STEQ America presents

IWT: M-Line
High Pressure
Impingement Cleaning System

Summary

An affordable, efficient, repeatable, automated cleaning system capable of eliminating the risk of cross contamination while supporting an increased manufacturing capability. This system should have analytical methods, sufficiently sensitive to detect relatively small amounts of APIs, soils, or cleaning chemistry for the complete validation of the cleaning process. In comparison to traditional recirculated cleaning concepts this simpler technology is relatively new to Pharmaceutical Manufacturing. This technology is compliant with regulatory guidelines outlined below; however, you should always evaluate your cleaning process against your specific requirements and manufacturing processes.

FDA's cleaning validation guideline

Volume 4 EU Guidelines

- *Chapter 3: Premises and equipment (1/10/2015)*
- *Chapter 5: Production (1/10/2015)*
- *Annex 15 to EU GMPs - Qualification and Validation (1/10/2015)*

PDA Tech. Report N°29 (TR 29) - Points to Consider for CV

Cleaning Science

The removal of the contamination is influenced by several critical factors that must be take into consideration:

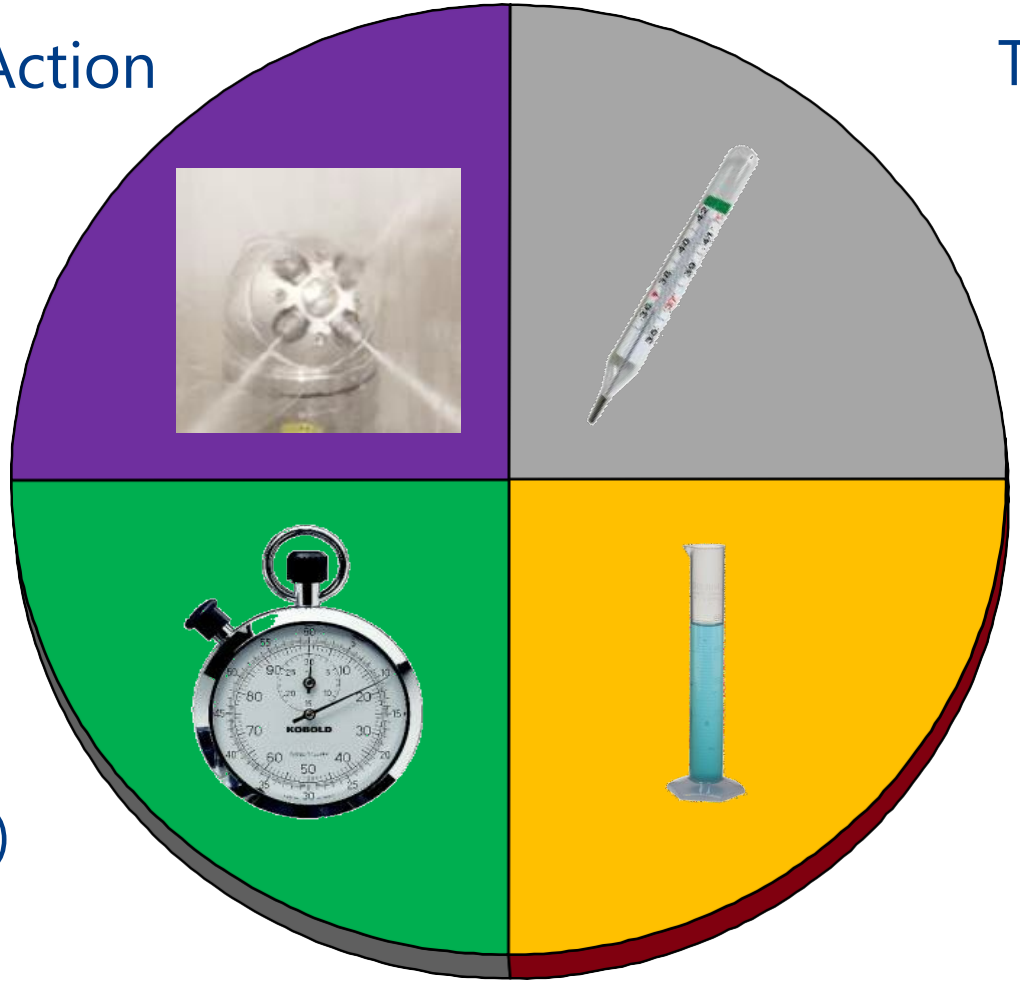
- Mechanical Action
- Temperature
- Chemical Action
- Exposure Time

All variables are strictly linked to each other and have a specific relative weight, it is key to find the right balance in order to achieve the expected cleaning results.

Cleaning Variables

Mechanical Action

Temperature



Exposure
(Contact Time)

Chemical action

Temperature

Temperature is a fundamental parameter than can help to achieve cleaning performances:

- A general rule, although there are some exceptions, the higher the temperature of the washing solution the higher the solubility
- The increase of the solubility leads to a reduction of the washing time which means shorter cycles

However, consider that increasing water temperature by means of a heat exchangers (steam or electrical), will increased operating expenses.

Chemical Action

Chemicals (commonly known as detergents) are used to aid in the cleaning activities:

- Detergents can either be alkaline, acid or neutral.
- The use of detergents reduces the cleaning time and the water consumption, however like the soil they must be removed.
- Removal is carried out by means of one or more rinse cycles and it is mainly verified by water conductivity monitoring and other analytical methods.

Exposure/Contact Time

Production products in varying type, form and characteristic require different contact time to achieve solubility:

- More time for Solids, Semi-solids, Gels, Ointments and Liquids
- Less time for Oral, Parenteral, Topical dosage
- More time and chemical for Insoluble in water or Hydrophobic

Solubility in water can vary for each type of product and have an affect on cleaning time. Longer the washing time the longer the exposure of the load to chemical and mechanical action.

Mechanical Action

Based on the material to be cleaned, product (soil) and quality requirements, you can choose the most effective washing technique:

- Traditional low pressure, high volume, recirculation of cleaning media (heated water and cleaning chemistry) to break down soils into smaller pieces and held in suspension by the detergent.

- High-pressure, low volume, non-recirculated cleaning media, usually ambient temperature and no cleaning chemicals

(High Pressure cleaning principle is based on the mechanical action generated by water sprayed at over 70 bar/1,015psi through orbital nozzles completely covering the surface to clean)

Mechanical Action

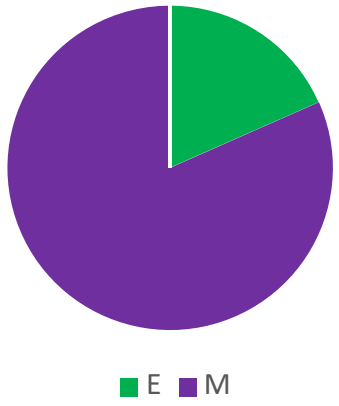
Impact of increasing the amount of impingement

Example of changing the cleaning ratio!

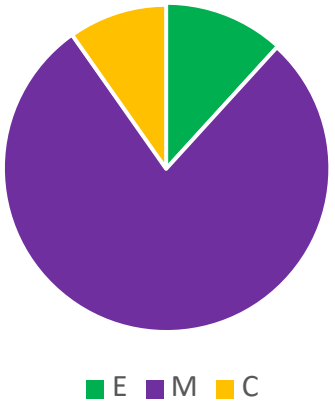
1. ↓ Exposure (Time/Contact)
2. ↑ Mechanical action
3. ↓ Temperature
4. ↓ Chemical action

Original SOP

Example #1



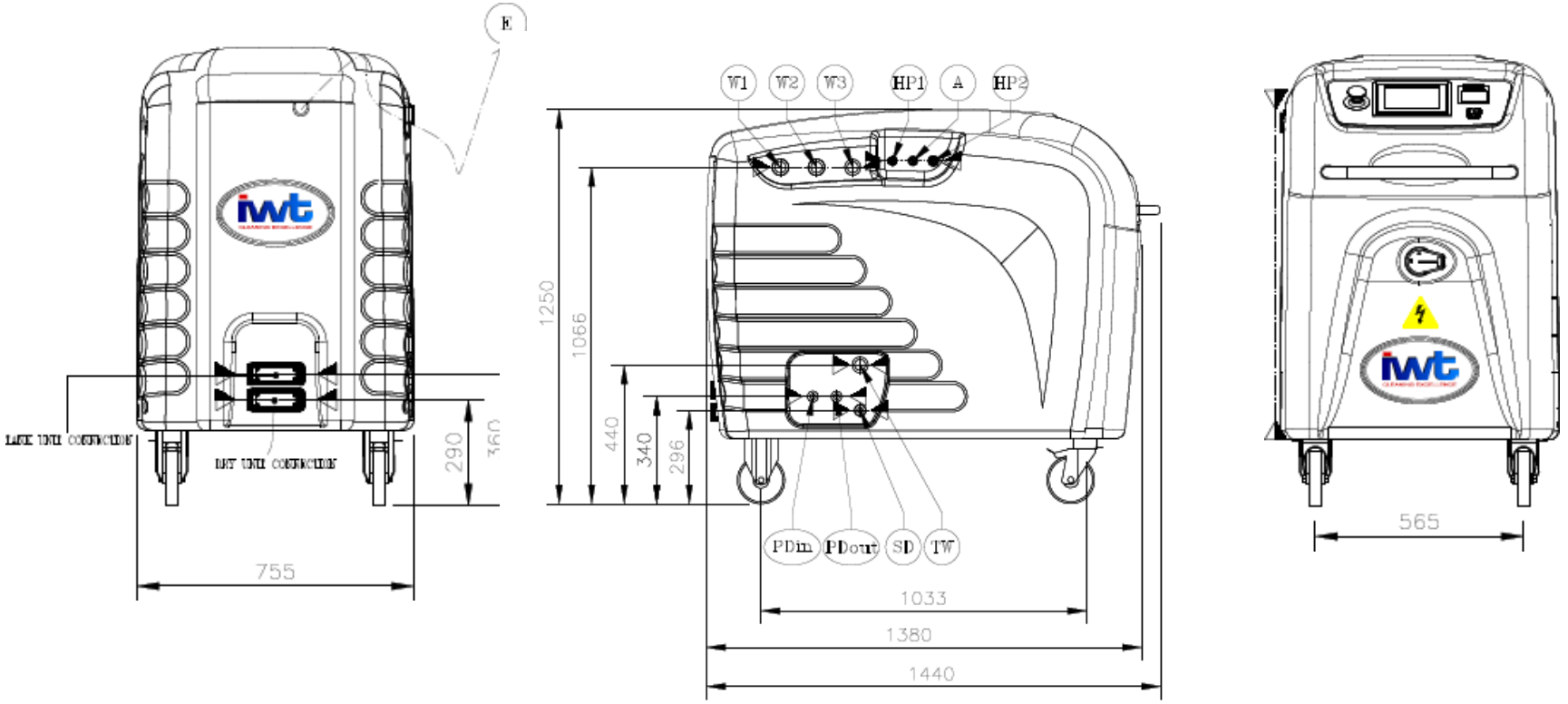
Example #2



M = Mobile

One Size

Suitable to process a wide variety of bulks



All-In-One

- Water pump
- Detergent handling unit
- Electrical cabinet

Single Pass System

No water recirculation means no cross-contamination.

High Pressure / Low Flow

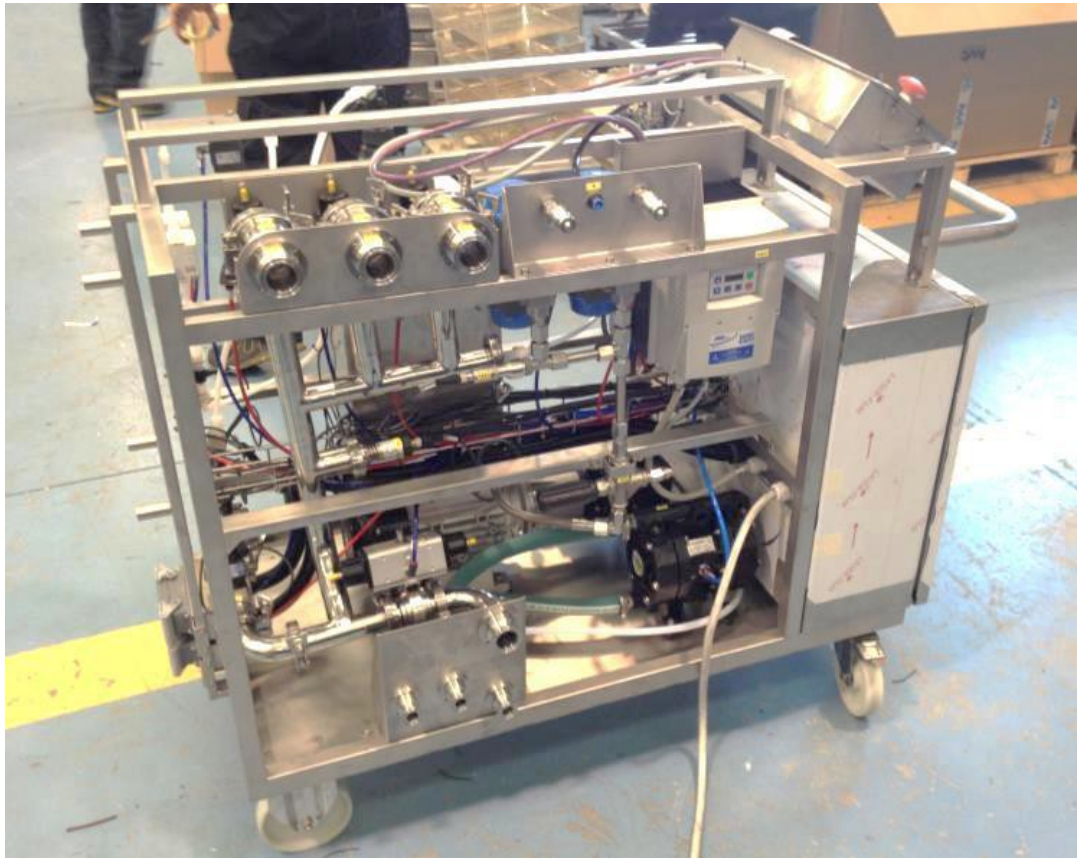
- Output pressure up to 70 bar
- Water consumption max 42 l/min
- ↑ Mechanical Action = ↓ Cycle Times = ↓ Water Usage

Siemens or Allen Bradley (Rockwell) PLC/HMI

- Automation and diagnostic function
- Reliable - Repeatable
  Easy to use with real time information
- Alarms - Safety
- 30 different recipes/10 phases per recipe
- Printer on board
- USB port for data backup/restore
- 21 CFR: Part 11 compliant

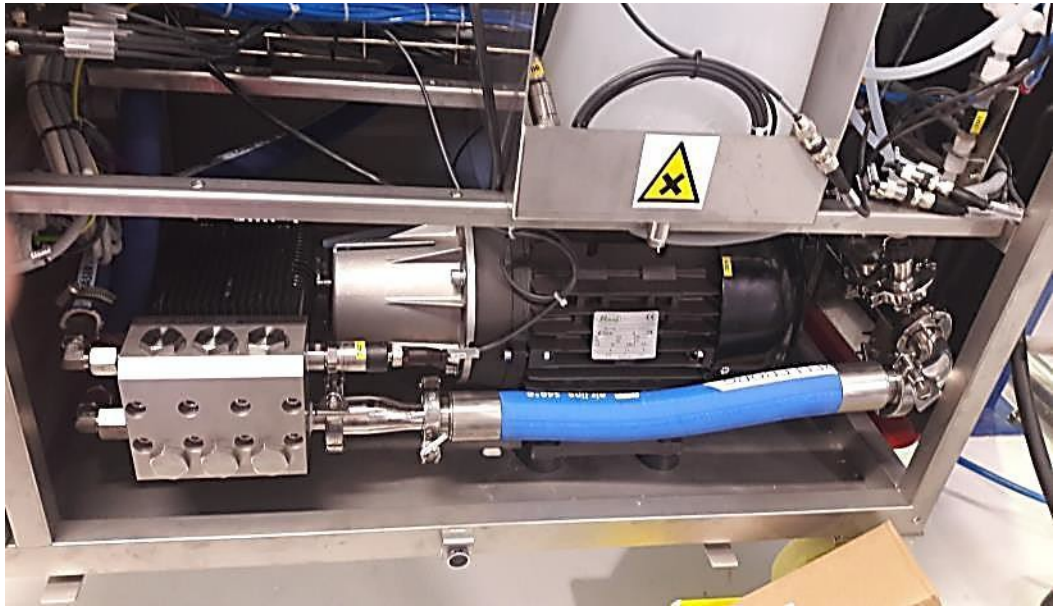
Quality

- Wetted parts entirely made of AISI316
- All polymers FDA approved
- High quality non-proprietary parts (Gemu, Hilge, Festo, SMC)



Quality

- High quality components (calibration certificates + data sheets)
- Calibrated instruments for accurate process control



FDA and GAMP5 compliant

- Meets the latest quality standards
- Special safety fittings on high pressure circuits
- Orbital weld piping with tagging
- Quick lock safe connections

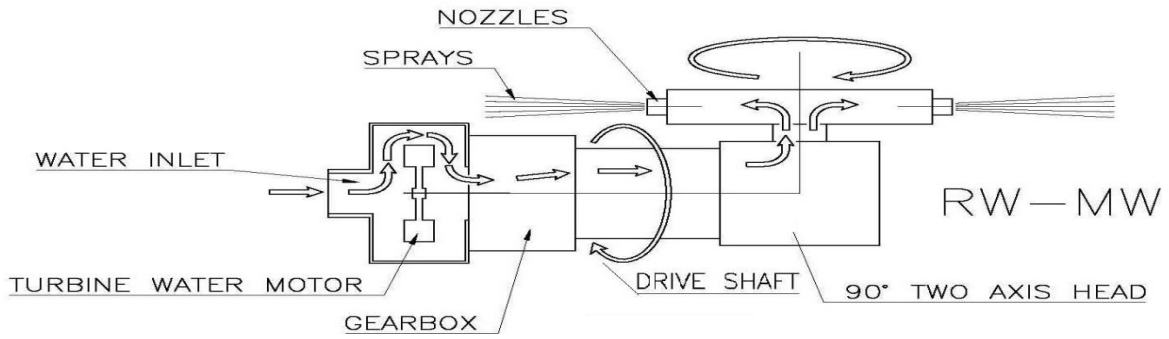
Supply

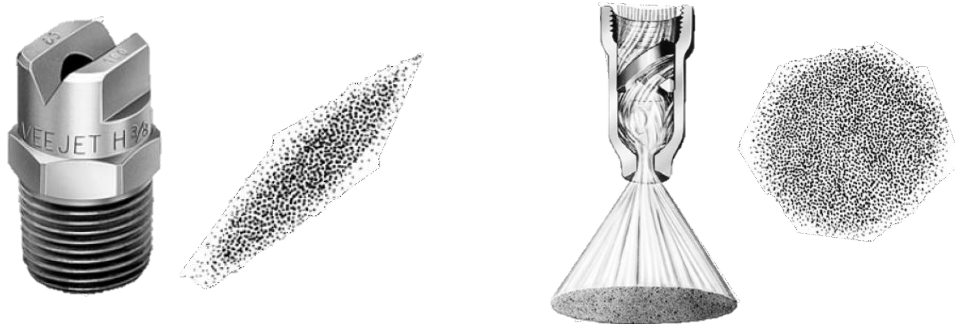
- 480V/60A 3-phase – custom connection plugs available
- Clean compressed air available for pipe flushing
- Up to 3 water inlet connections
- Wash and rinse with different quality water

Features

Versatile Cleaning Solutions

- Up to 2 HP outlets available
- Flexible hose available in multiple lengths
- Several lance lengths available
- Different heads available
- 360° coverage of internal surfaces with up to 1.5m effective cleaning range





CLEANING EXCELLENCE

M-LINE
HIGH PRESSURE MOBILE WASHER

STEQ America

Detergent Dosing System

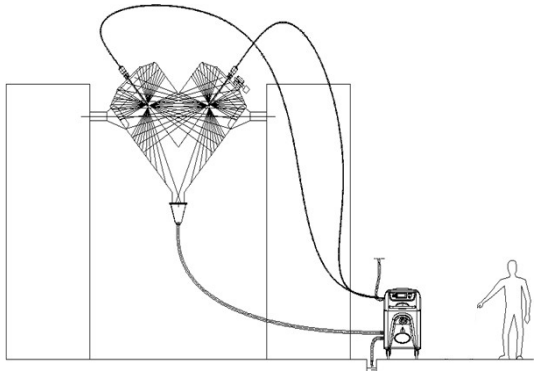
- Patented in-line dosage system
- Up to two dosing systems available
- Precise dosing measured by calibrated flowmeter
- Selecting the correct chemicals may increase the efficiency of the cleaning process

On-Board Process Drain

- Enables delivery of effluent to storage container or remote drain
- Ensures compliance with effluent regulations

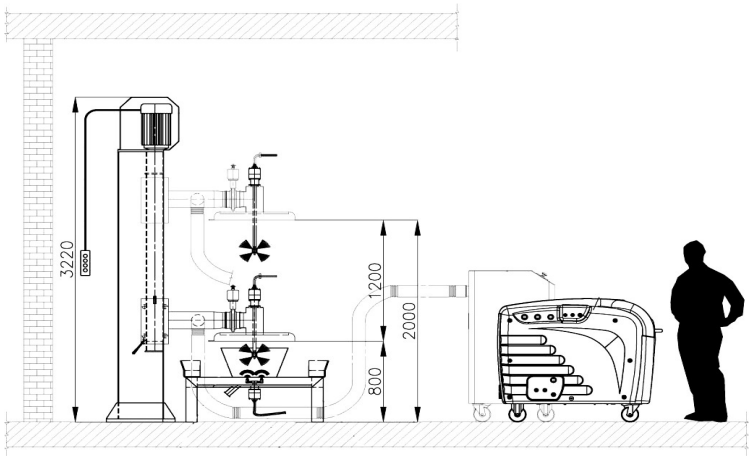
Water Conductivity Control

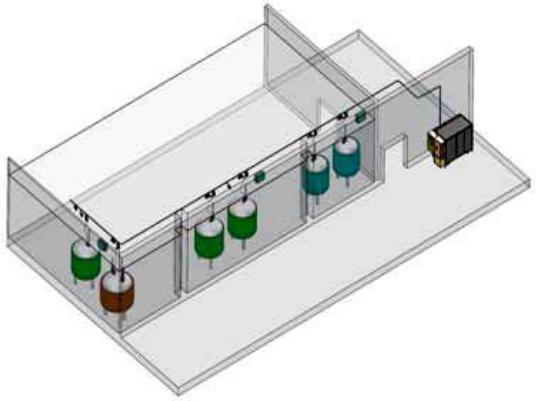
- Guarantees complete rinsing of the load
- Automated for a repeatable process
- Probe housing integrated with drain
- Validated procedure reduces the frequency of QA testing

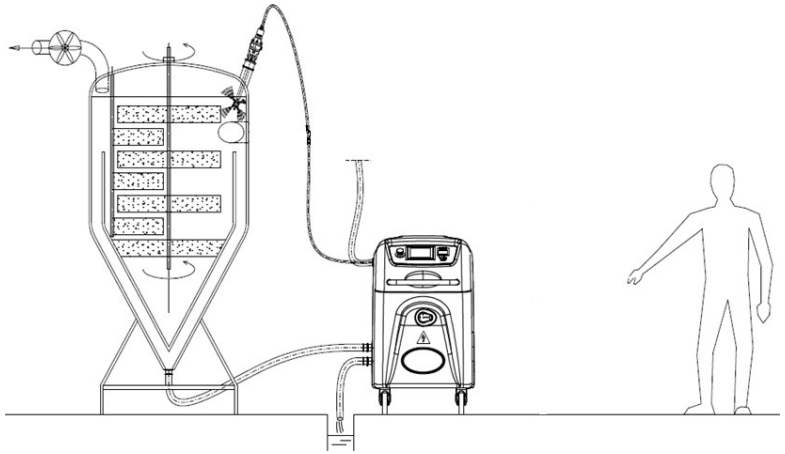


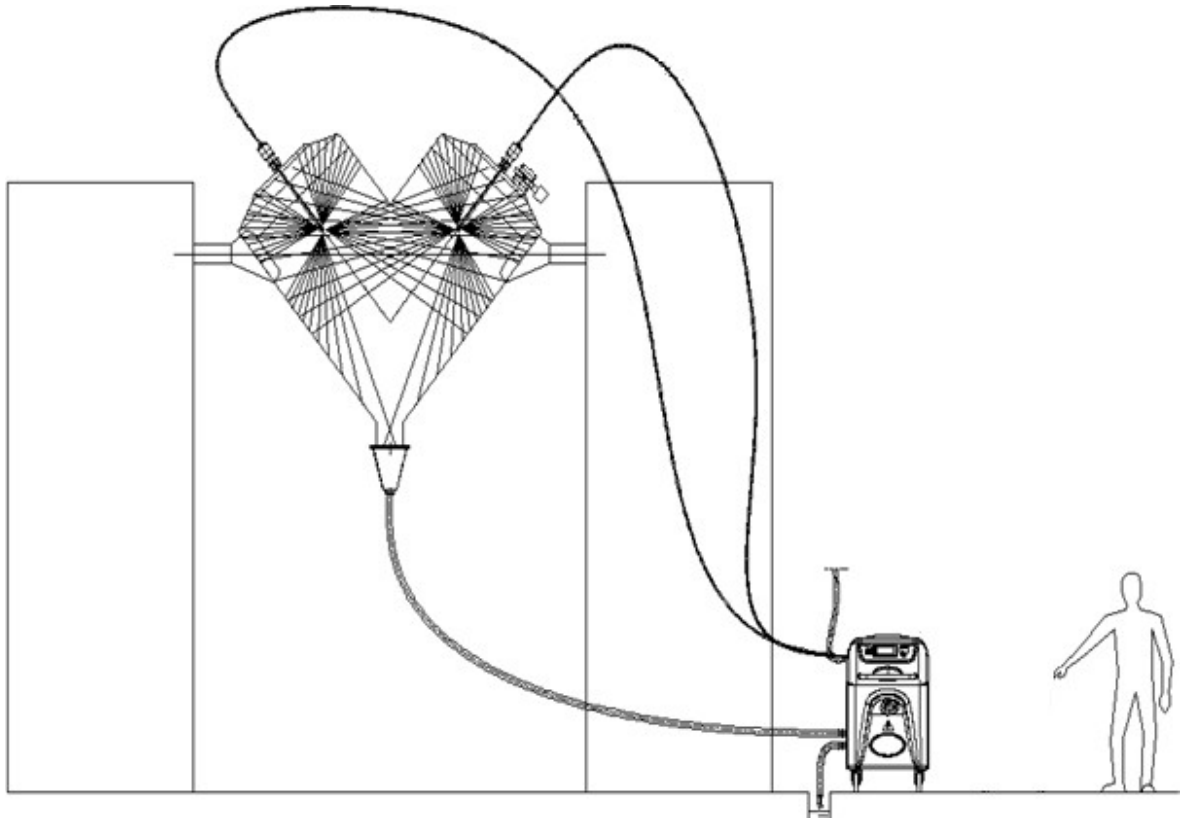
One Unit – Many Applications

- Versatility opens up wide variety of applications
- Unique product in the market







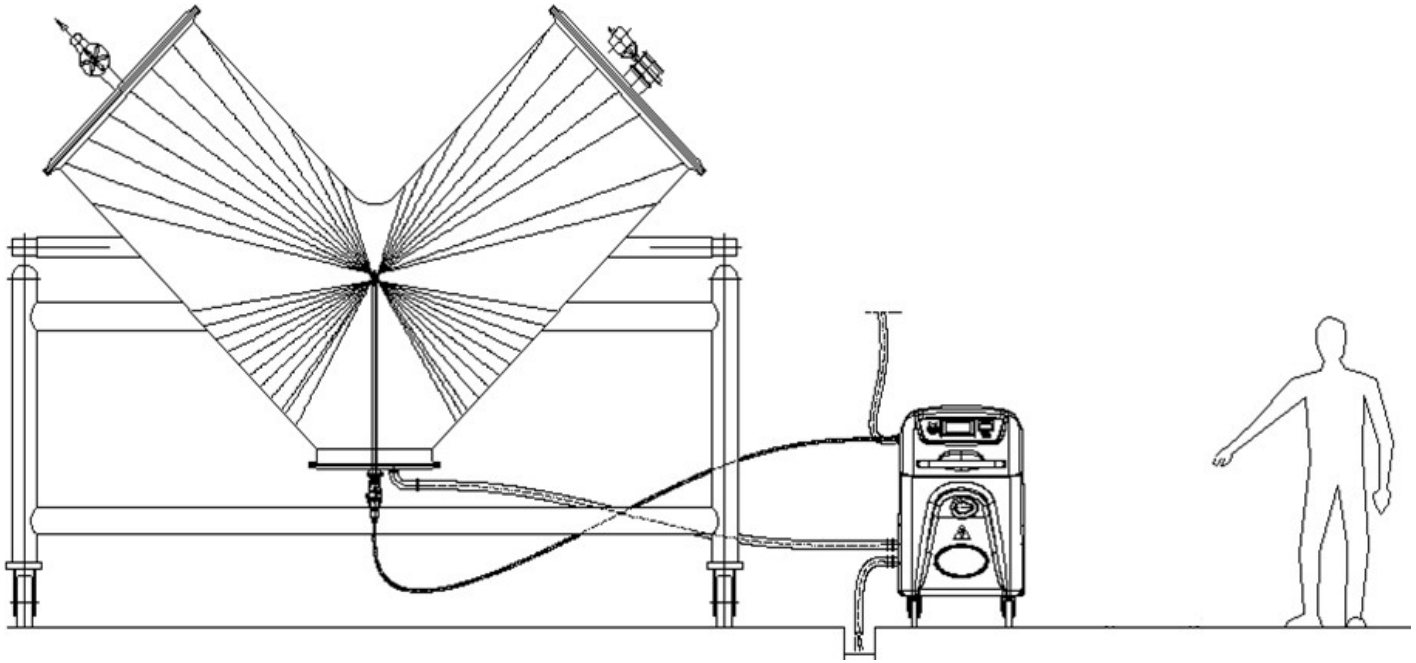


V-Blender CIP Cleaning

- Large blenders may require multiple insertion positions
- Alternating phase lance set-up (pictured) reduces cycle time – can be
- Drain utilizing process pump or alternatively floor drain

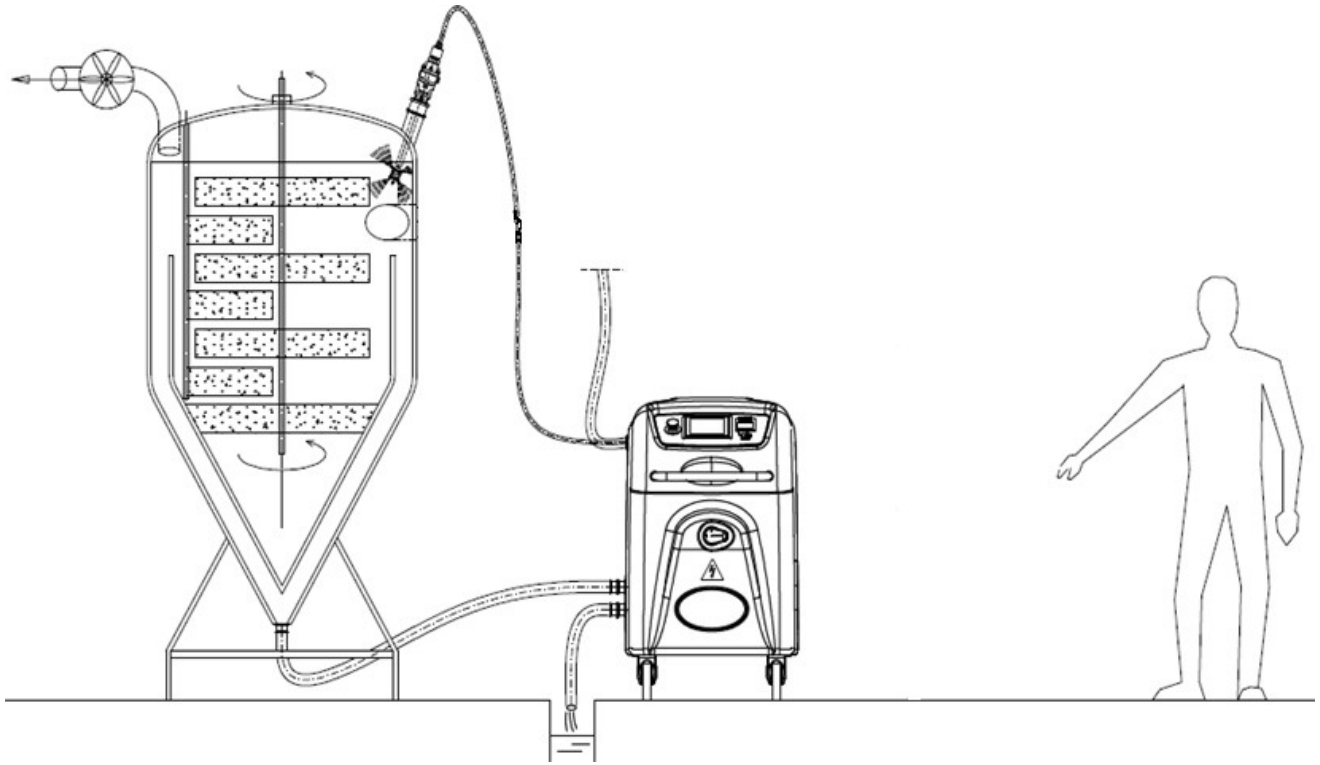
V-Blender CIP Cleaning

- Smaller blenders may only require one lance interface



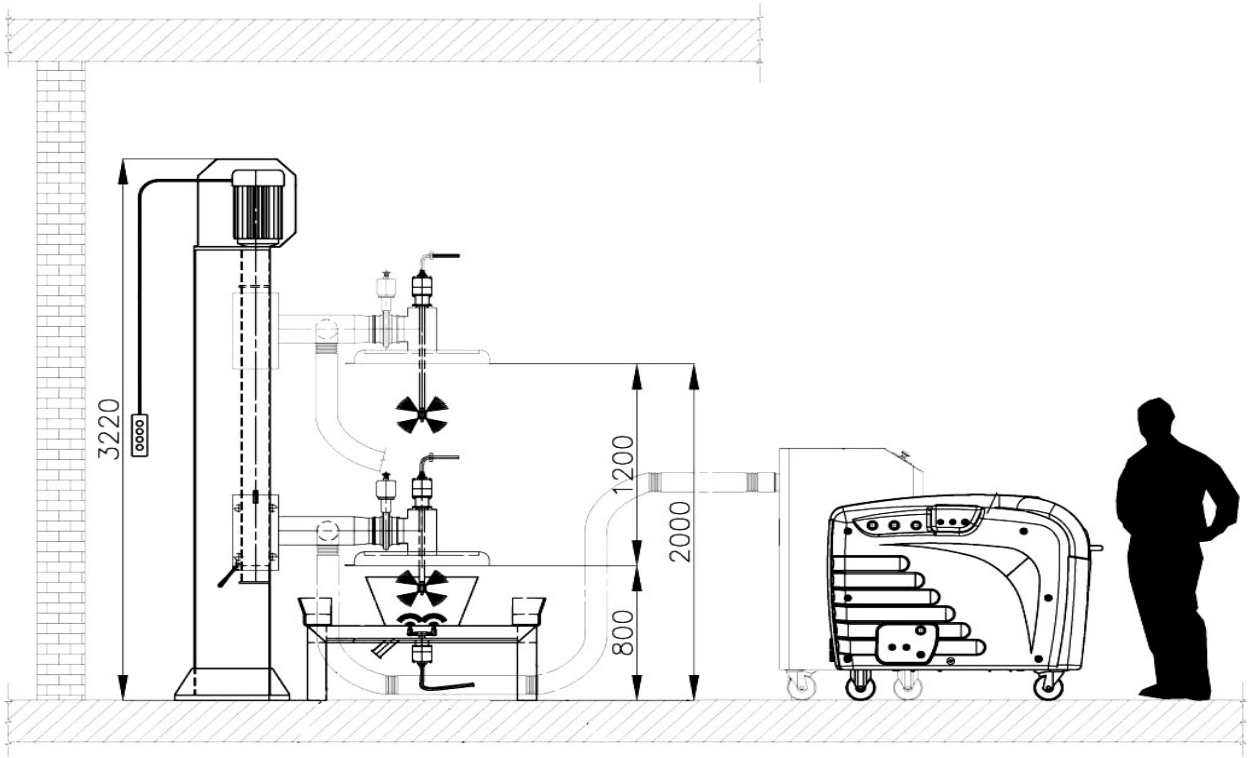
Mixer CIP Cleaning

- Internal baffles/obstructions may require mixer rotation and/or multiple lance interfaces
- Phases can be programmed to advance automatically or manually

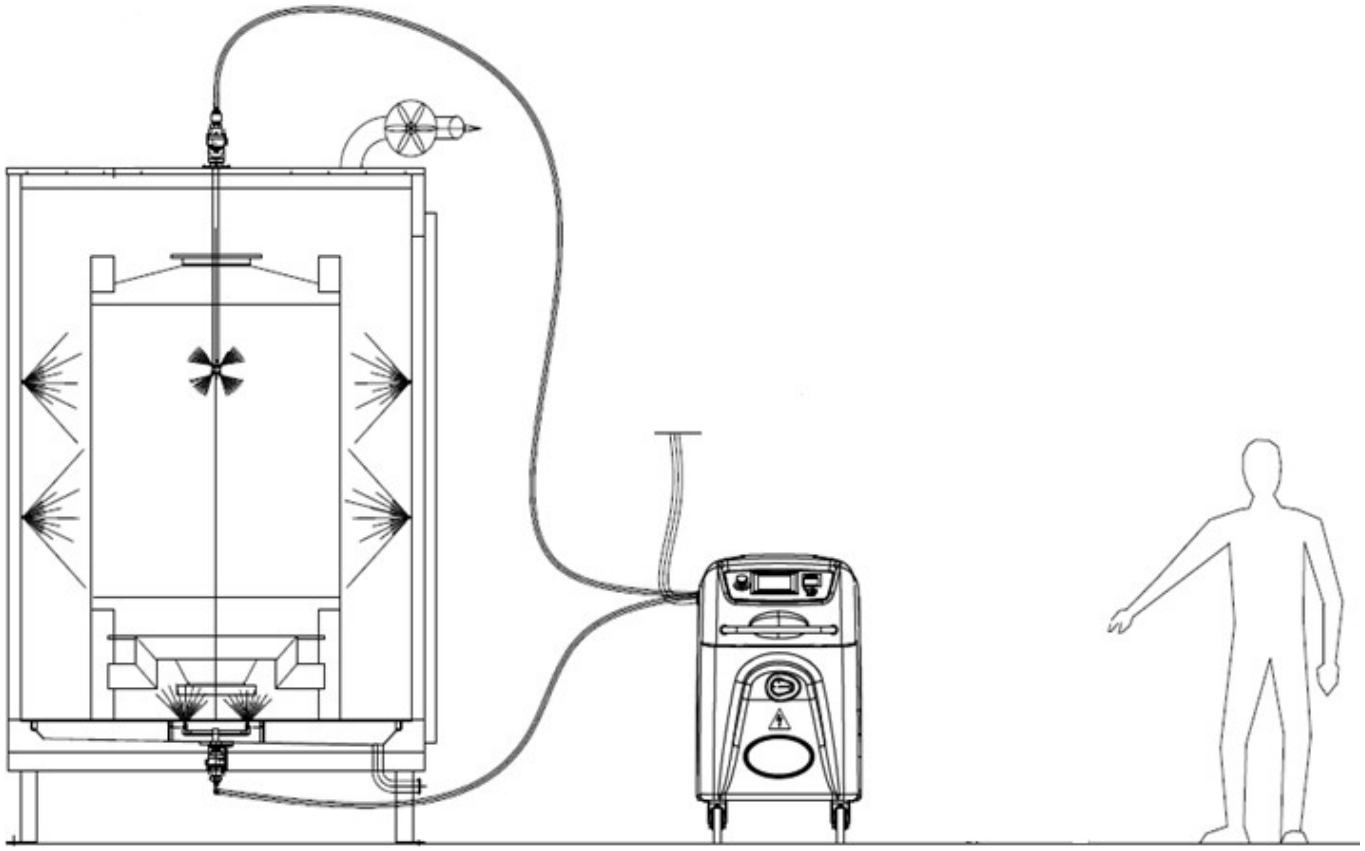


Bin Washing Station

- Lifting column
- Bins of various sizes

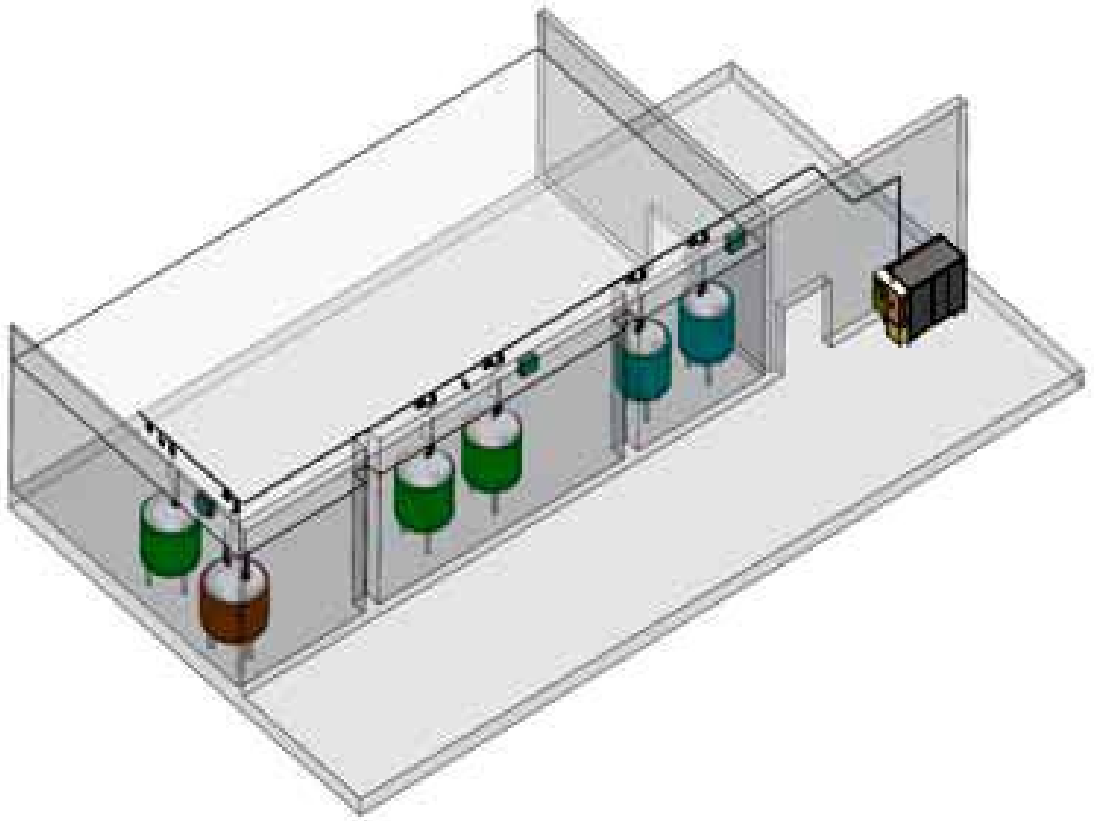


Applications



Bin Washing Cabin

- Fixed lance positions
- Bins of various sizes



S-Line High Pressure Washing System

- Fixed CIP

cGMP Documentation Packages Available

- Design qualification FDS - SDS
- Qualification protocols FAT – SAT/IQ/OQ
- Materials certificates and traceability
- P&ID component table, pneumatic & wiring diagrams
- Calibration procedures for ease of qualification
- Maintenance procedures and troubleshooting

Cost Analysis

Mobile Washer
Running cost calculation

Project	**CUSTOMER NAME**			
Equipment:	**Mobile High Pressure washing system**			
Cleaning procedure for:	**BINs with different capacity 500-1000-2000 L**			
Product:	**Best case considering a product soluble in cold water**			
Detergent:	**not required**			
Water pressure:	**75 Bar at the nozzles**			
Typical Cycle Evaluation				
Minimum utilities required:				
Utility	**Flow-rate**	**Unit**	**Pressure Bar**	**Temp °C**
Demineralized water	40	l/min	2÷4	20
Number of cleaning heads	1			
Filtered compressed air	70,00	Nm^3/h	6	
Electricity	**Power kW**	**Cons. KW/cycle**		
Instelled power	6,00		0,20	
Estimated cycle time	**Time**	**Unit**		
Total Washing time	2	min.		
Total Purge time	2	min.		
Total cycle time	4	min.		
Estimated cunsumption per cycle				
Utility	**Consumption**	**UM**	**°Unit cost E**	**Total Eur**
Demineralized water	80,00	Liters	0,0012	0,10
Compressed air	2,33		0,0010	0,00
Electrocal Power	0,20	kW	0,0850	0,02
Total cost per cycle			**Euro**	0,12

Accurate Cycle Evaluation

- Cost of ownership calculation
- Automated repeatable process
- Documented cycle time, media consumption and service

STEQ America

- US based support
- Demo unit available with qualified technical support personnel
- Project management services
- Installation, commissioning & training
- Validation support services
- Maintenance services

Conclusions

Tangible benefits of automated technology:

- Automated cleaning procedures are crucial to achieve a high hygienic standard in pharmaceutical production
- Automated cleaning allows for validated processes and regulatory compliance
- A well-planned working methodology regulated by proper SOP's assures better cleanliness with guaranteed no cross contamination
- Guarantee the repeatability of the results
- Minimize operator contact time with API's and chemicals, thus improving health and safety conditions

Conclusions

Tangible benefits of the M-Line:

- Flexible equipment line allows an unlimited range of cleaning solutions from a stand-alone drum/bin washer through very specialized and custom-sized applications
- Energy consumption reductions
- Reduction in water consumption (a precious resource!)
- Reduced effluent pollution due to lower or no use of detergents
- Documentation of the successful cleaning process and tracking of resource consumption
- Experienced support from project design through after-care

Your authorized IWT representative:

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