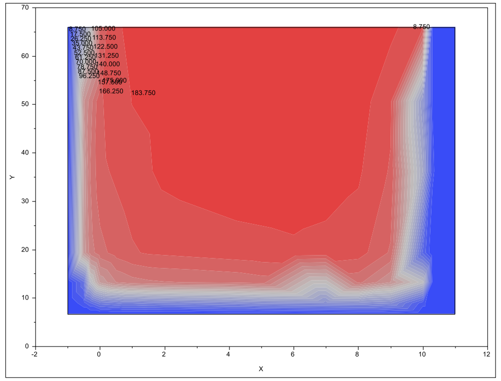
=> Very Homegeneous in area of use



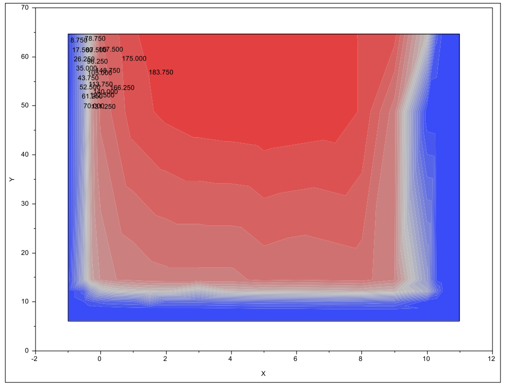
z =53.42mm



z =98.1mm



z =134.5mm



z=178mm

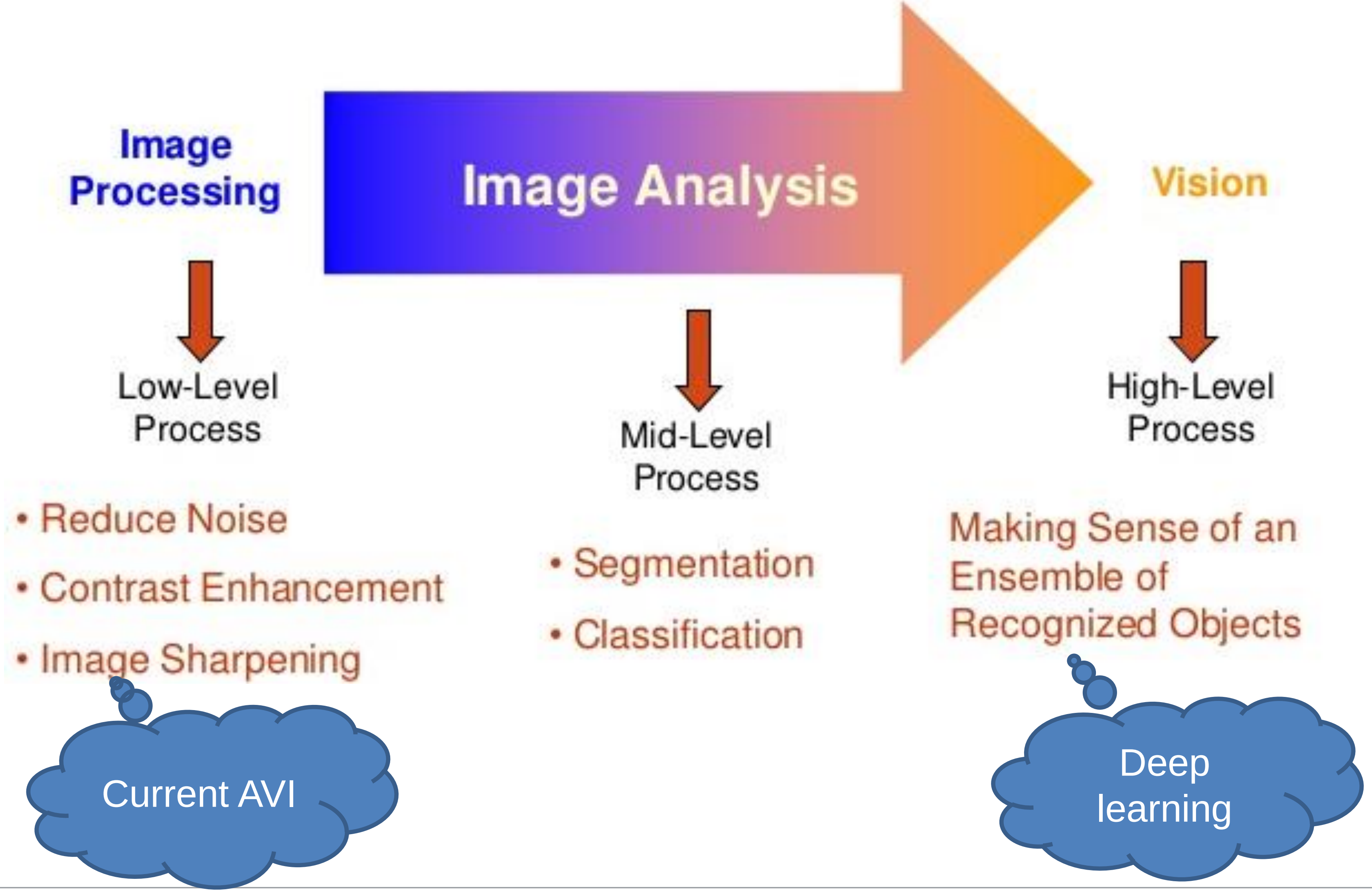
Critical Design Element:

LED have a border effect
Working area should be not so close from border
Need to have sufficient sized LED

Digital Image processing

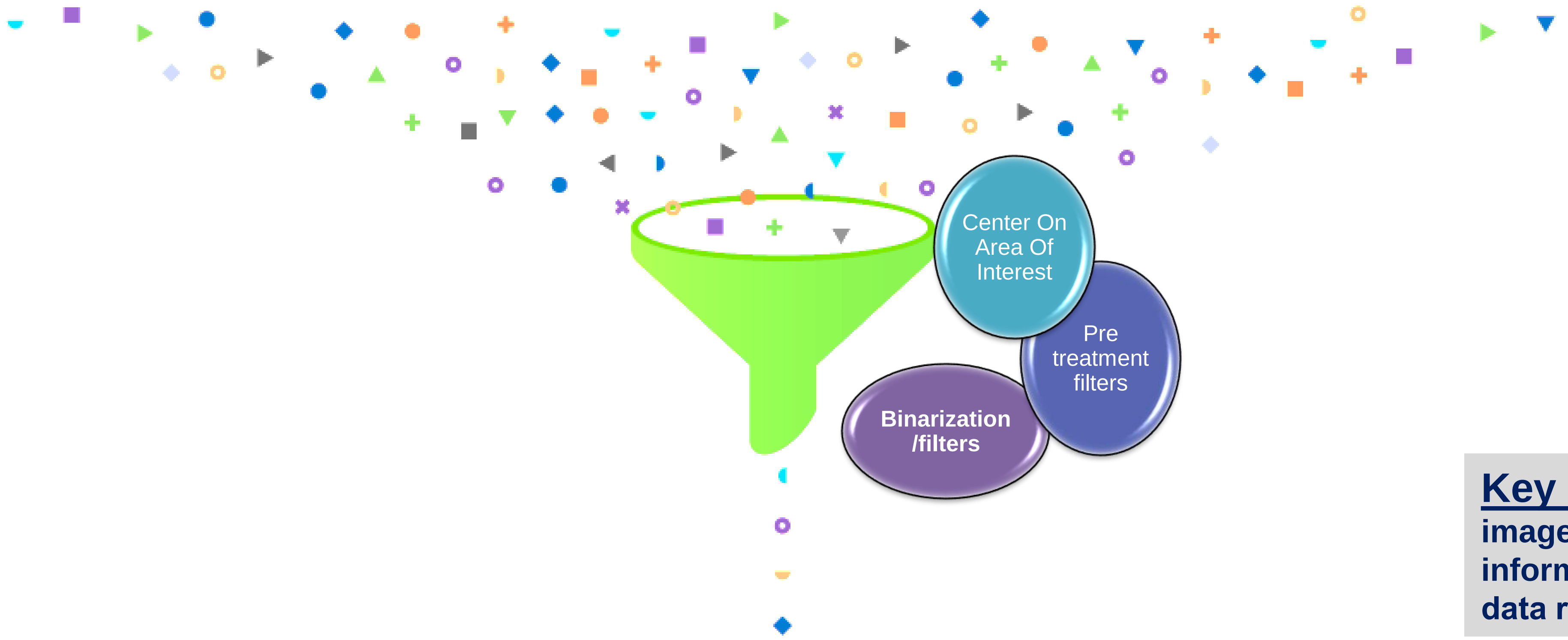
CONNECTING PEOPLE SCIENCE AND REGULATION®

image processing level



What is the goal of image processing ?

A data reduction, a feature extraction

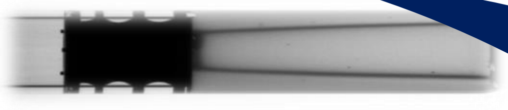


Decision Pass/Fail

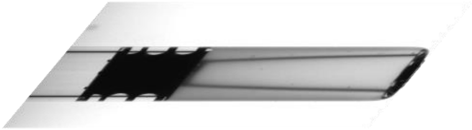
Key learning: an image has too much information need some data reduction…

Main steps in image processing

1 3D Object presented



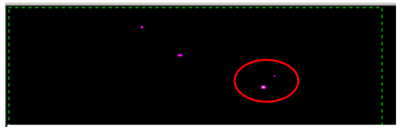
2 2D image



3 Area Of Interest (=AOI)

4 Binarization

5 Object detection



Feature Name	Current Value
Box X Min	227.0
Box Y Max	72.0
Box Y Min	70.0
Center of Gravity X	228.2
Center of Gravity Y	71.0
Convex Perimeter	12.0
Elongation	1.4
Feret Elongation	1.4
Feret Max Diameter	4.2
Moment Central X1 Y1	0.0

6 Image feature

7 Image understanding

8 Pass / Fail

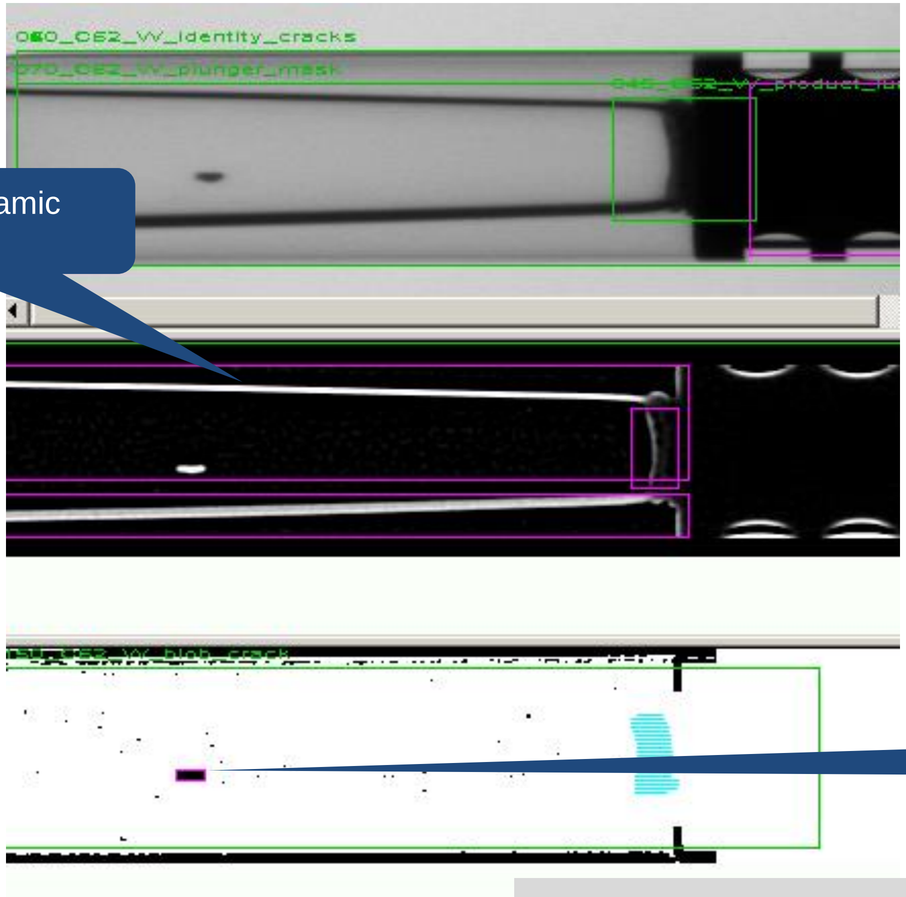
<10ms

Key learning: this engineering step of vision recipe development is done to reduce information of images and to enhance specificity of decision…
…..in less than 10ms

Critical Design Element:

Image processing must be editable with recipes (no hard coding)
Recipe must be version controlled
Any change on vision recipe must be tracked with audit trail

Image processing example

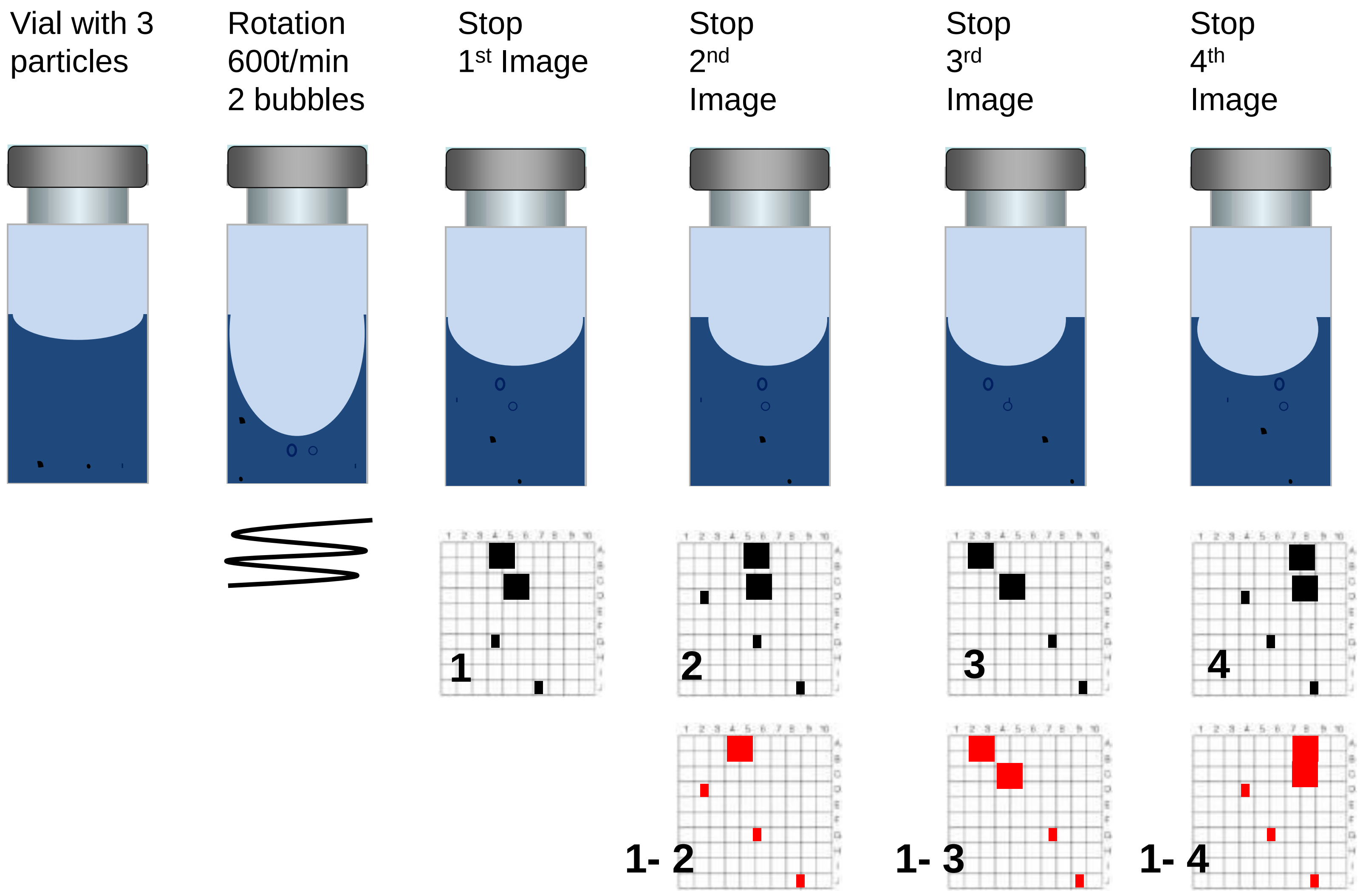


1 meniscus dynamic masking

2 Particle is localized

Key learning:
Color / Shape / Position features can help to discriminate particle and bubbles

Particle Detection strategies : image subtraction an old approach



NOT SENSITIVE TO FIXED PARTICLES + Above liquid

Key learning:
Image Subtraction is not very sensitive for particle detection in small suspension unit + no detection above liquid + no detection of fixed particles

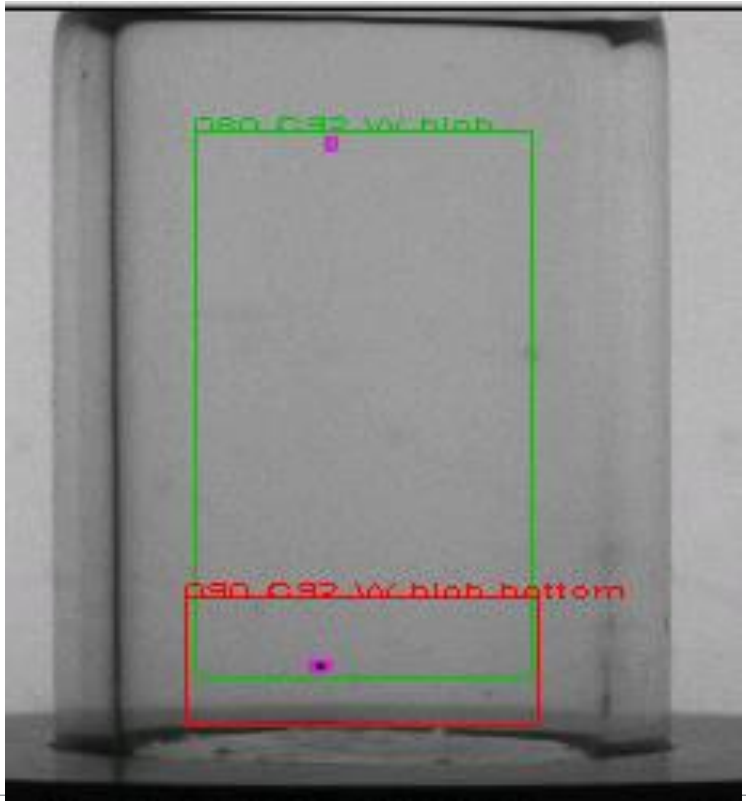
Particle Detection strategies : Fast rotation

How to inspect Automatically a suspension that has a high optical density + scattering?

= Fast rotation To present liquid in thin layer

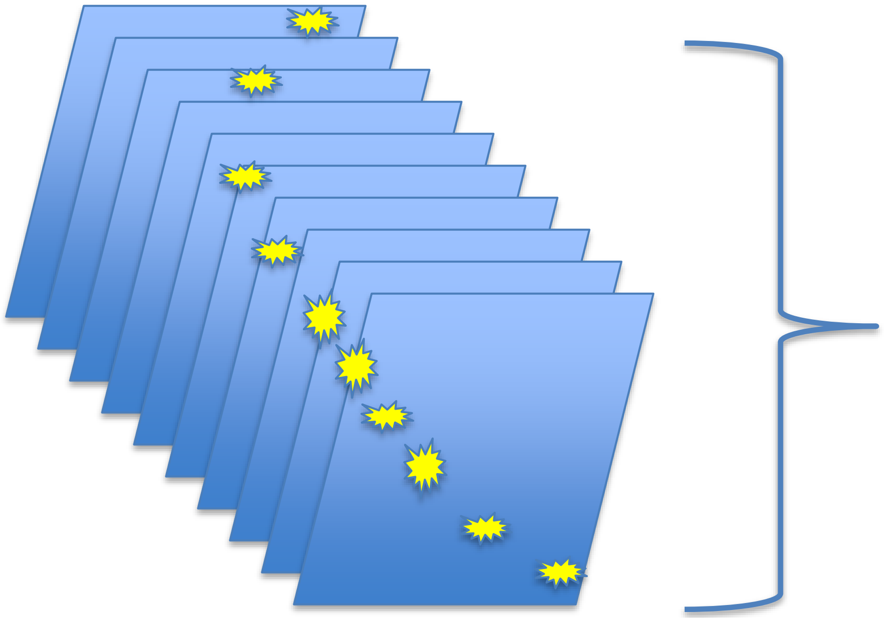
- ⇒ Lower optical path (density beer lambert)
- ⇒ Minimized scattering effect

0 t/min | 600 t/min | 1800 t/min | 3600 t/min

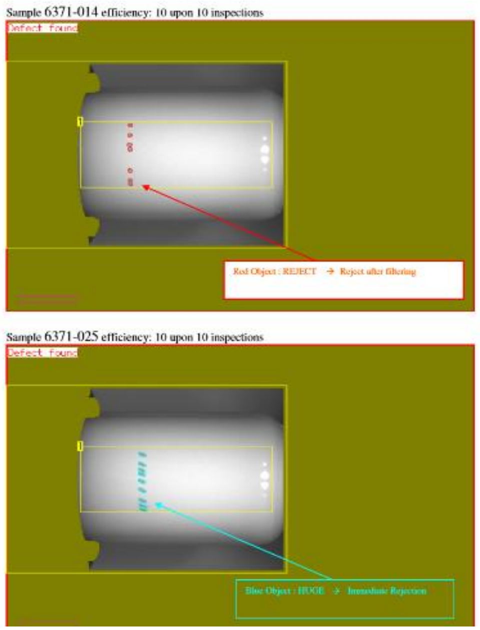


Particle Detection strategies : Particle tracking

- With modern vision machine more images are available
- Images can be treated not only 1 by 1 individually but in stack of images
- Rendering particle trajectories analyzed
- And differentiation to artifacts like bubbles

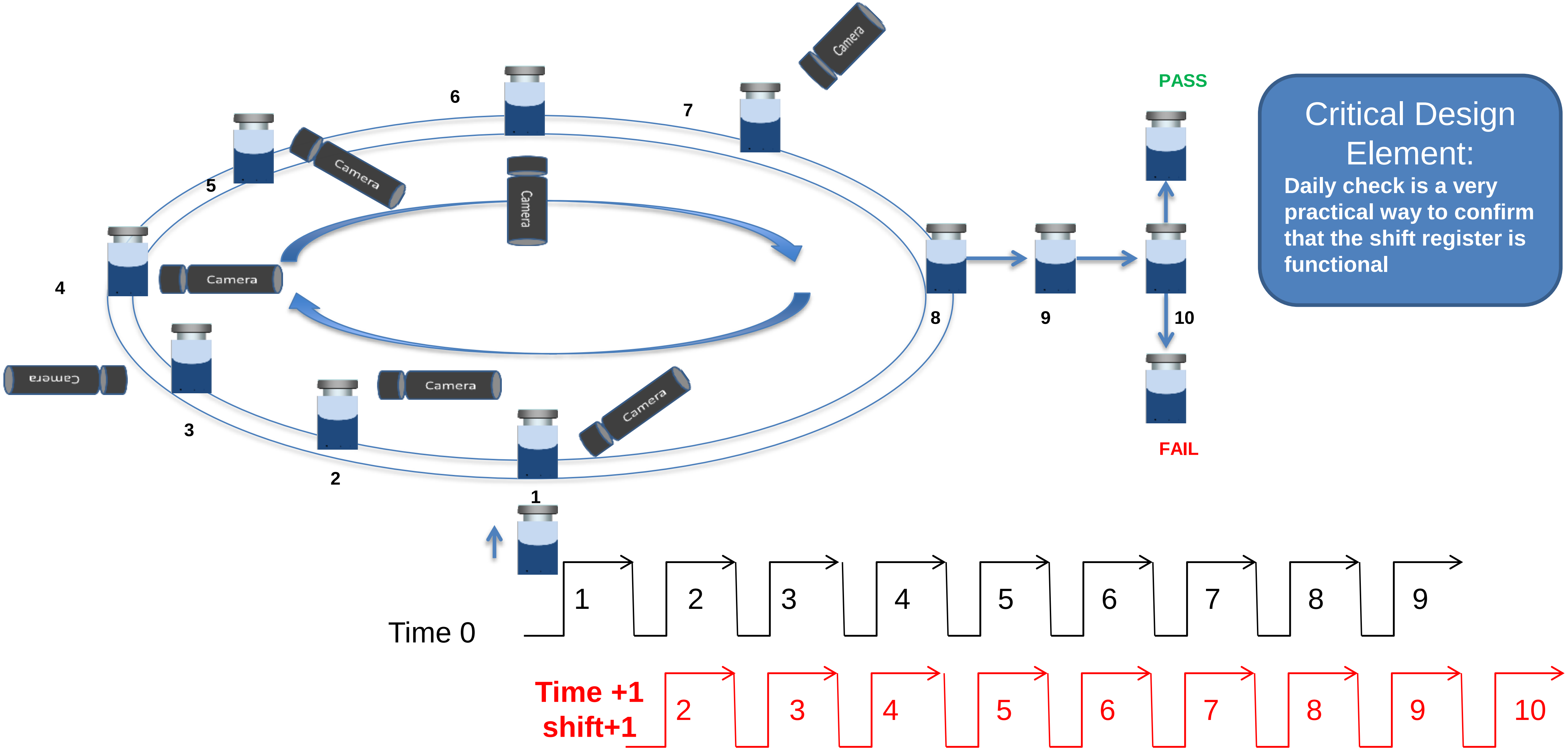


Analyze of 1 stack of 10 to 60 images all at once to track particle trajectories



Automation principle of shift register

Automation basic concept / shift register

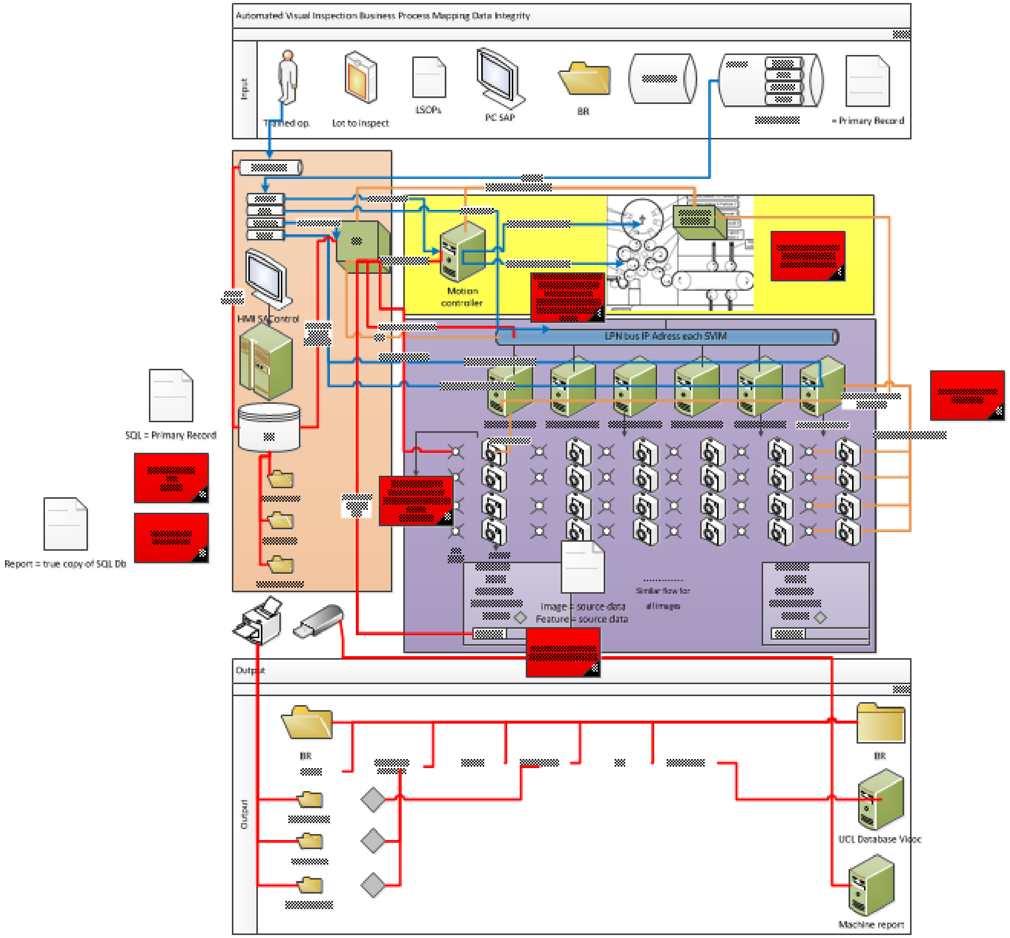


Critical Design Element:

Daily check is a very practical way to confirm that the shift register is functional

Automation business mapping

- move forward to elaborate a fully transparent flow of information inside AVI



Automation

Mechanic

Vision

Critical Design Element:

Drawing a business process mapping for information flow inside your AVI is a way to share knowledge between experts, supplier and QA and end user

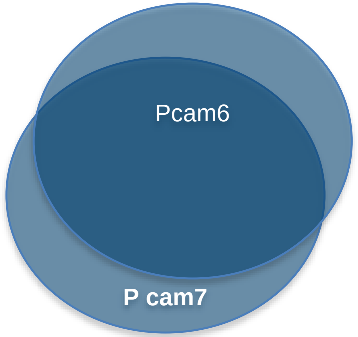
Concept of collaborative cameras

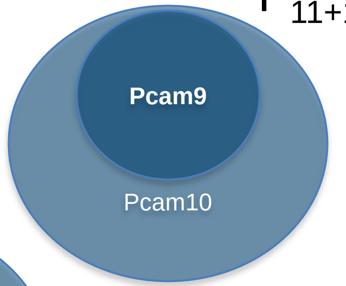
multiple images, multiple cameras => probabilistic behavior

- **Multiple camera on AVI machines**

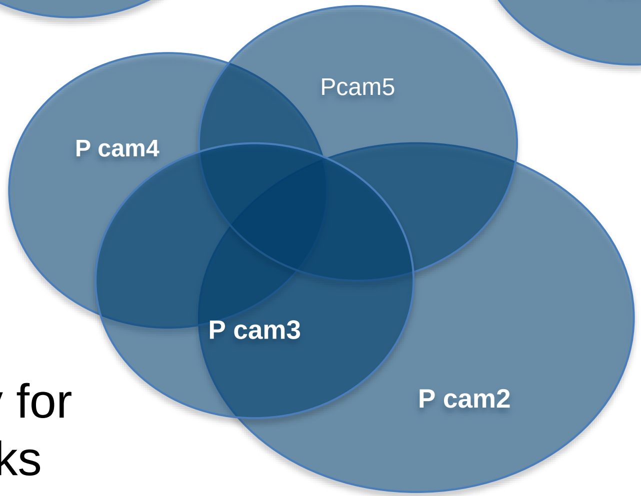
A & B mutually exclusive
$P_{11+12}=P_{11}+P_{12}$

2 collaborative
Cameras for a
specific area
i.e. = Syr. flange

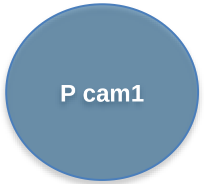




2 Camera specific
for a defect area
i.e. = Syr. closure



4 collaborative
Cameras for a
specific area
i.e. = Syr. Body for
particle or cracks

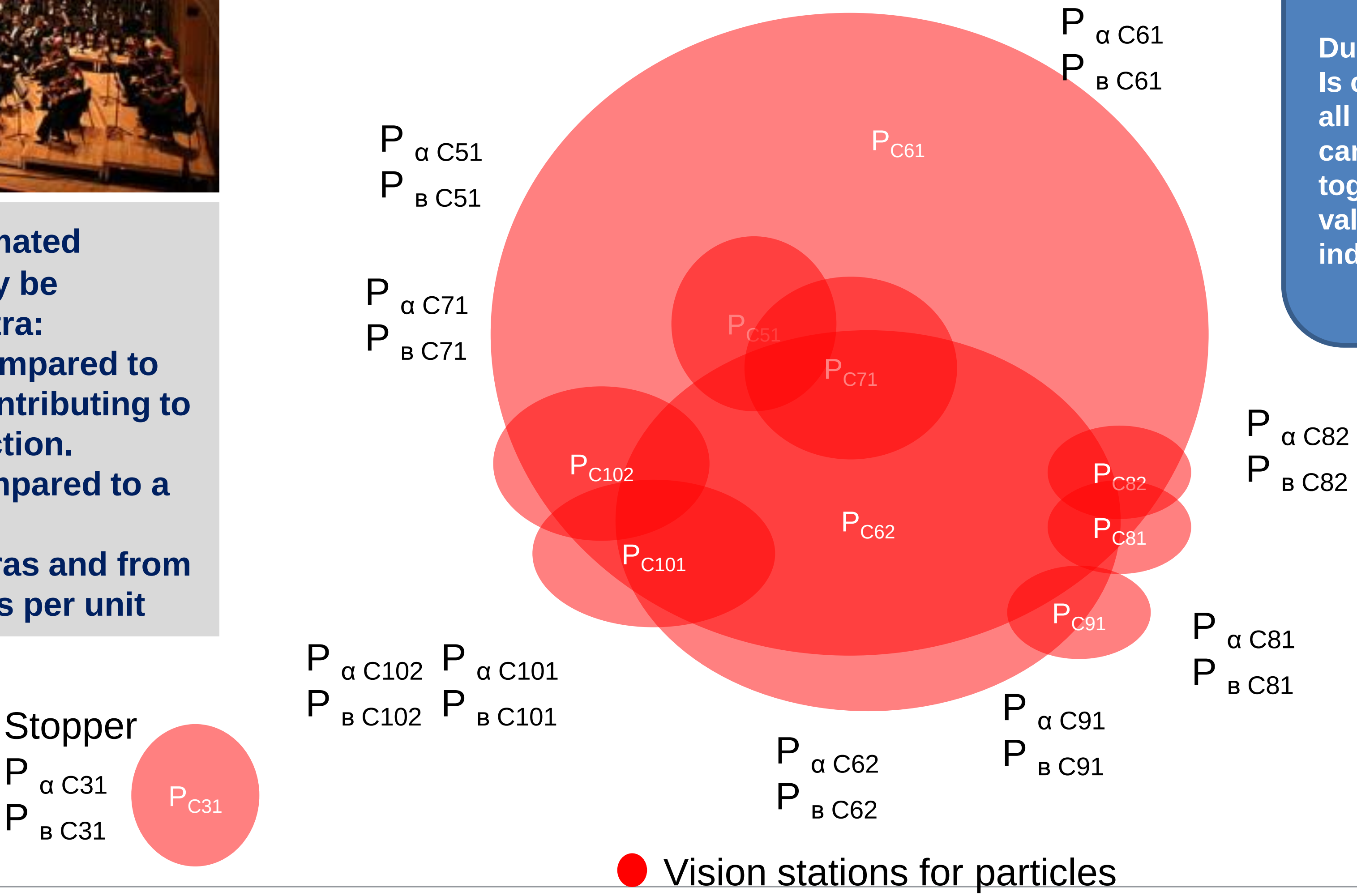


Camera specific
for a defect family
i.e. = Fill level

multiple images, multiple cameras => probabilistic detection

Key learning: **Automated Inspection machine may be compared to an orchestra:**
each camera may be compared to an instrument group contributing to an overall particle detection.
Each image may be compared to a individual player.
We have up to 15 cameras and from 32 images to 150 images per unit

Venn diagram for detection probability



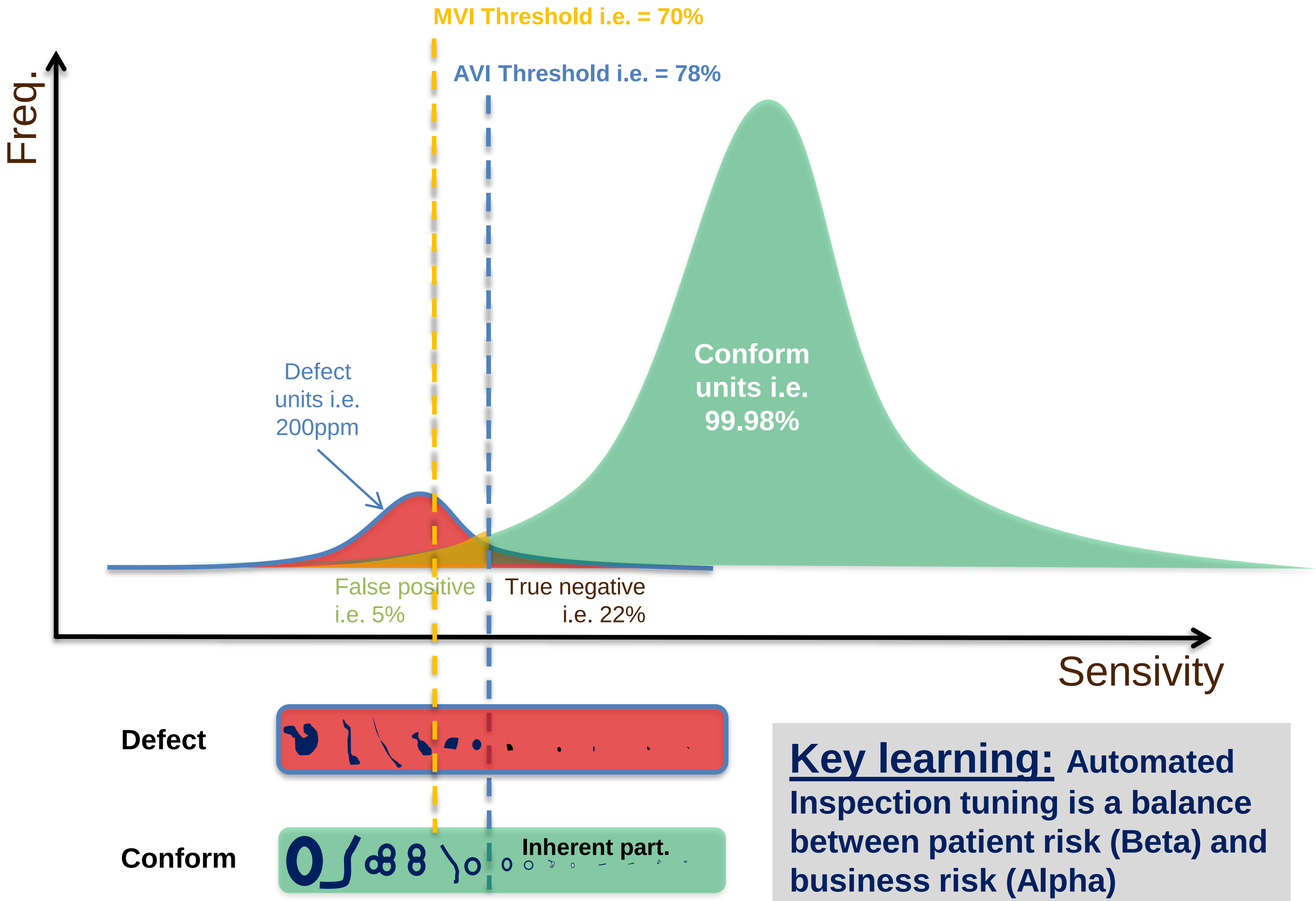
Critical Design Element:

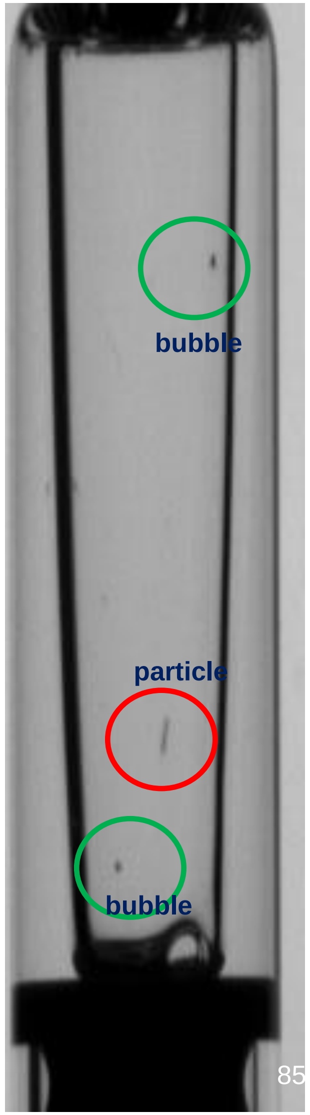
During validation it Is critical to activate all collaborative camera working together, you cannot validate camera individually

False reject

True reject

False reject / balance patient vs business risk





Key learning: Automated Inspection tuning is a balance between patient risk (Beta) and business risk (Alpha)

False reject / balance patient vs business risk

		Actual Value (as confirmed by experiment)	
		positives	negatives
Predicted Value (predicted by the test)	positives	**TP** True Positive	**FP** False Positive
	negatives	**FN** False Negative	**TN** True Negative

Critical Design Element:

Control of false reject could be considered as a validity criteria
Unit used for this test should be first inspected.

Binomial law shows that min 3300 units can give an accuracy of +/-1% of False reject rate

100 to1000 units for evaluation of False reject has a poor accuracy

You have learnt

AVI

- CQAs, CPPs
- critical design elements
- Core part of AVI
- Sequence images
- Mechanical presentation
- Camera
- What sees AVI
- LED
- Computer vision
- Automation
- False reject

AVI

- What CDEs, CPPs, CQAs
- Why is capability management key
- What are the core parts of AVI
- What tools do you need to keep AVI in validated state
- Do you validate per camera or the whole