Cleaning in Place – Concepts and case study

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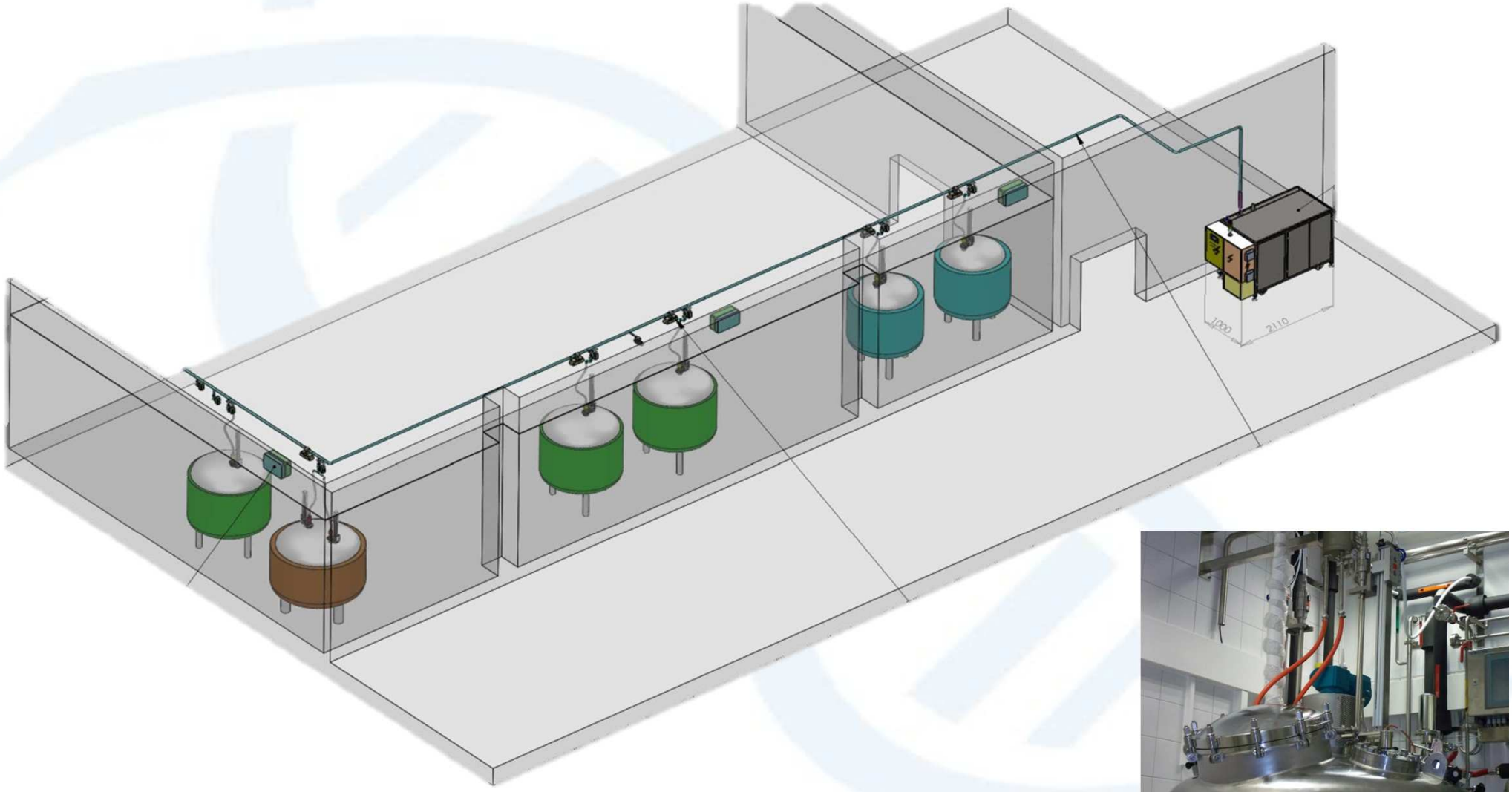
Pharma Cleaning Forum
Israel Edition

CLEANING EXCELLENCE

Example of CIP



Benefit

CIP (Clean-in-Place), is a method of cleaning the inner surfaces of closed systems without disassembly. The advantages of this method are:

- improved safety for workers involved in production of potential dangerous compounds,
- faster cleaning,
- reduced water usage,
- less labor spending,
- repeatable operations,
- possibility to include a programmed cleaning cycle that is fully automated.
- possibility to start a cleaning process after the end of a campaign, and starts again a production cycle immediately after the finishing of the cleaning

Benefit: safety of the operator

Manual washing means:

- Use of hot water
- Use of detergents
- Use of tools (scrubbing-brush, scraper, etc.)
- Risk of inhalation of dangerous vapors

An Automated CIP protects the operator against the above listed risk

Benefit: cleaning validation

Validation refers to establishing documented evidence that a process or system, when operated within established parameters, can perform in effectively and reproducibly way

Cleaning solutions – Machines

S-Line

M-Line

S-Line

- The S-line is a CIP skid system that can be connected to existing enclosure and/or fixed bulk equipment (mixers/blenders)
- It's designed and built to provide high performance
- cGMP and FDA compliant
- Sanitary and self-cleaning hydrokinetic heads
- Wetted parts entirely made of AISI316
- FDA approved polymers
- Non proprietary parts (Gemu, Hilge, Festo, SMC)
- Optional SIP module for sterilization processes
- Optional heated buffer tank
- Optional in-line sanitary heat exchange

S-Line

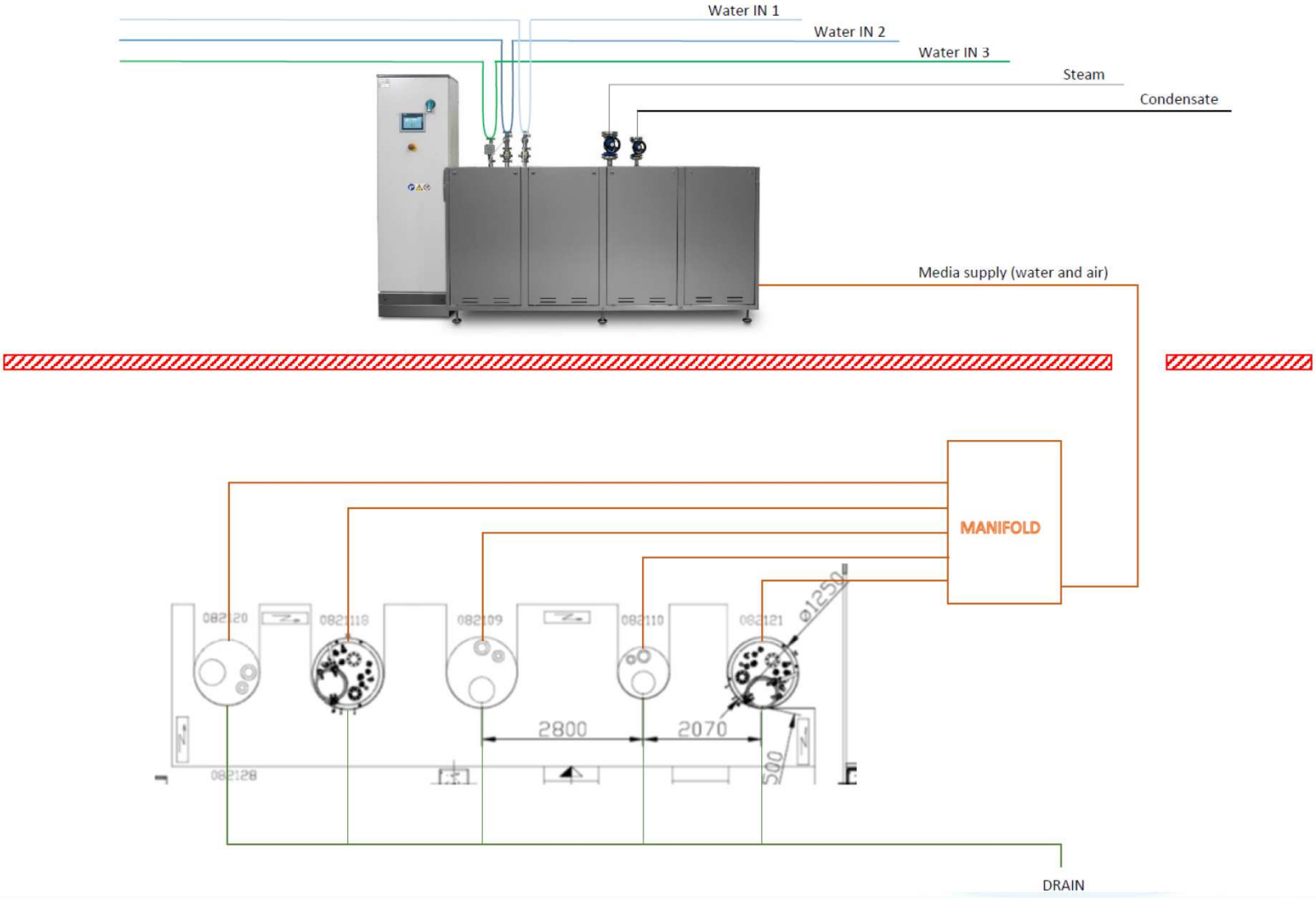
Available in different configuration:

- 1, 2, or 3 water inlet connection
- 1 or 2 in-line detergent dosing station
- Standard operational cleaning pressure (around 8 bar with 40 liter/minute flow-rate)
- High operational cleaning pressure (around 70 bar with 40 liter/minute flow-rate)

High pressure is the perfect solution for the cleaning of sticked on powders and semi-solid products because the high pressure provides a strong mechanical action able to remove the dirty from the stainless steel surfaces of the equipment under process.

S-Line is typically used with Hydrokinetic Heads.

Example of CIP with S-Line



Sanitary self-cleaning hydrokinetic heads

- High quality components (calibration certificates + data sheets)
- Reduction in consumption of energy, water, and cleaning agents
- Time and labor required for cleaning is minimized
- ATEX exempt and FDA-compliant
- Different cleaning times
- Easy-to-maintain
- Self-cleaning head
- Full coverage

Cleaning solutions – Machines

S-Line

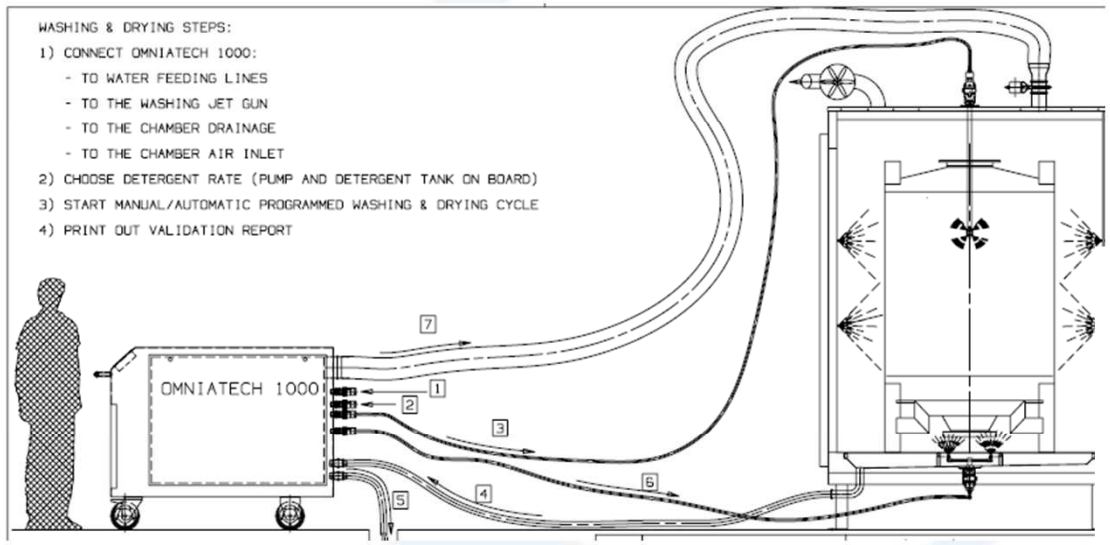
M-Line

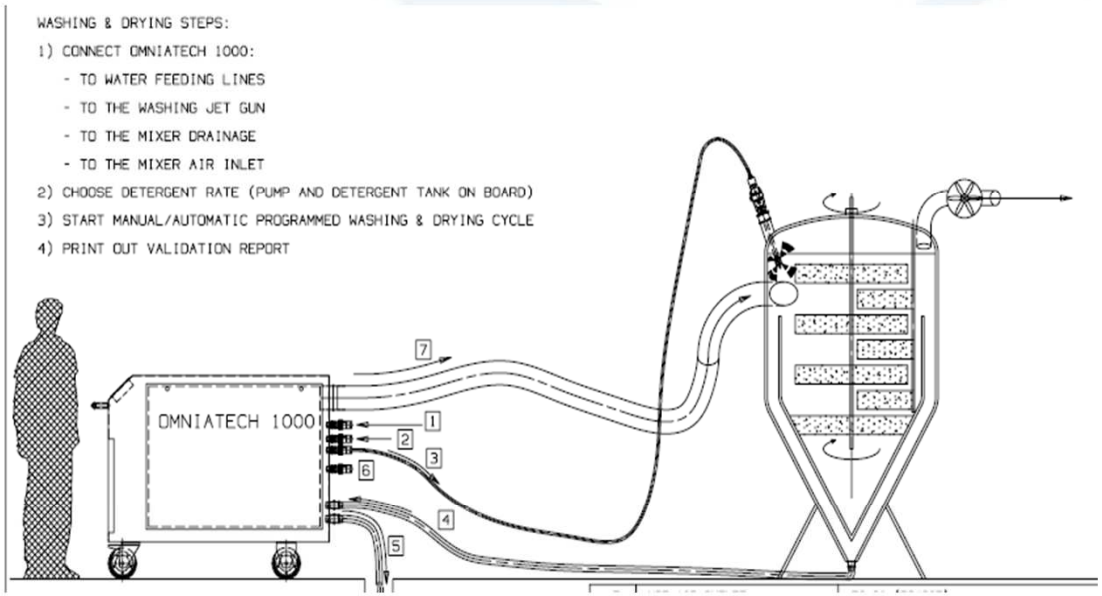
High Pressure MOBILE washing unit:

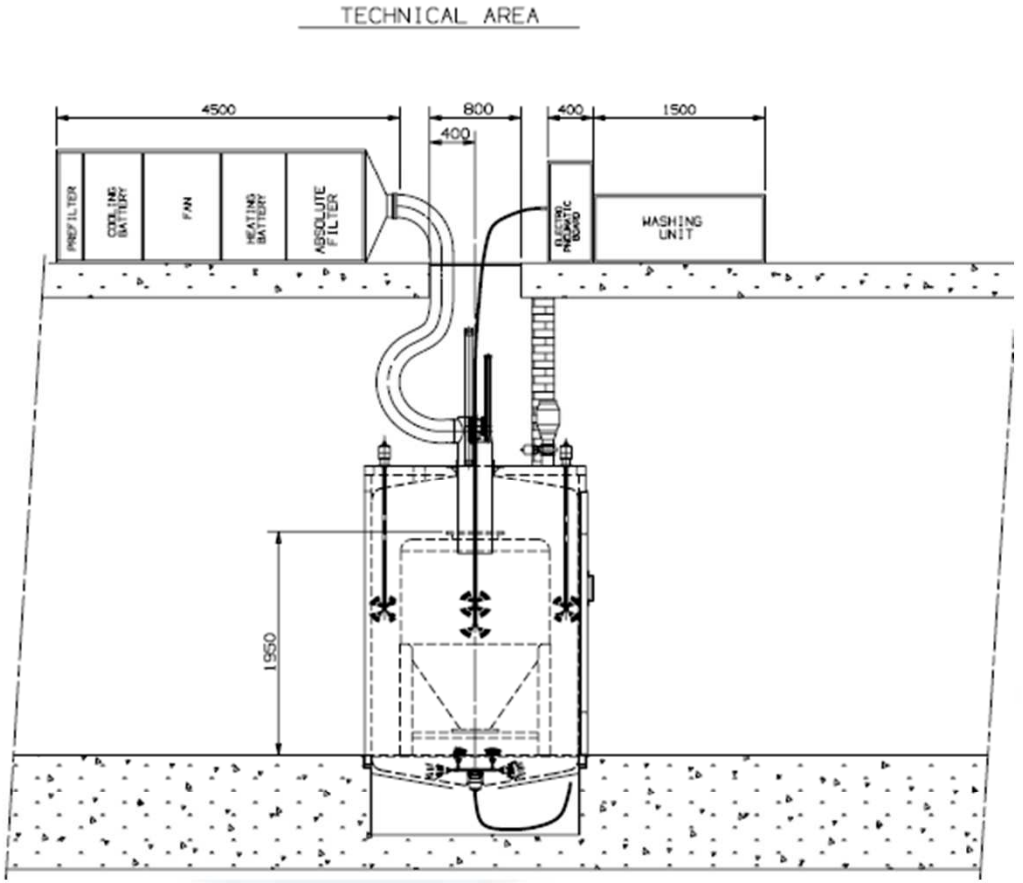
- Washing pressure up to 80 bar (40 liters/minute)
- cGMP and FDA compliant (low pressure part)
- Two detergent dosing pumps
- Manual spray lance
- Equipped with hydro-kinetic lances
- PLC + HMI + on board printer
- Drying and tank modules
- 2 water inlet connections
- Customizable automatic cycles

The way forward of cleaning

Example of CIP with M-Line and S-Line

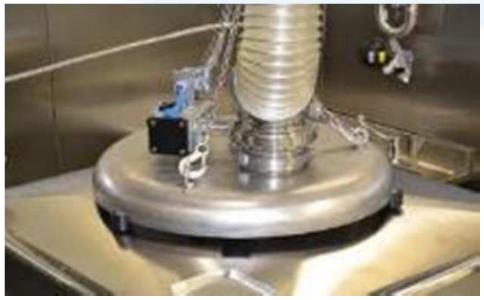






Automatic containers washing, based on validable recipes

The big flexible hose is for the drying air



IWT can provide the washing cabin although the M-line can be easily installed also in existing washing area

Manual use

Example of CIP with M-Line

Spray devices

Spray devices

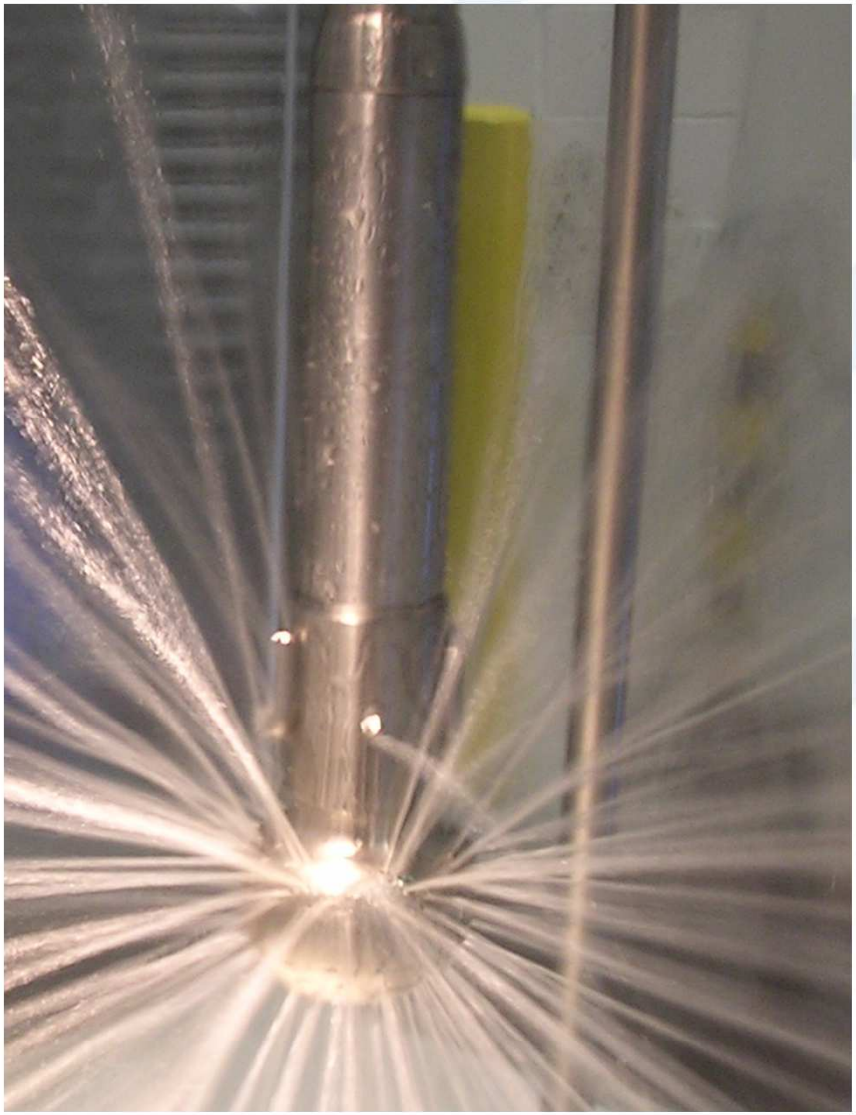
Static Spray Balls

Easy to cleaning application, such as :

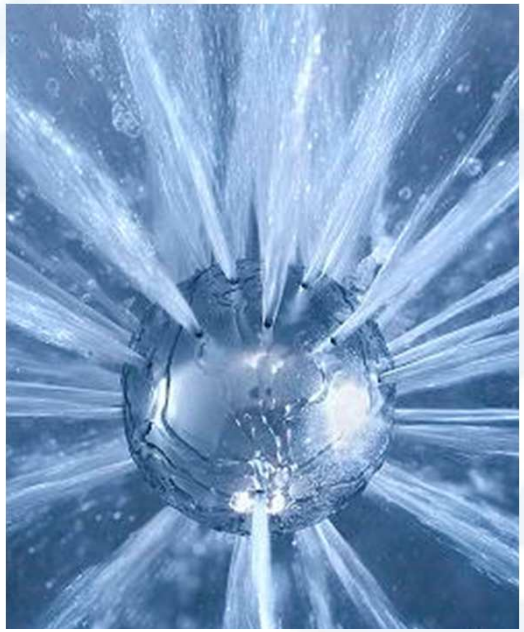
- Water tanks,
- CIP tanks
- Max. Tank diameter : 3 meter
- Operating pressure : 2-3 bar
- Cleaning cost : High
- Cleaning efficiency : Low

Jet break-up, Static Spray Ball

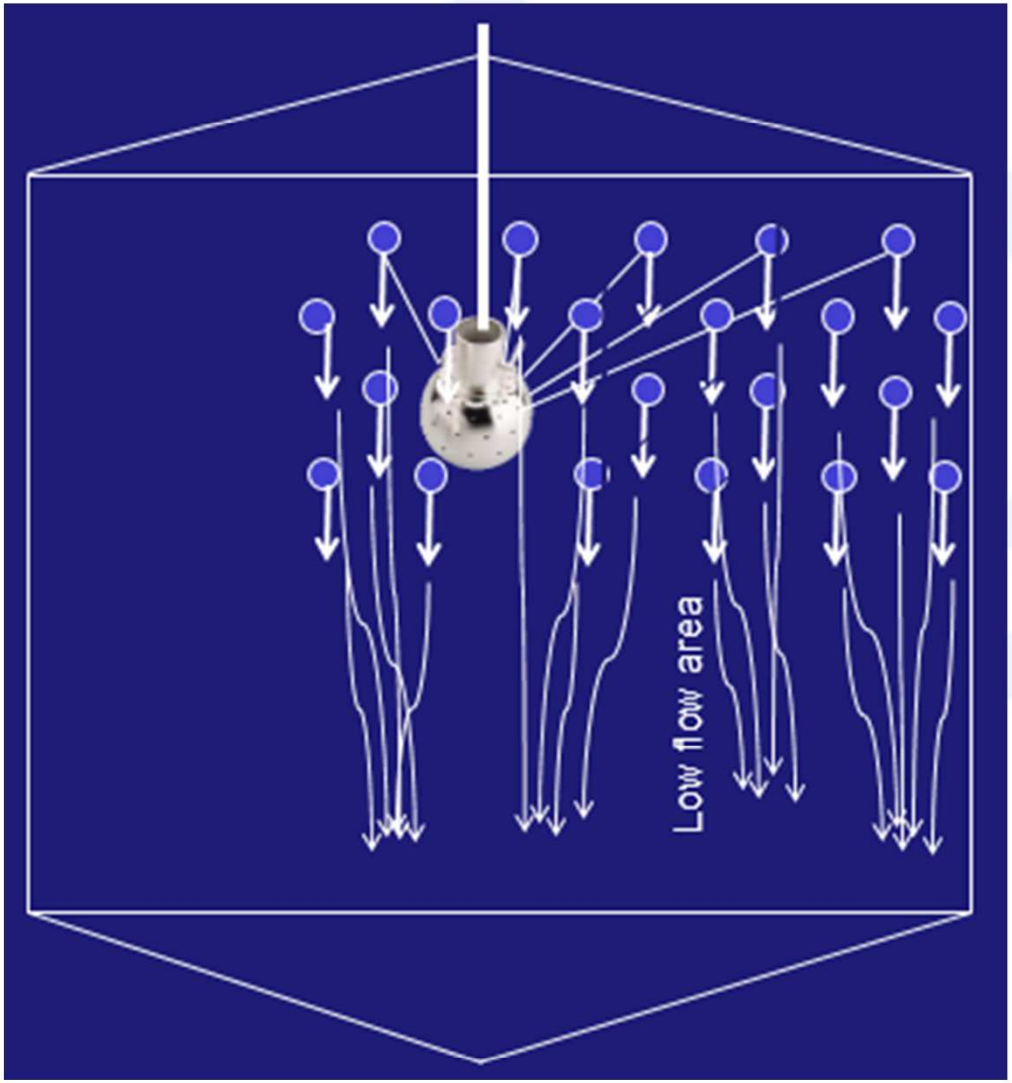
Self cleanability



- Poor external self cleanability
- Clean only by cascading flow



Static Spray Ball



Cleaning methods:
- Cleans in spots (small footprint)
- Cascading flow (Undeveloped falling film)

Cleaning cost:
- High operating cost

Cleaning efficiency:
- Low

Typical Pressure:
- 2 bar

Before and after cleaning

Before

After : 30 sec.

Spray devices

Rotary Spray Heads

Easy to cleaning application, such as :

- Syrup tanks,
- Small process tanks
- Operating pressure : 2-3 bar
- Cleaning cost : Medium
- Cleaning efficiency : Medium

Jet break-up, Rotary spray head


Slowmotion

Self cleanability (exterior)

- Clean mainly by cascading flow
- Clean mainly by cascading flow

Rotary spray head

Cleaning methods:
- Cleans with fans of water, covering the area where the Static Spray ball does not hit

- Cleaning cost:
Medium operating cost

-Cleaning efficiency:
Medium

-Pressure:
2 bar

Spray devices

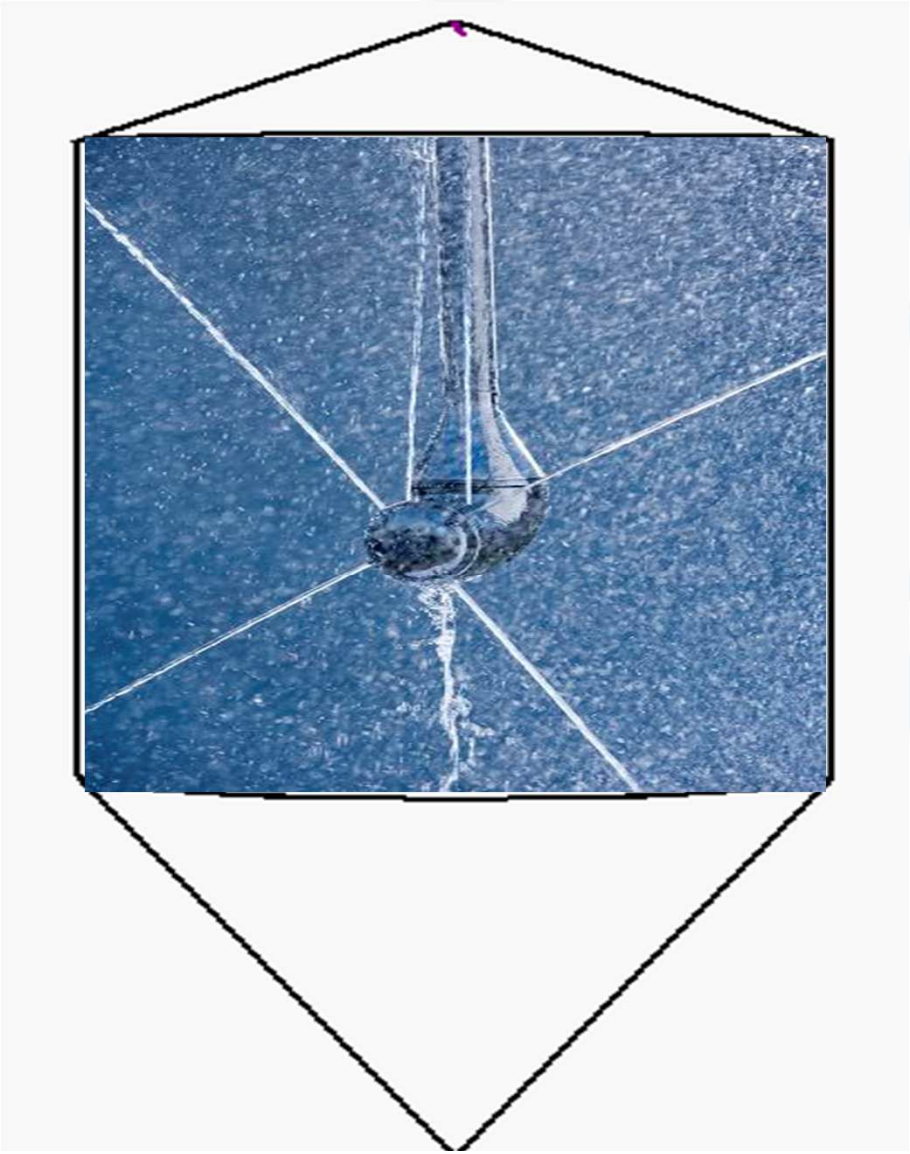
Rotary Jet Hydrokinetic Heads

Difficult to cleaning application, such as :

- Fermentation tanks
- Big process tanks
- BIN for powder production
- Max. Tank diameter : wide range
- Operating pressure : from 3 to 140 bar
- Cleaning cost : Low
- Cleaning efficiency : High

Jet Break Up, Hydrokinetic Head

Hydrokinetic Head



Cleaning methods:
- Cleans with jets in a 3D pattern, hitting the complete tank surface + internal structure

- Cleaning cost:
Low operation cost

-Cleaning efficiency:
High

-Pressure:
2 bar

Benefit of using Rotary Jet Head

Benefit	Result
Fast payback	Due to low operating cost, less than 1 year.
Faster cleaning	More production time
More effective cleaning	Minimizing risk for product lost due to contamination caused by poor cleaning.
Impact cleaning	Reducing the use of chemicals, saves money.
Automated cleaning	Validated process, ensures high product quality.

Cleaning heads

- Pharma-grade head
- Full coverage of the internal walls of the vessels (tested with riboflavin)
- 1 head with 4 spraying nozzles rotating on 2 different axes
- Wide portfolio of cleaning hydrokinetic heads

Hydrokinetic head

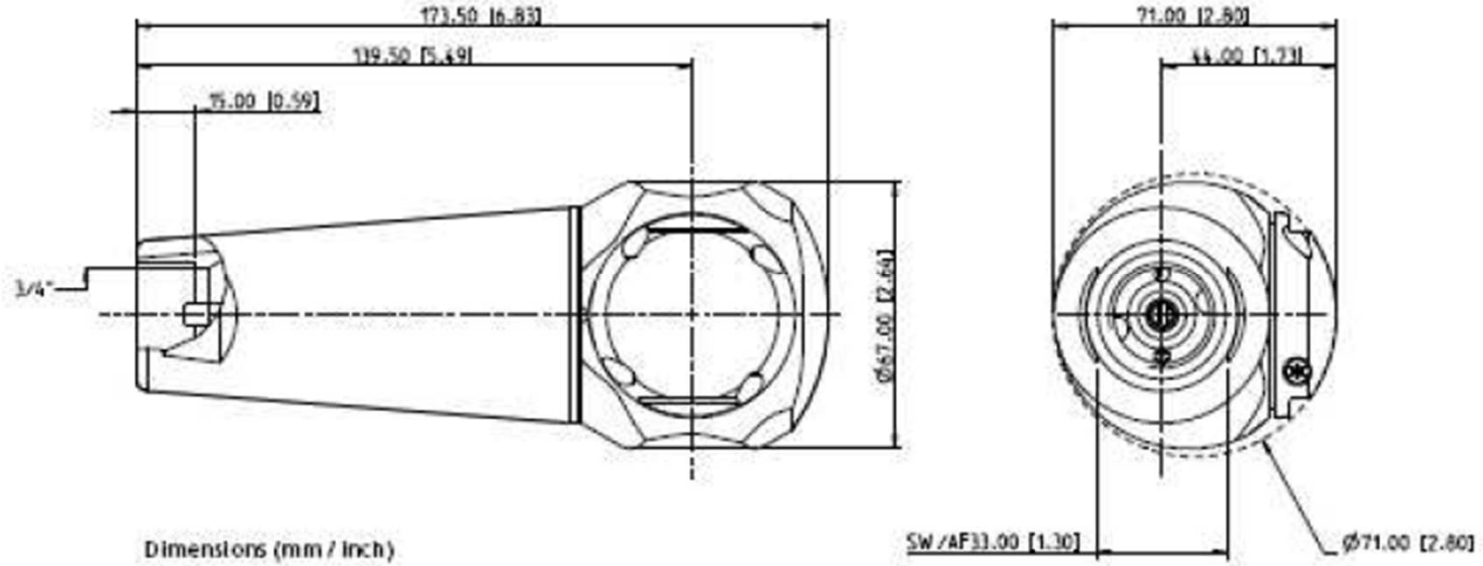
Special features
Powerful compact jet cleaner
Fits through 72.9 mm / 3 inch diameter hole
Low flow rate
High spray dwell time
Similar to Twister for maintenance purposes

Approx. cycle times		
Pressure	Nozzles Ø 3 mm	Nozzles Ø 4 mm
4 bar	2 min	3 min 30 s
6 bar	1 min 45 s	2 min 45 s
8 bar	1 min 30 s	2 min 15 s
10 bar	1 min 15 s	2 min

Version*	Article number
¾" BSP / 3 mm nozzles / C-PTFE**	4660-4990-212
¾" BSP / 4 mm nozzles / C-PTFE**	4660-4990-221
¾" NPT / 3 mm nozzles / C-PTFE**	4660-4990-214
¾" NPT / 4 mm nozzles / C-PTFE**	4660-4990-223

* optional with Pin Fix connection

** suitable for use in potentially explosive atmospheres



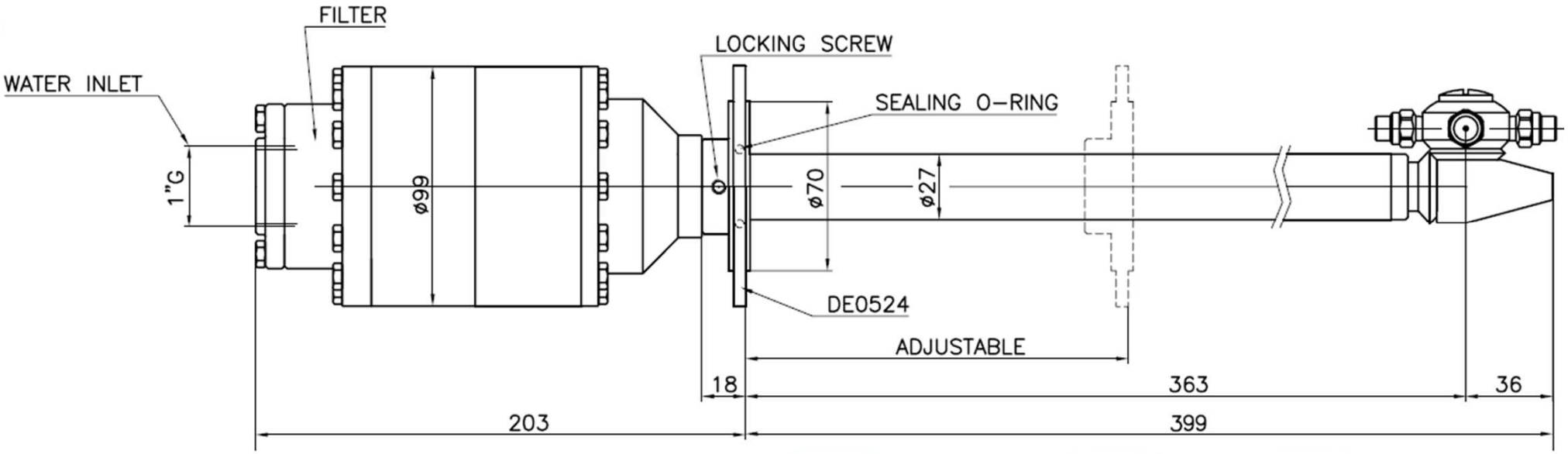
Dimensions (mm / inch)

This is only an example of the most used head

Self-cleaning system

Cleaning heads

- Alternative for non sterile production – removable head



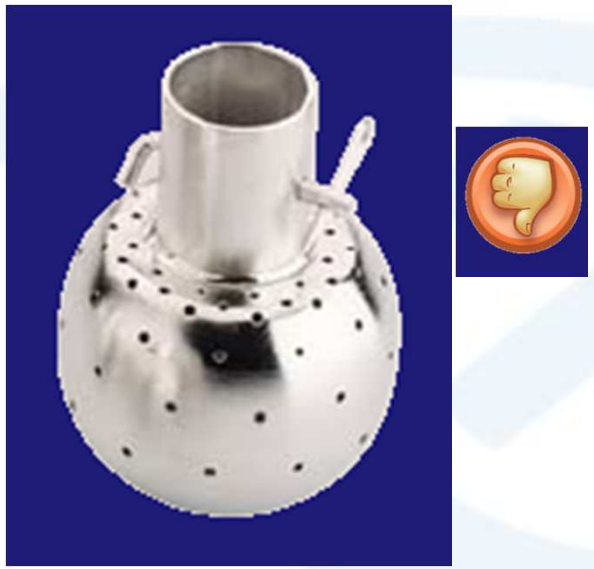
Hydrokinetic head

TECHNICAL DATA	
O.RING	NBR – EPDM – VITON
SLIPPER	PTFE+CARBON FIBRE
BUSHING	AISI 316
FILTER	700 MICRON
NOZZLES POSITIONS	2 – 4
NOZZLES THREAD	1/8"NPT
TESTING NOZZLES	0 x 0000
OPERATING FLOW RANGE	10 – 60 L/min
TESTING FLOW	00 L/min
OPERATING PRESSURE RANGE	0 – 200 bar
TESTING PRESSURE	000 bar
CENTER LINE MIN PASS THROUGH HOLE	95 mm
MANUAL MIN PASS THROUGH HOLE	76 mm
PIPE LENGHT	1018 mm (STANDARD)
MAX OPERATING TEMPERATURE	90 °C
MATERIAL	INOX AISI 316
CONICAL GEARS	FIXED Z=29 ROTATING Z=31
MODULE	1
ROTATION SPEED RANGE	15 TO 25 RPM
FULL CYCLE	31 ROTATIONS
FULL CYCLE TIME	1.5 min AT 20 RPM

This is only an example of the most used head

Coverage

Compare



Cleaning efficiency

Cost per cleaning

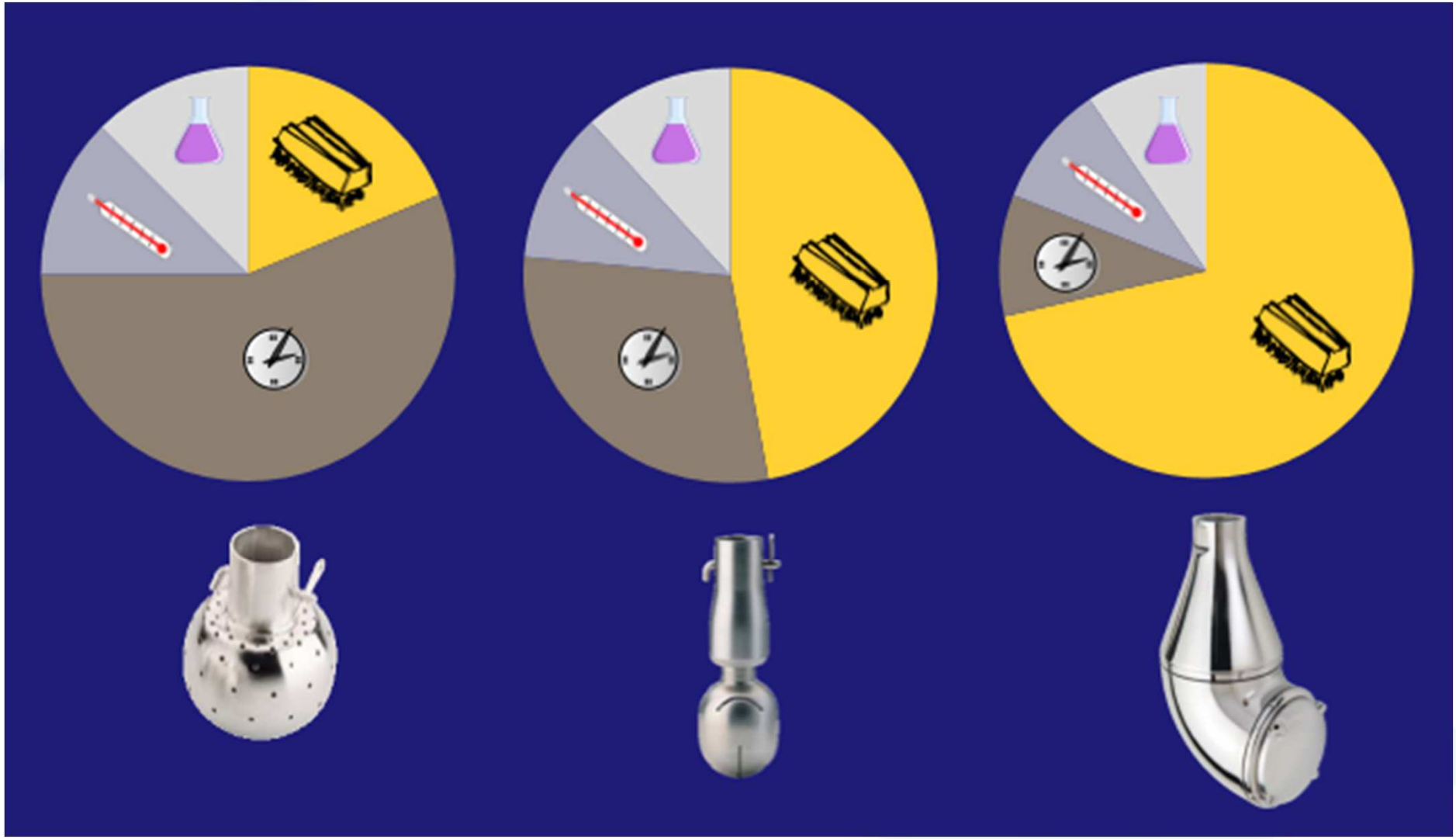
Cleaning efficiency

Cost per cleaning

Cleaning efficiency

Cost per cleaning

Performances



High-Pressure Cleaning solution Case study

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CLEANING EXCELLENCE

Issue

Situation:

- UCB Manufacturing, Shannon, Ireland
- Cleaning of blenders and bins
- Solution to eliminate labor intensive and costly manual cleaning
- Guarantee of cleaning efficiency to facilitate inspections/audits

Issue

Bins cleaning issues:

- Semi-automated procedure via Matcon washing system
- Old, unreliable, inefficient: no longer utilized
- Poor cleaning efficiency

Issue

Bins cleaning hopes:

- Save as much as possible of the old setup (saving costs)
- Re-use the bin support and the cone valve opening mechanism

Issue

Bins cleaning targets:

- Automated and efficient cleaning
- Fully validated process
- Peace of mind of QA and Auditors

Issue

Blender cleaning issues:

- Unsafe and difficult to validate manual cleaning
- Enormous water consumption up to 2 m^3 for each cleaning
- Long cleaning time up to 4 hours – 1 person

Issue

Blender cleaning target:

- Simple, reliable and validated cleaning procedure
- Reduce water consumption and labor
- Improve the cleaning efficiency (removing also the old residues)

Trials

Site meeting outcome:

- Need of a solution to simplify the cleaning activities
- Willingness to invest
- Lack of trust in the sales persons
- New and unknown cleaning technology

The approach was: “I would but I cant”

Trials

Strategy:

- Availability to run some trials
- Possibility to demonstrate the efficacy of the solution
- Real time and on-site evaluation of the solution

The agreement: “Ok, let’s do some site tests”

Results

Bin cleaning test:

- M-Line for High Pressure Cleaning
- 70 bar and 40 liters/minute
- Water temperature 70°C
- Cleaning with hot water only, no detergent
- Cleaning evaluation by QA
- Natural drying time under evaluation

Results

Bin cleaning results:

- Cleaning time 90 sec
- QA approved the cleaning result
- Natural drying took 10 to 15 min, acceptable
- Operation and validation teams were astonished about the results

Trials

Technical details:

- Dimensions of the blender
- Number of lances and entry points
- Info on the product to clean

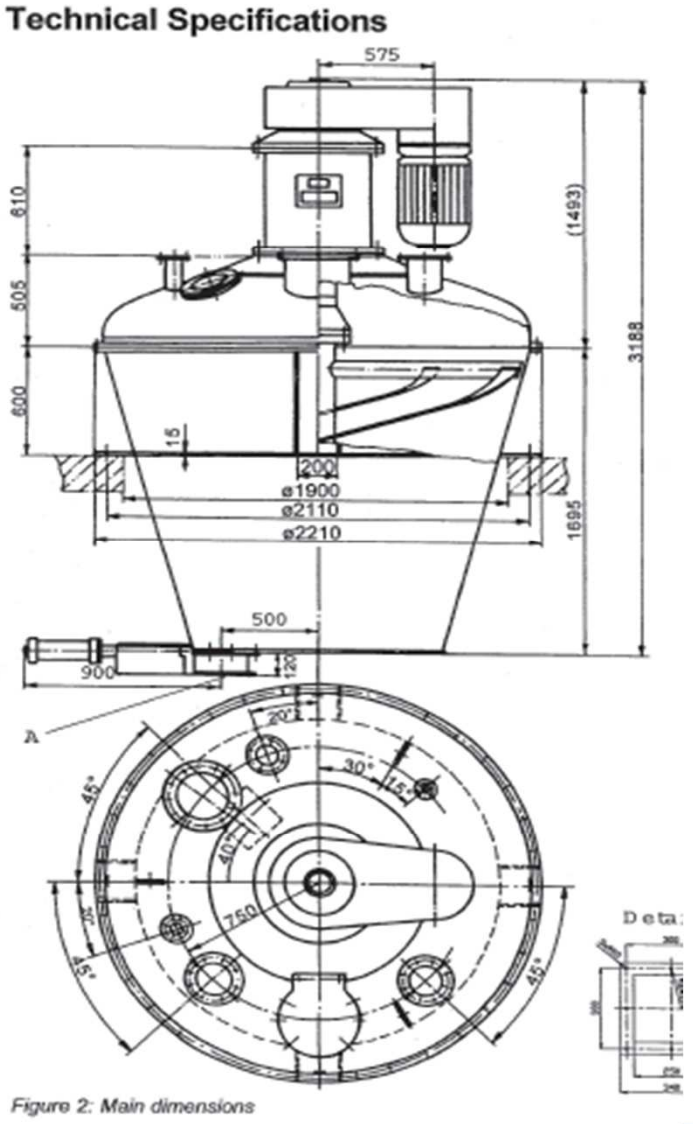
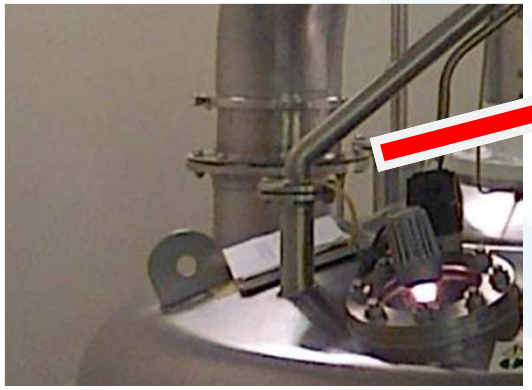


Figure 2: Main dimensions

Trials

Technical details:

- Overall dimensions: 3m high by 2m wide
- Full coverage was a challenge
- Two points of entry available
- Agreed the use two lances, diff. high
- Adaptors for the lances required



Results

Blender cleaning test:

- Max water availability 300l
- Initial cleaning time 180 sec (90 sec each lance)
- Natural drying time under evaluation
- Cleaning with hot water only, no detergent
- Cleaning evaluation by QA

Results

Blender cleaning, 1st attempt:

- Poor result due to lack of coverage (zebra effect)
- Still visible “whitish” effect
- Poor water drainage due to the flat the bottom part of the blender
- Flooding causes splashes everywhere

Results

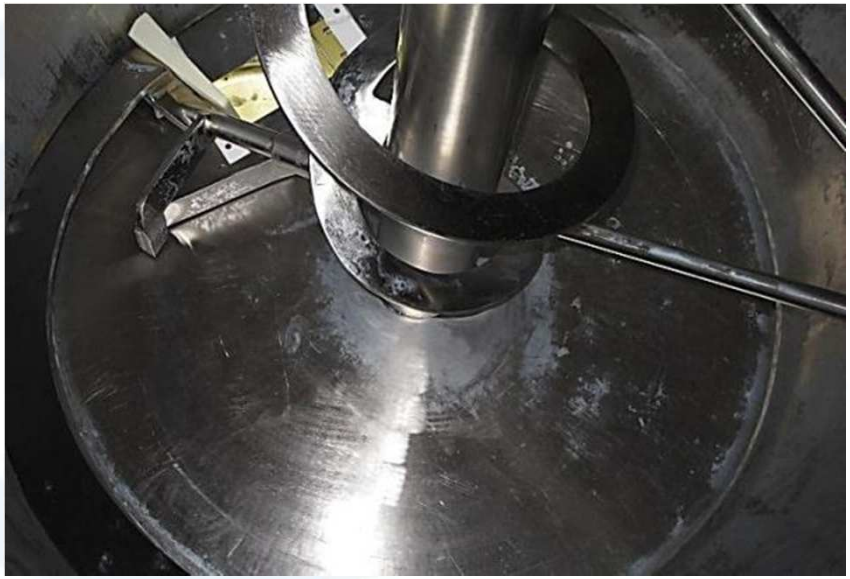
Blender cleaning, 2nd attempt:

- Extended the cleaning time
- Work/pause to allow better drainage to avoid flooding

Results

Blender cleaning results:

- Cleaning time 420 sec (210 sec each lance)
- QA approved the cleaning result
- Natural drying took 10 to 15 min, acceptable
- Whitish residues considered acceptable due to damaged of stainless steel surface over the years



Conclusion

- Site tests were fundamental to overcome customer skepticism
- New technologies may be misinterpreted or not trusted at once
- Peaceful investment following tangible demonstration of efficacy
- Mobile system lends itself to testing by the customer

Conclusion

Bin:	 **BEFORE**	**AFTER** 
Cleaning	Poor	Excellent
Cycle time	> 15* min.	1,5* min (90 sec)
PW consumption	140 l	63 l
Controls	After each cycle	Less frequent
General impression	Staff concerned	Staff satisfied

* Natural drying not considered

Conclusion

Blender:	BEFORE	AFTER
Cleaning	Poor / Unsafe	Very good
Cleaning time	4 hours	7* minutes
PW consumption	> 2,000 l	< 300 l
Controls	After each cleaning	To be agreed
General impression	Staff concerned	Staff satisfied

* Natural drying not considered

Conclusion

Thanks for the attention