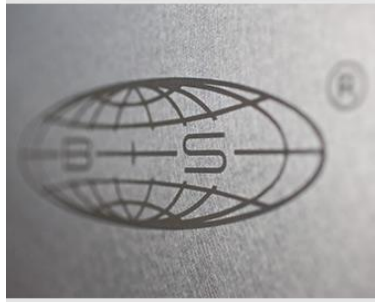
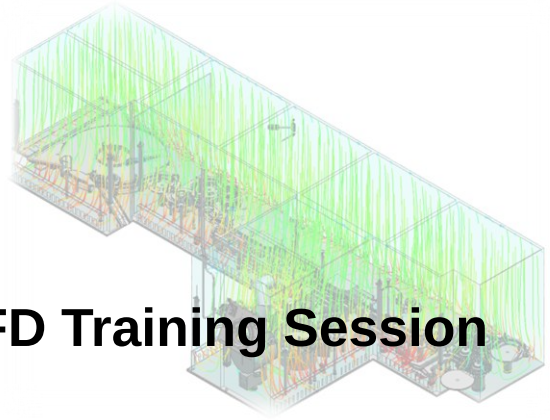


PDA Brazil Chapter
Aseptic Processing Workshop

Sep 18 - Sep 22, 2017 |
CRQ - Pinheiros | São Paulo, Brazil

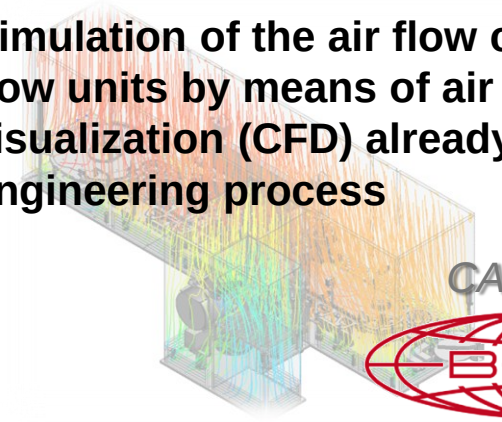


BAUSCH+STRÖBEL®

CFD Training Session

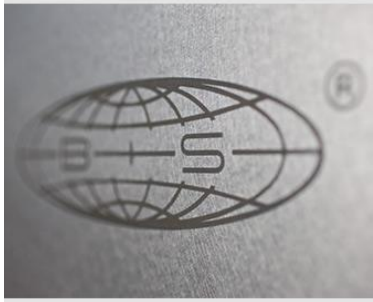
Frank Härterich
B+S Germany

Simulation of the air flow conditions below laminar flow units by means of air flow calculation and visualization (CFD) already during the product engineering process



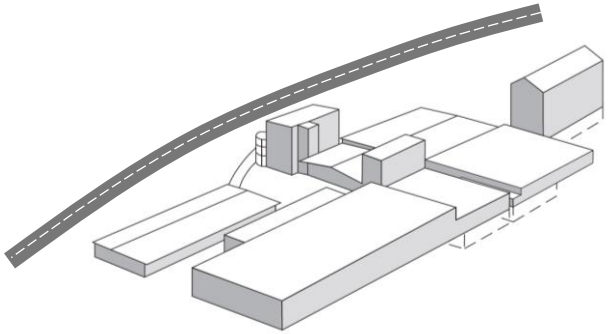
CAE Center

B+S



B+S Ilshofen / Germany

B+S Ilshofen / Germany



- Production capacity: approx. 400 machines / year
- Turnover: approx. 180 million Euro / year
- Export: approx. 90%
- Pharm. Industry: approx. 98%
- Employees: approx. 1,400
  (of which approx. 150 trainees)
  (of which approx. 240 design)
  (of which approx. 650 production)
  (of which approx. 50 QA/QM/QC)
- Company area: approx. 90,000 m²

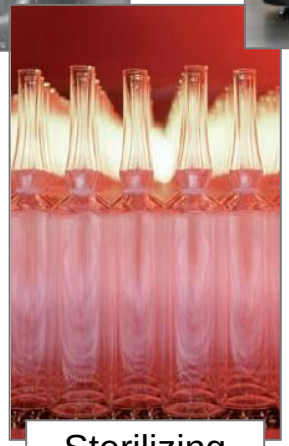
What we do - Production programme

Cleaning

Filling

Inspection

Tray-loading



Sterilizing

Closing

Labelling

Assembly

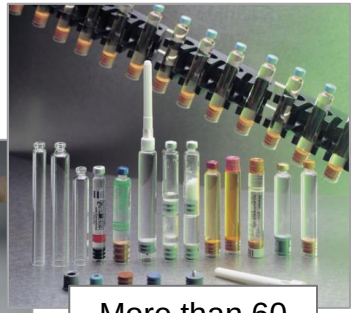
What we did - Projects realized since 1967

More than 160
ampoule lines

More than 400
vial/bottlle lines

More than 150
Syringe lines (nest)

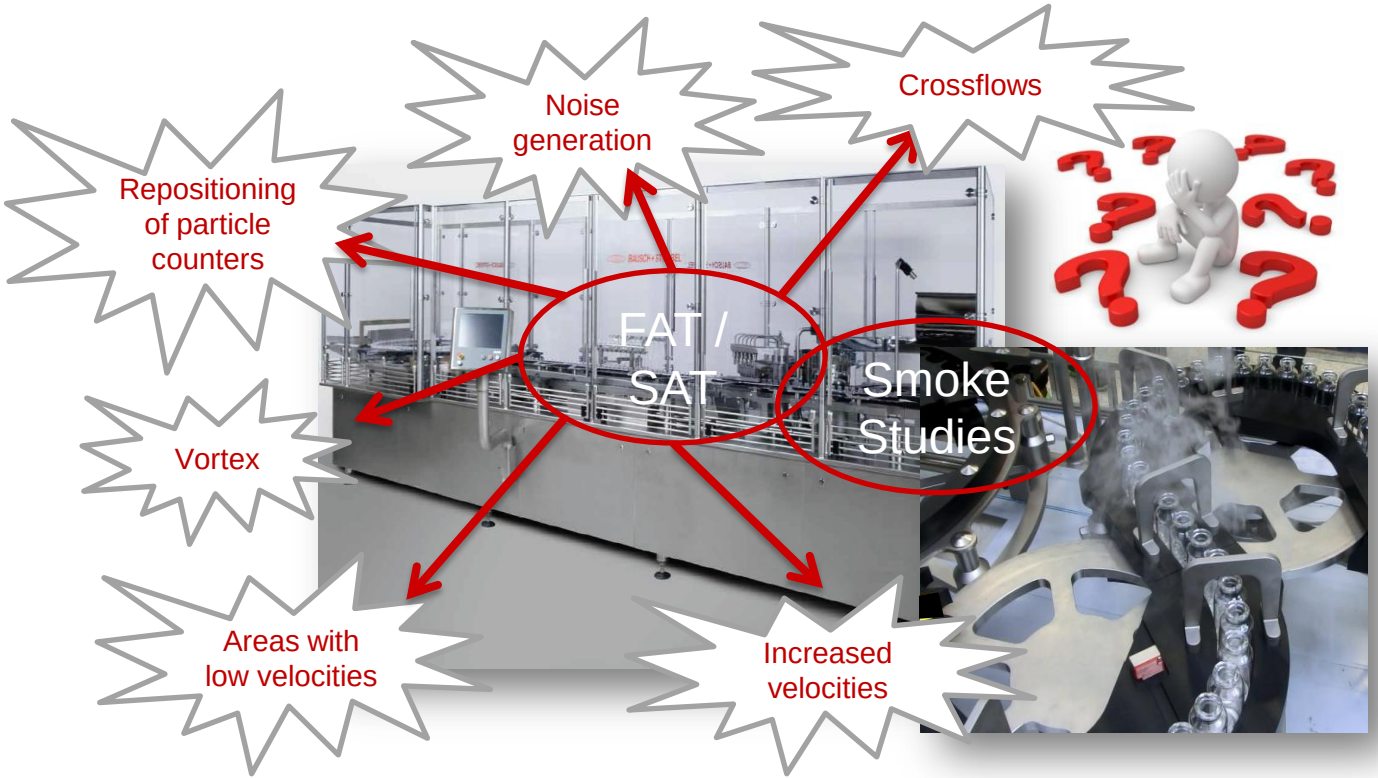
More than 50
syringe lines (bulk)



More than 60
Cartridge lines

A total of more than 13,000
machines worldwide

Status quo



Status quo

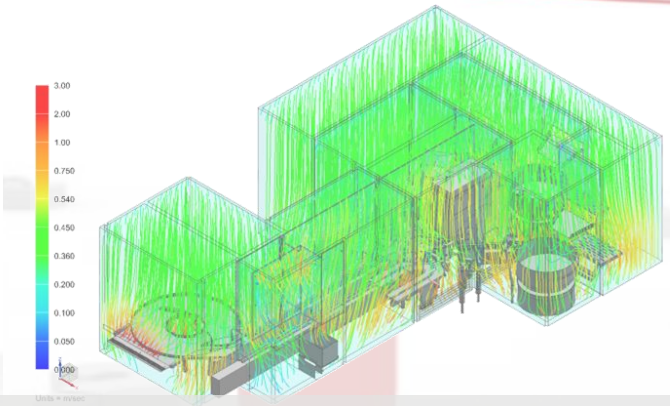
Adjustments

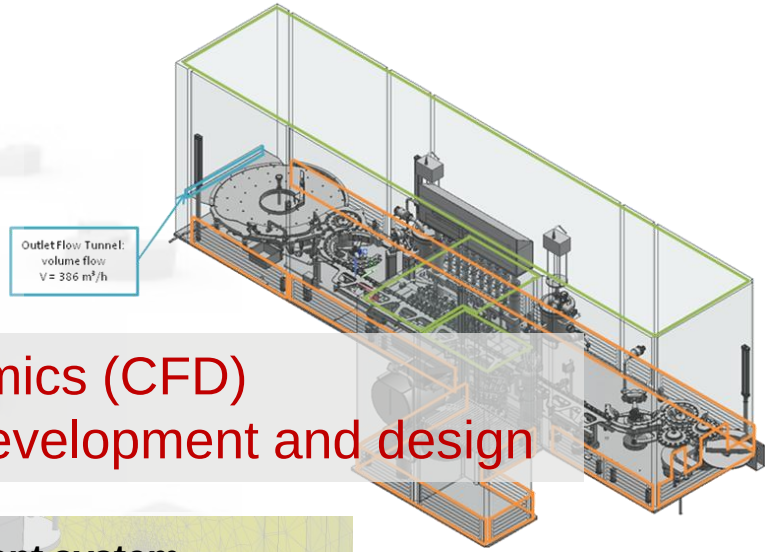
Containment system
Design
Positions of components

Compromise

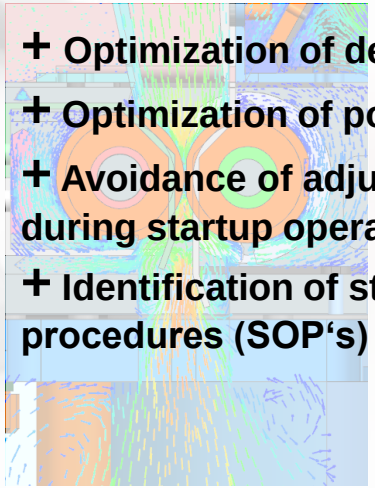
+

Prevention

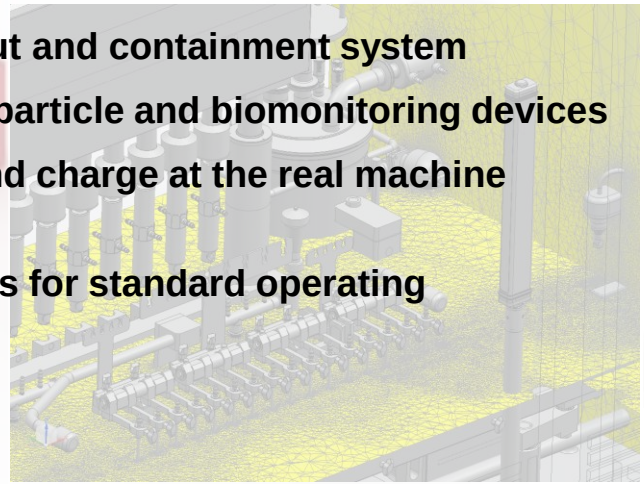




Computational Fluid Dynamics (CFD) at the virtual machine during product development and design



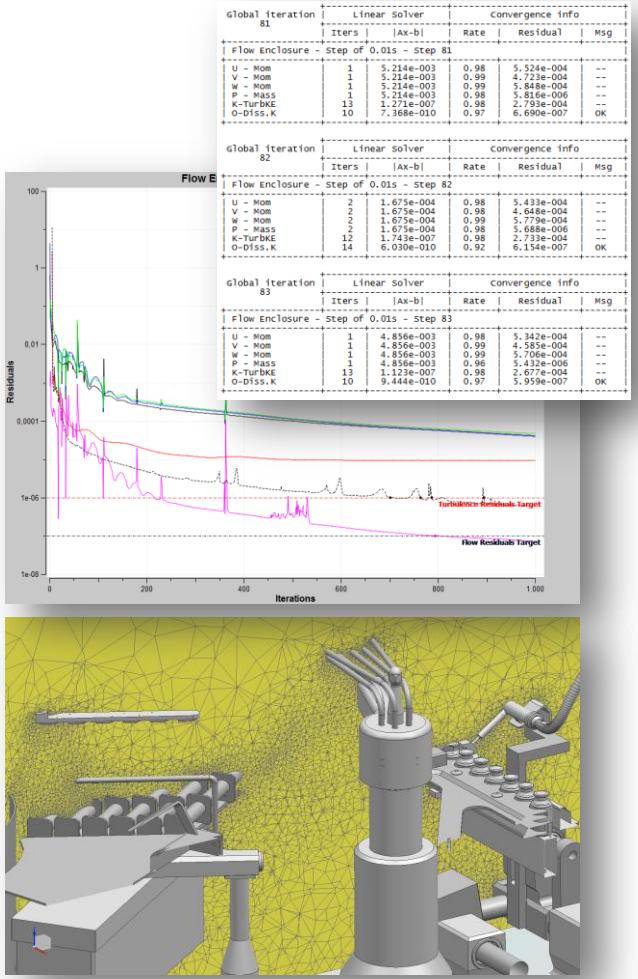
+ **Optimization of design, layout and containment system**
+ **Optimization of positions of particle and biomonitoring devices**
+ **Avoidance of adjustments and charge at the real machine during startup operations**
+ **Identification of striking areas for standard operating procedures (SOP‘s)**



Theoretical connections of the basic principles

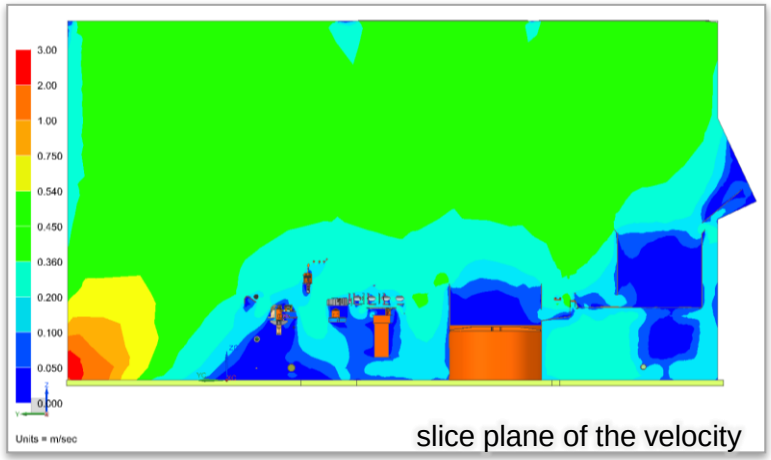
- The objective of the CFD calculations (Computational Fluid Dynamics) is to solve fluid mechanics problems with the help of numerical methods. To gain highly detailed information about the flow fields with regard to time and space 7 conservation equations for mass, impulse, turbulence and energy are solved.

- The flow volume is discretized, i.e. split into individual volumes, for the CFD analysis. In each of these volume elements 7 conservation equations must be solved and their results must be saved.

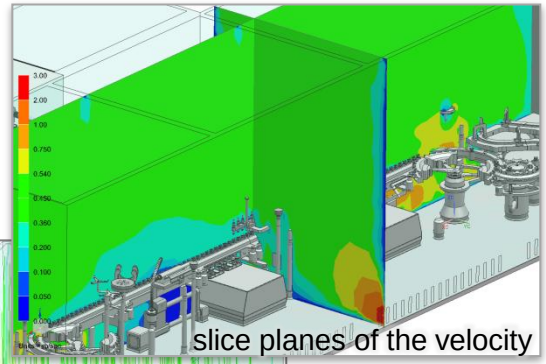


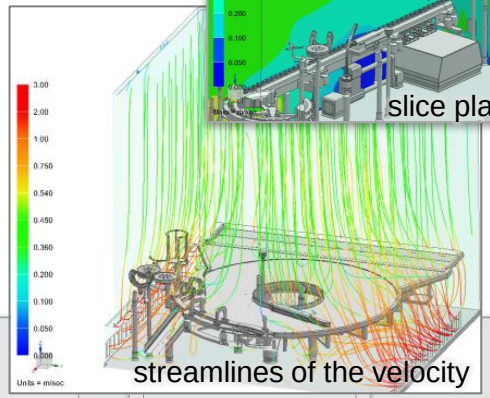
Evaluation of the results

- Depiction in planes
  - Pressure
  - Velocity distribution
  - Flow pattern
- Depiction of areas with low velocities
- Depiction of the streamlines in the work area of the machine

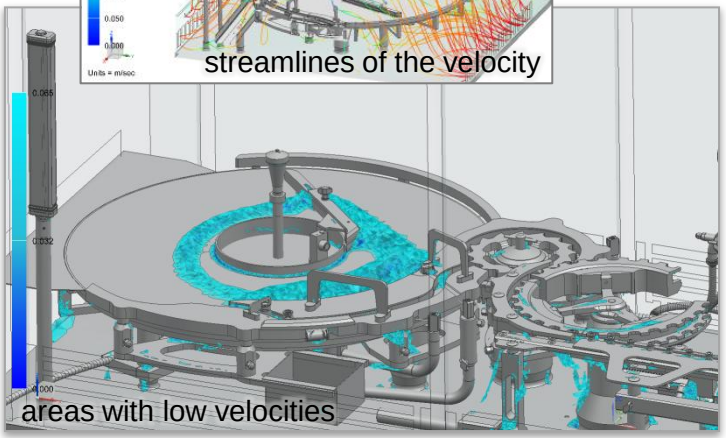


slice plane of the velocity


slice planes of the velocity

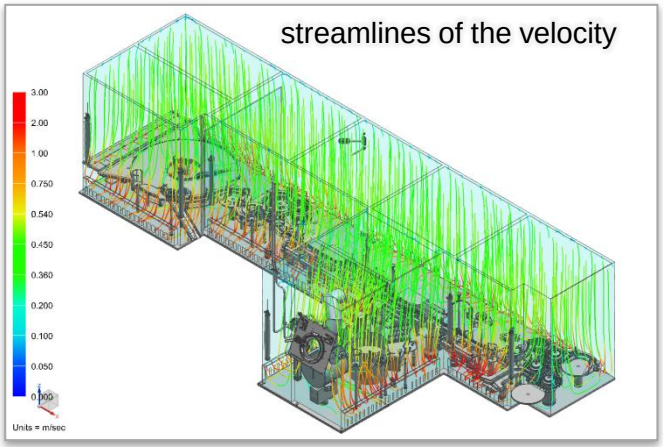


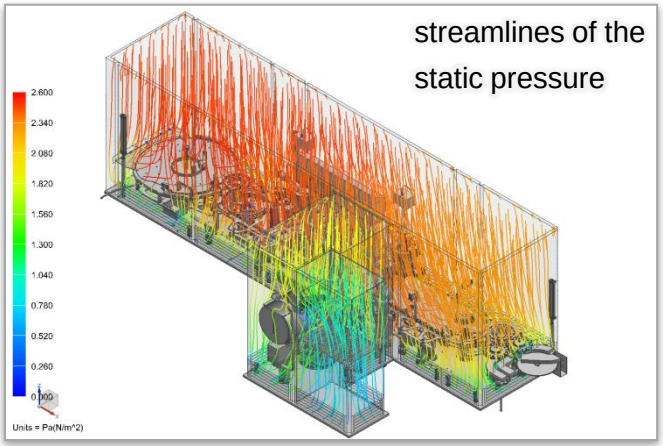
streamlines of the velocity

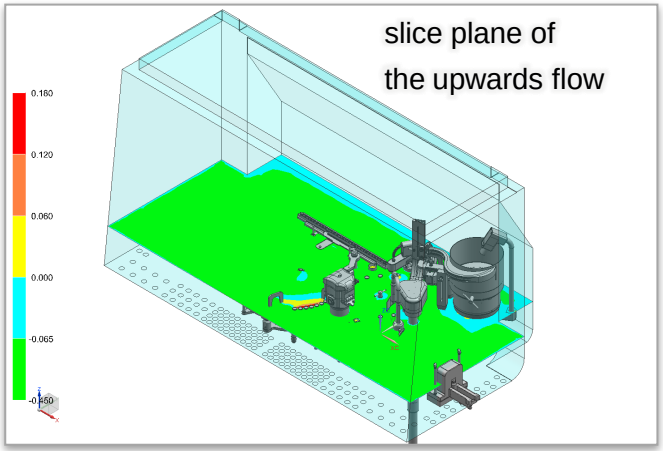


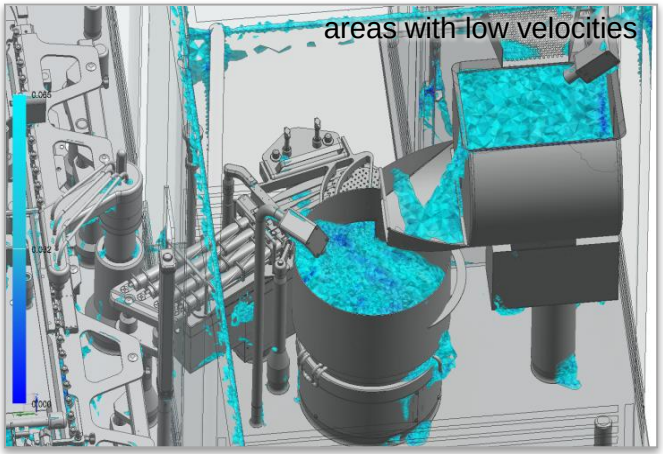
areas with low velocities

Evaluation of the results

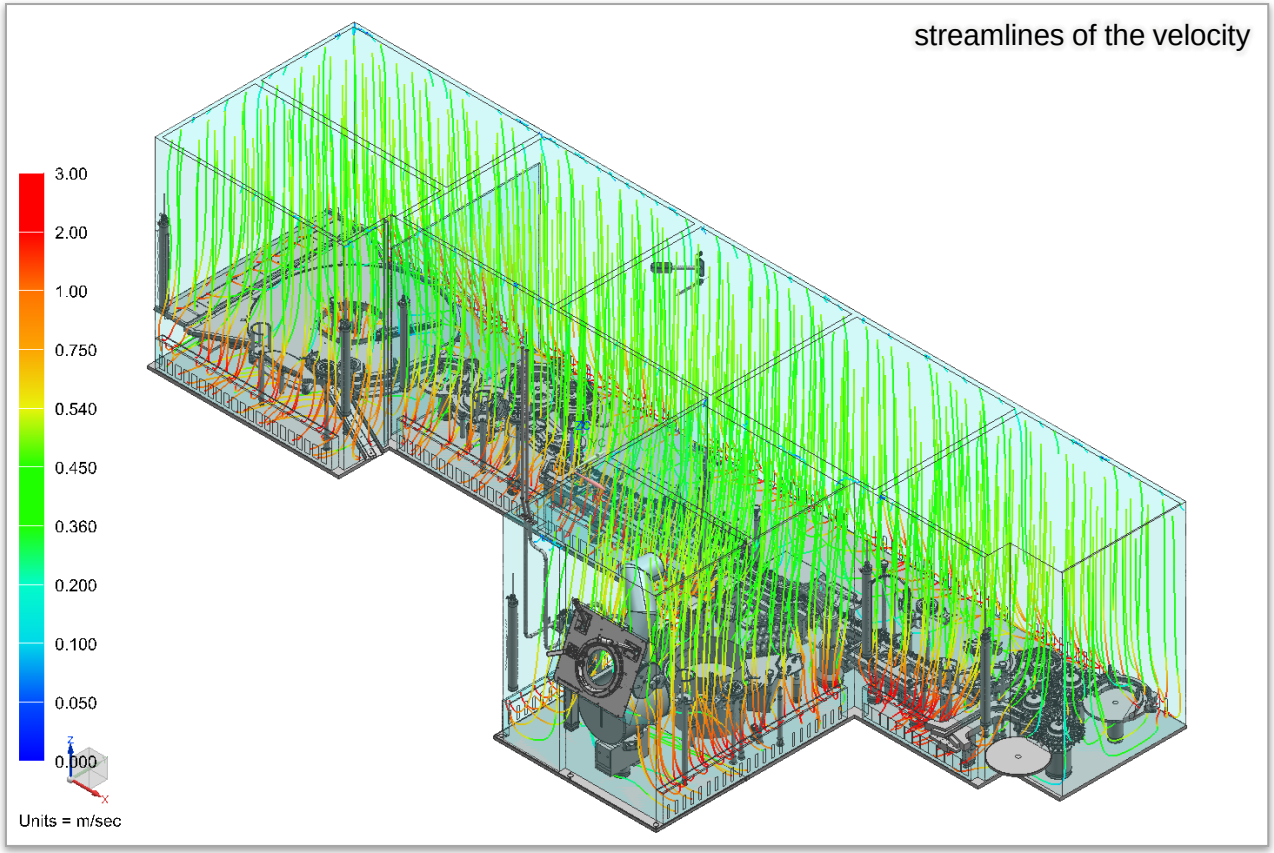




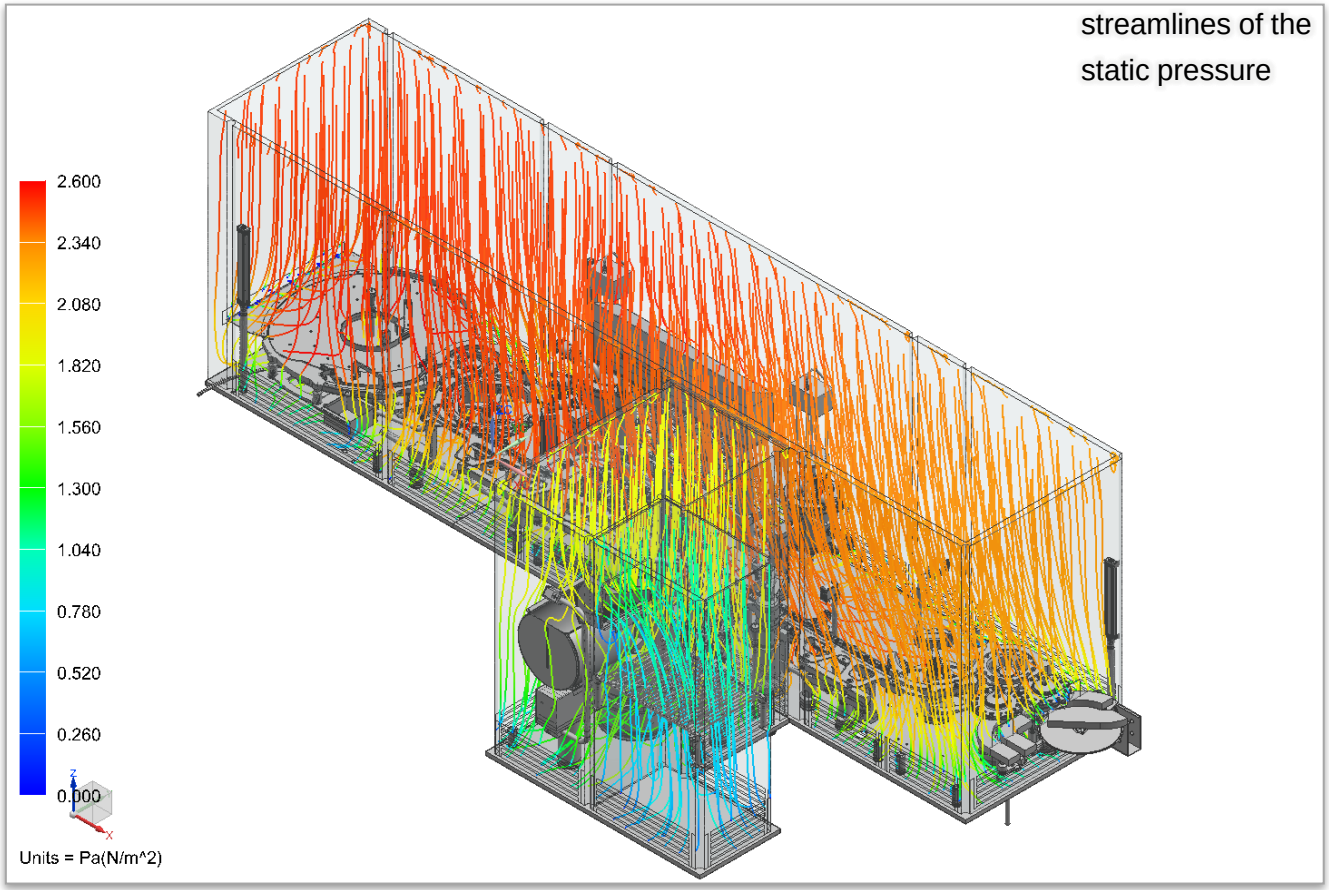




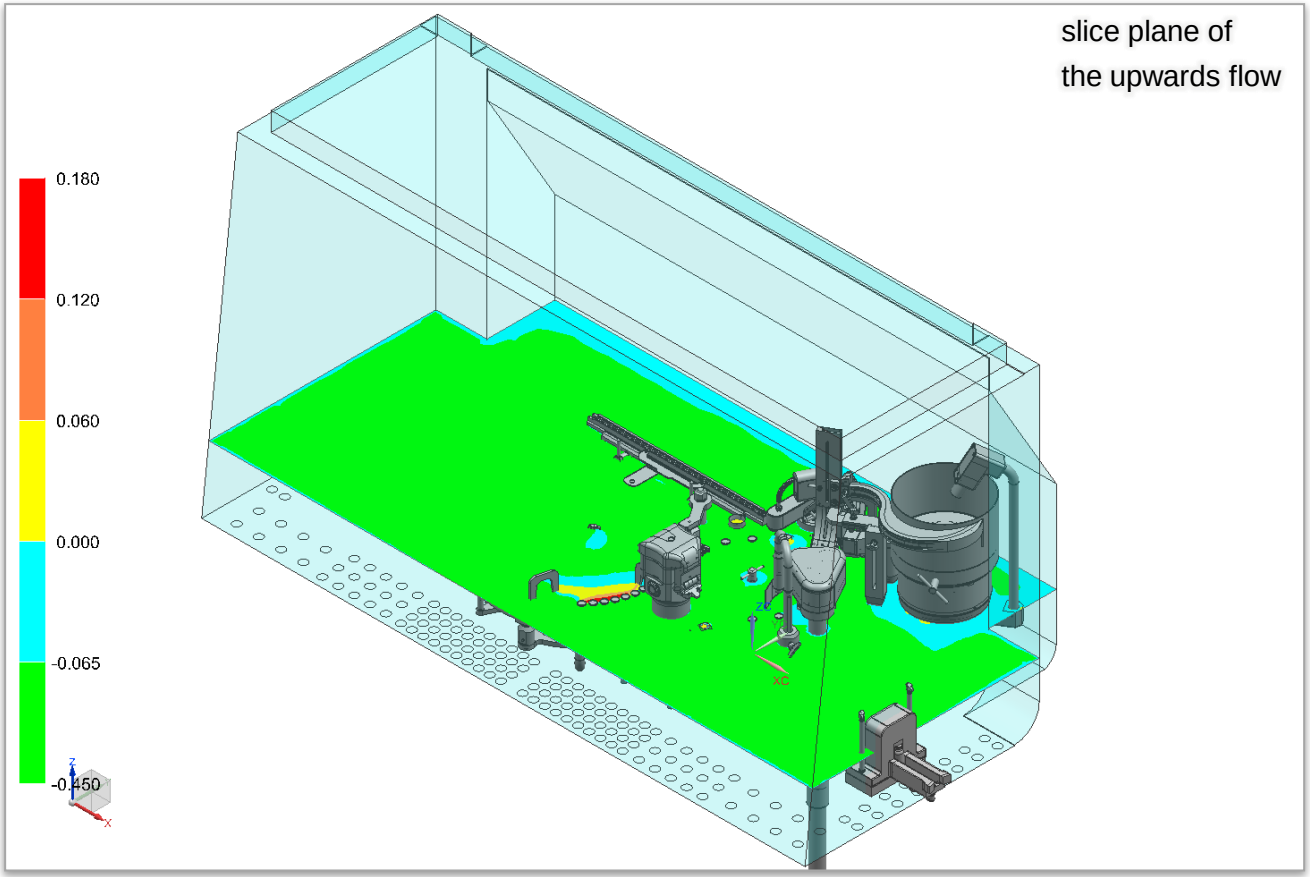
Evaluation of the results



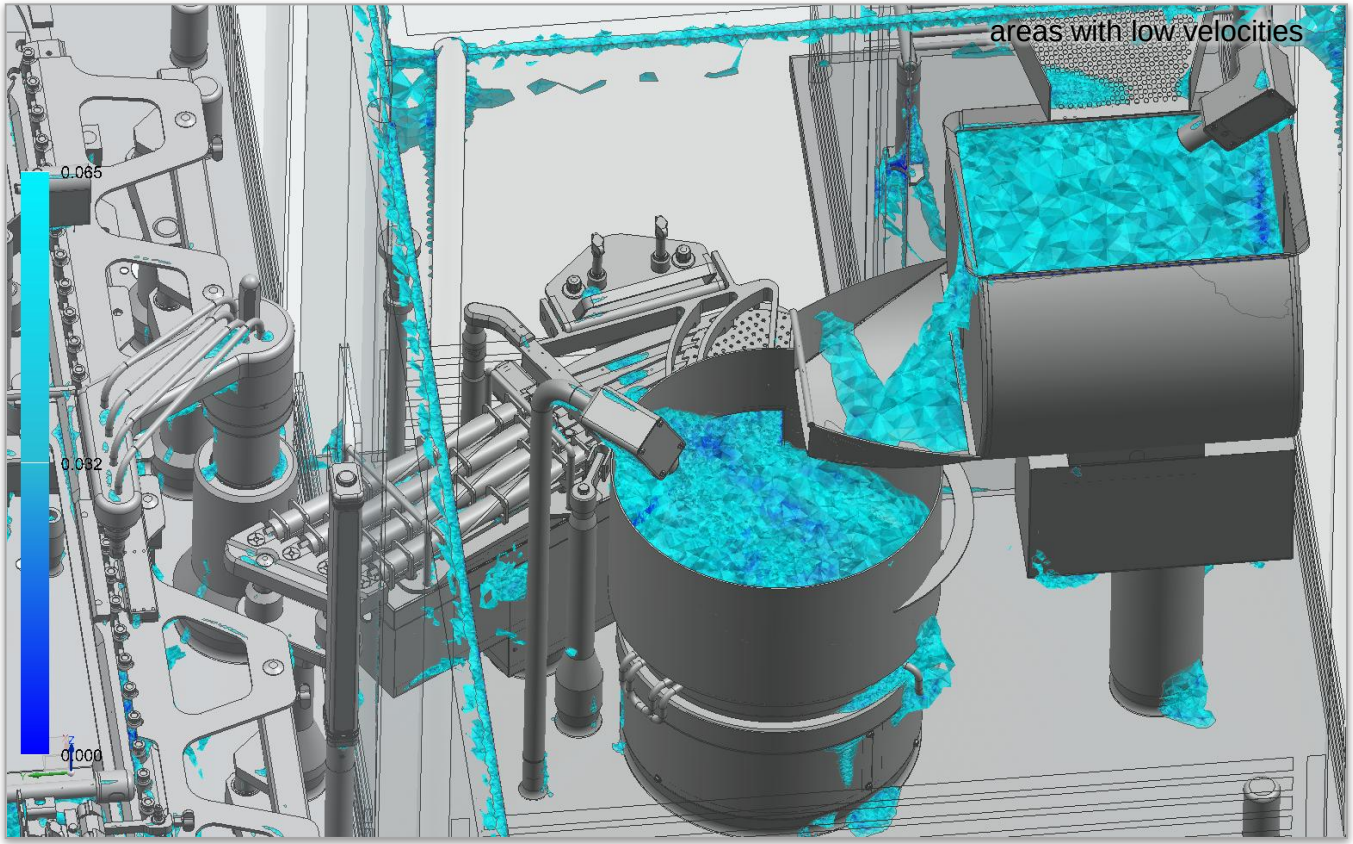
Evaluation of the results



Evaluation of the results

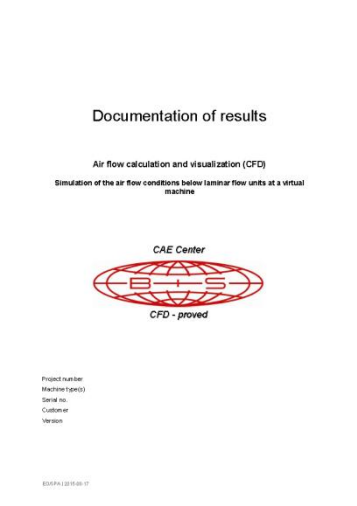


Evaluation of the results



Documentation of results provided for the customer

- Theoretical principles
- Procedure
- Depiction of the calculated geometry with inlet and outlet definition
- List of boundary conditions
- Quality criteria of the simulation
- Visualization and interpretation of the results


Documentation of results

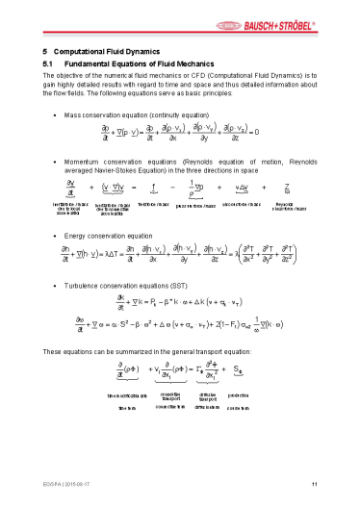
Air flow calculation and visualization (CFD)

Simulation of the air flow conditions below laminar flow units at a virtual machine

CAE Center

CFD - proved

Project number
Machine type(s)
Serial no.
Customer
Version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5 Computational Fluid Dynamics

5.1 Fundamental Equations of Fluid Mechanics

The objective of the numerical fluid mechanics or CFD (Computational Fluid Dynamics) is to gain highly detailed results with regard to time and space and thus detailed information about the flow fields. The following equations serve as basic principles:

- Mass conservation equation (continuity equation)

$$\frac{\partial \rho}{\partial t} + \nabla(\rho \cdot \vec{v}) = \frac{\partial \rho}{\partial t} + \frac{\partial(\rho \cdot v_x)}{\partial x} + \frac{\partial(\rho \cdot v_y)}{\partial y} + \frac{\partial(\rho \cdot v_z)}{\partial z} = 0$$

- Momentum conservation equations (Reynolds equation of motion, Reynolds averaged Navier-Stokes Equation) in the three directions in space

$$\frac{\partial \vec{v}}{\partial t} + (\vec{v} \cdot \nabla)\vec{v} = \vec{f} - \frac{1}{\rho}\nabla p + \nu \Delta \vec{v} + \frac{\vec{\tau}}{\rho}$$

- Energy conservation equation

$$\frac{\partial \eta}{\partial t} + \nabla(\eta \cdot \vec{v}) = \lambda \Delta T = \frac{\partial \eta}{\partial t} + \frac{\partial(\eta \cdot v_x)}{\partial x} + \frac{\partial(\eta \cdot v_y)}{\partial y} + \frac{\partial(\eta \cdot v_z)}{\partial z} = \lambda\left(\frac{\partial^2 T}{\partial x^2} + \frac{\partial^2 T}{\partial y^2} + \frac{\partial^2 T}{\partial z^2}\right)$$

- Turbulence conservation equations (SST)

$$\frac{\partial k}{\partial t} + \nabla k = P_k - \beta^* k \cdot \omega + \Delta k\left(\nu + \sigma_k \cdot \nu_T\right)$$

$$\frac{\partial \omega}{\partial t} + \nabla \omega = \alpha_\infty S^2 - \beta \cdot \omega^2 + \Delta \omega\left(\nu + \sigma_\omega \cdot \nu_T\right) + 2(1 - F_1)\sigma_{\omega 2} \frac{1}{\omega} \nabla k \cdot \omega)$$

These equations can be summarized in the general transport equation:

$$\frac{\partial}{\partial t}(\rho \phi) + \nabla_j \frac{\partial}{\partial x_j}(\rho \phi) = \Gamma_\phi \frac{\partial^2 \phi}{\partial x_j^2} + S_\phi$$

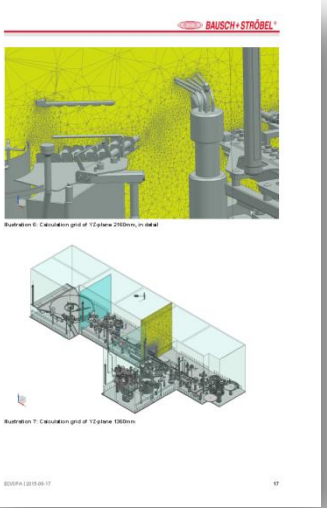
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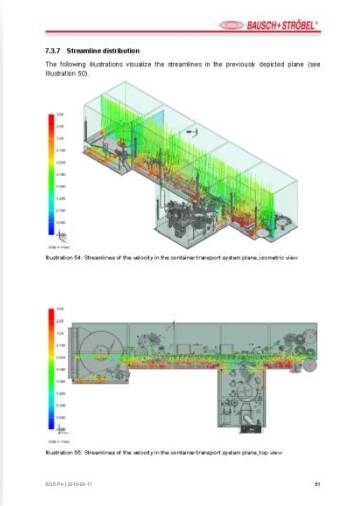
Illustration 6: Calculation grid of YZ-plane 2160mm, in detail

Illustration 7: Calculation grid of YZ-plane 1360mm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7.3.7 Streamline distribution

The following illustrations visualize the streamlines in the previously depicted plane (see illustration 50).

Illustration 54: Streamlines of the velocity in the container transport system plane, isometric view

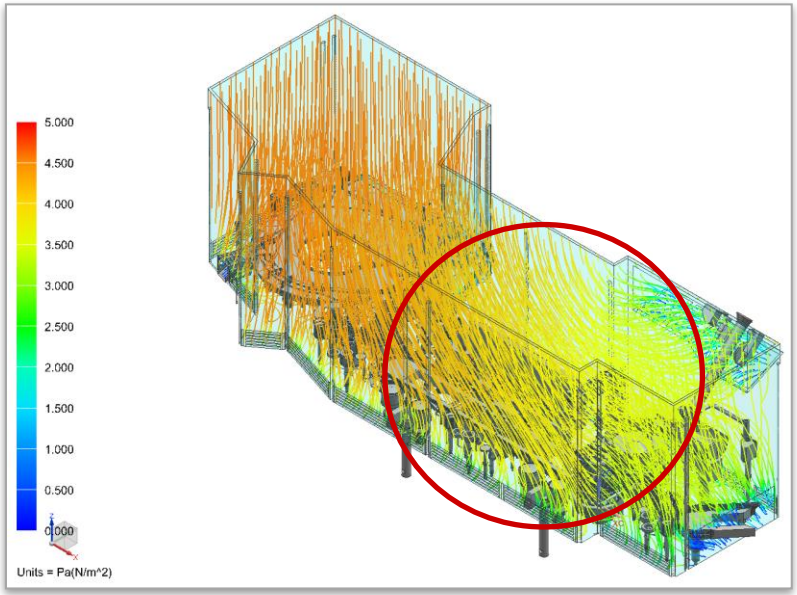
Illustration 55: Streamlines of the velocity in the container transport system plane, top view

Use cases
Optimization of the design of the containment system

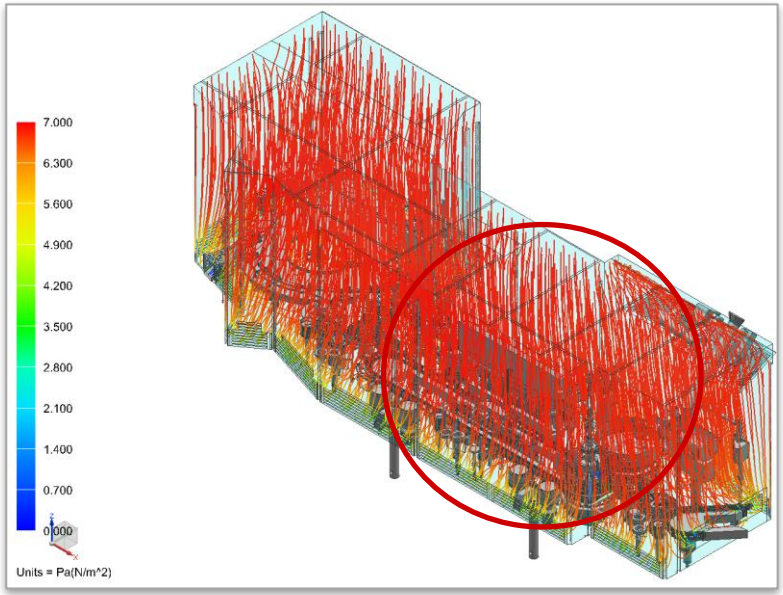
- Problem: crossflow due to pressure drop
- Solution: balance of inlets and outlets in several sections through the machine

streamlines of the static pressure

before



after

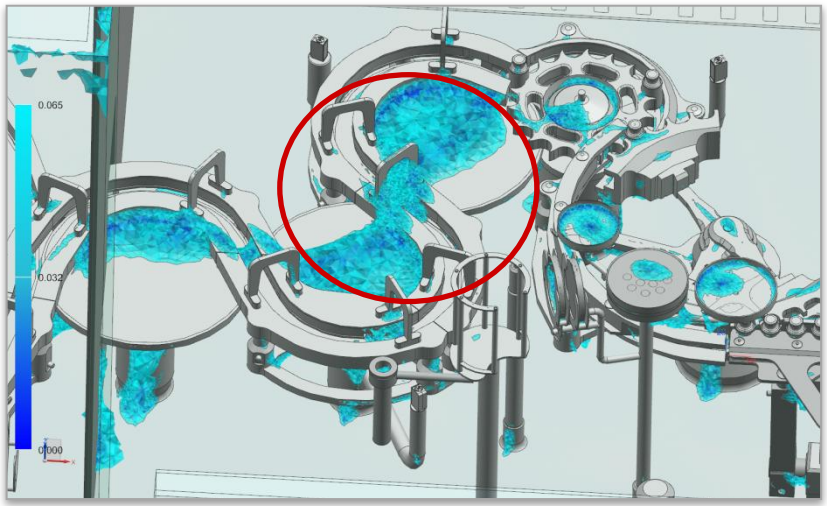


Use cases
Optimization of the design of components

- Problem: areas with low velicities above the open container
- Solution: design optimization of the rotary tables (holes)

Areas with low velocities

before



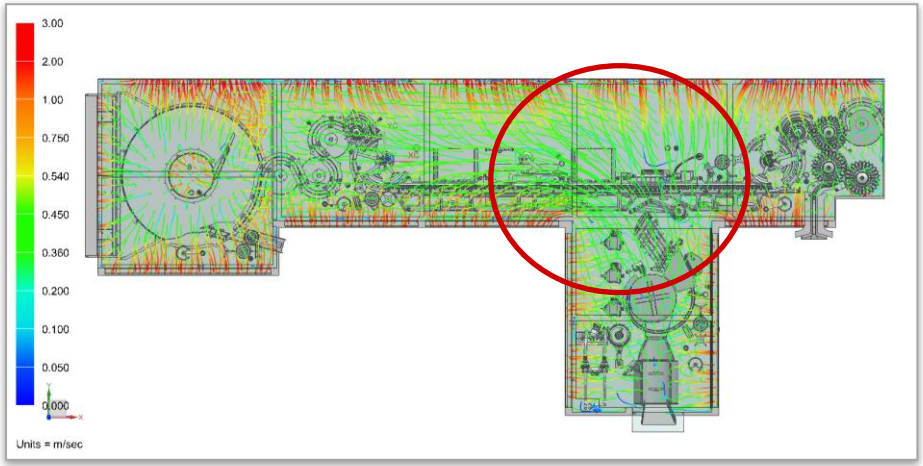
after

Use cases
Optimization of the setting of the containment system

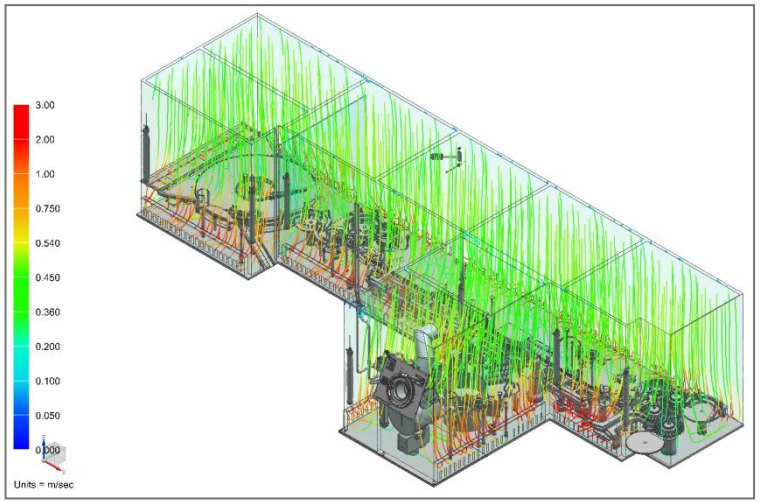
- Problem: crossflows due to different suction capacities through the double windows
- Solution: calibration of the suction values by means of adaption of the air grid positions

streamlines of the velocity

before



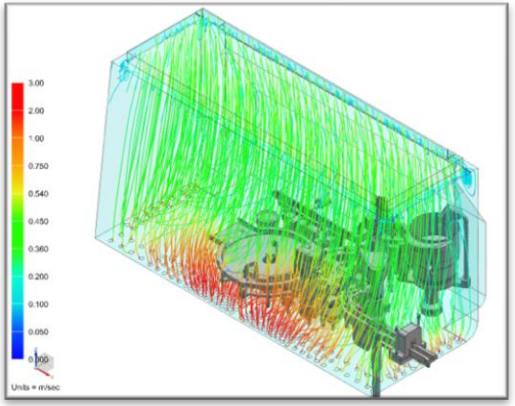
after



Opportunities and hazards

- Inspection of the air flow behavior within the machine respectively of the parts during the early design phase
  - ➢ Avoidance of design adjustments during FAT or SAT
- Hazard of performing the simulation too late
  - ➢ Design optimization not possible anymore or very expensive
- Increasing know-how by performing many costumer projects
  - ➢ Bausch+Ströbel develops machines and prototypes with regard to optimized air flow conditions
  - ➢ Bausch+Ströbel customers can use the simulation within their customized projects for validation and optimization and get a detailed documentation about the air flow conditions

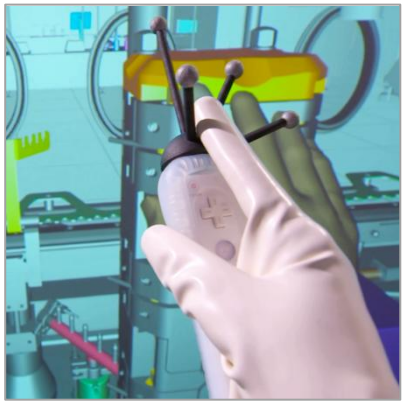
CFD - proved

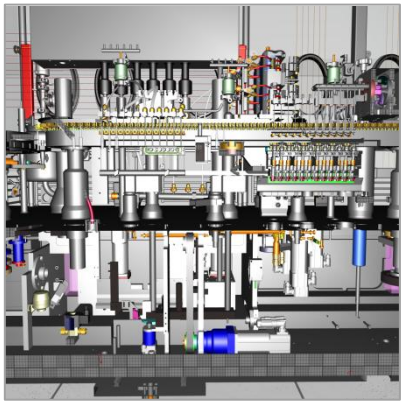


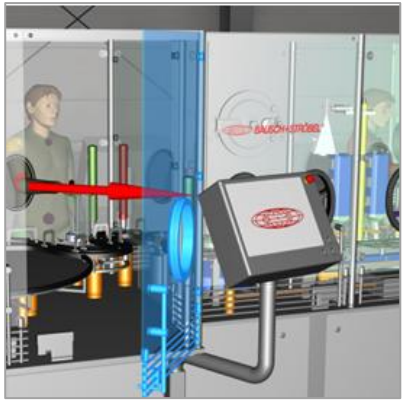
Virtual Reality

“Virtual Reality is a three dimensional world, that simulates reality as closely as possible.“

- Full-scale stereoscopic machine visualization
- Intuitive interaction in a virtual environment
- Integration of real components
- Realistic behavior of objects in real time





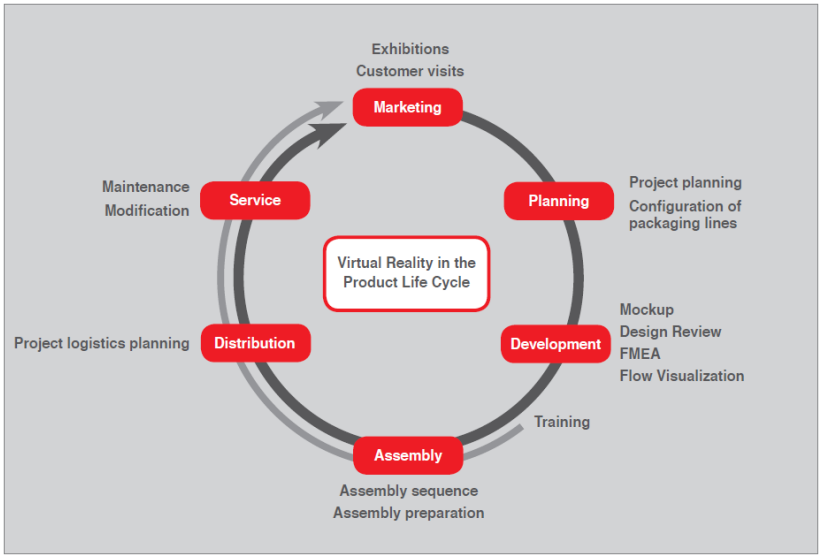


VR included in customer projects – why?

Benefits

- Improved communication
- Enhanced machine awareness
- Time savings thanks to timely decision making
- Cost savings thanks to timely fault localization
- Ideal tool for effective cross-disciplinary teamwork

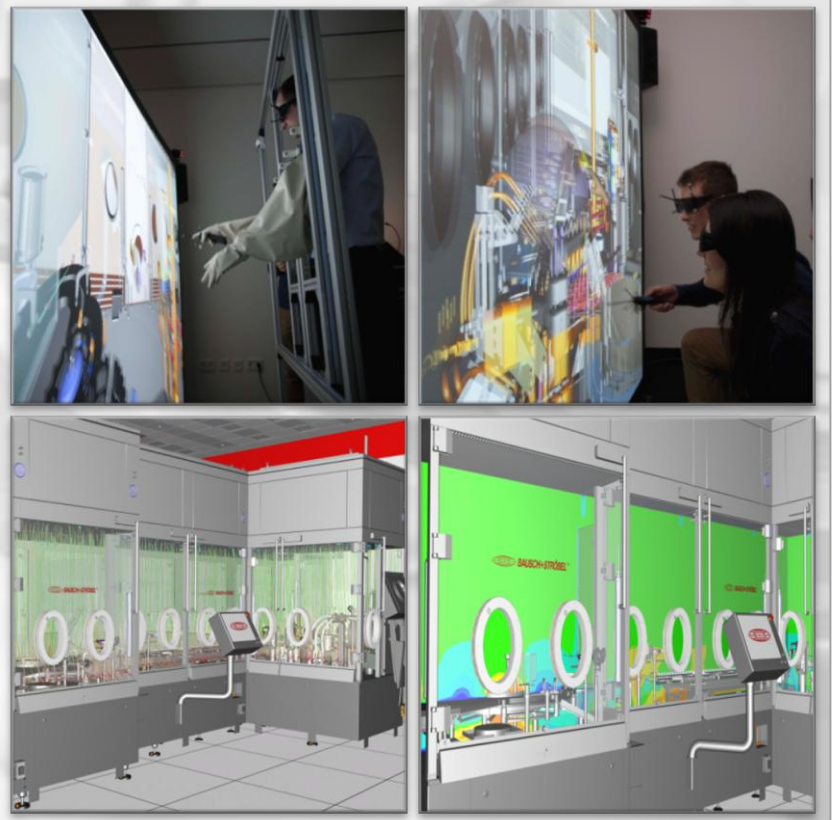
→ Faster and more efficient processes



Bausch+Ströbel Virtual Reality Center (VR)

"Virtual Reality is a three dimensional world, that simulates reality as closely as possible."

- Different service packages available
  - VR Design Review - High understanding for the machines also for non-technicians
  - VR Mockup – Detailed human engineering inspection by means of the virtual CAD model
  - VR FMEA - Better understanding for the FMEA using the VR system
  - VR Training - Machine training at an early stage without the real machine
- Visualization of CFD results as a additional service package (seperate or as a part of the VR Mockup or the VR Design Review)

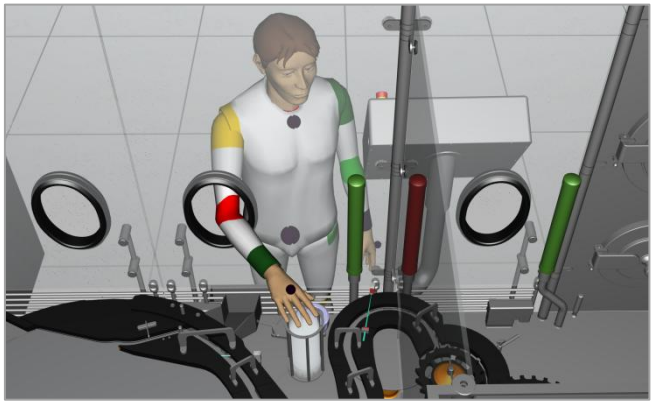


VR Mockup – Detailed human engineering inspection by means of the virtual CAD model

Benefits

- Standardized approach
- Integrated logging capability
- Reproducible action and result
- Objective ergonomic analysis
- Detailed representation of the virtual machine
- Minimal time required

After the first third of the design process!



Project-related VR Mockup services

- Ergonomic study including statistical outliers (5th and 95th percentiles)
- Subjective validation by the machine operator using a mockup frame
- Integration of the machine into the customer‘s virtual cleanroom
- Documentation in the form of a comprehensive results file

VR Design Review – High understanding for the machines also for non-technicians

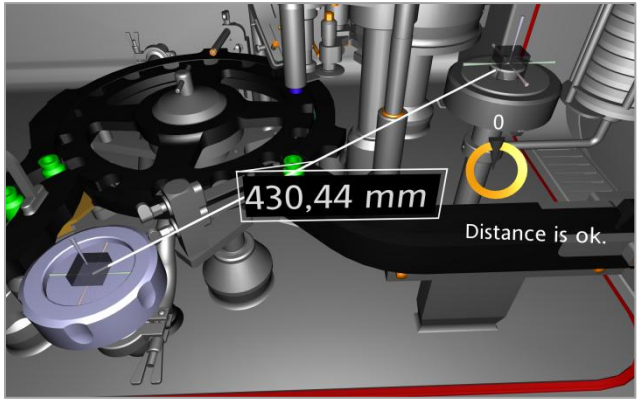
Benefits

- Fast and efficient implementation
- Straightforward explanation of processes

In the last third of the design process!

Project-related VR Design Review services

- Virtual model can be used as a basis for discussing the specific project
- Design modifications can be indicated directly and, in some caes, even shown during the Design Review
- Sectional views for explaining how the machine works
- Integratability into the customer‘s virtual cleanroom
- Review of space availability inside and outside the machine
- Documentation in the form of a comprehensive results file



Best performance for your product!

We are happy to answer your questions!