FAST MOVING TECHNOLOGY

STÄUBLI

Stericlean+ robots

NEW

Robotics | Experts in Man and Machine

STERICLEAN +

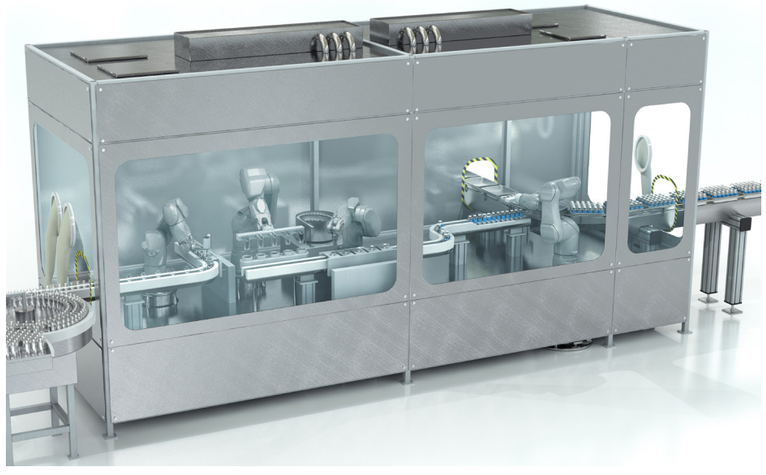
Precision, reliability and cleanability symbiosis

New regulatory changes in pharma manufacturing, the demand for personalized medicines, new treatment options and innovative approaches in prevention and diagnostics are among the key challenges facing the pharmaceutical industry. With impressive levels of flexibility, robot-based automation solutions are the first choice for small batch production runs in personalized medicine. They offer the additional advantage of reducing human contact to a minimum, and thereby avoiding the risk of contamination.

Stäubli has been a partner to the pharmaceutical industry for decades, responsible for pioneering developments such as our acclaimed Stericlean models, which facilitate automation in aseptic environments.
More recently, we have worked in close partnership with OEMs and integrators to expand our robotics portfolio for pharmaceutical applications. From there, we have developed the product that meets all the requirements of the market.

Rudolf M. Weiss,
Global Head of Pharma Robotics

Unique hygienic robots for pharma aseptic processes



Pharmaceutical manufacturing is a highly controlled and regulated environment. The production is made in an isolator, where decontamination is mandatory and monitored. Almost every process can be automated to gain in flexibility and sterility. To respond efficiently to market expectations, production must be easily scalable, the robot's flexibility being a key factor to enable this. Whether in a small isolator with a single robot capable of handling several independent or linked operations, or in a complete production line equipped with multiple robots, they allow management of different RTU containers in order to change production easily, should the need arise.

PHARMA OFFERING

4 new models made for isolator

The Stericlean+ brings in the industry an optimal hygienic design.

stericlean +

Aligned with the new regulations

FDA compliant material

Improved hygienic design

Higher cleaning performance

tested by skan

Validated Robots

A VALIDATED ROBOT

Customer benefits

- More transparency
- Compatible proof
- Save time for machine qualification documentation
- Support on your risk assessment
- More acceptance

Validation and documentation package

In August 2021, Stäubli partnered with SKAN's analytical services (SKANalytix) to improve the aseptic robot design and provide the much-needed validation and documentation package for the customers. The Stericlean+ will be easily integrated in the pharma automation, thanks for its entire documentation that will support pharmaceutical industry for the Qualification of the whole machine.

"With a comprehensive and well-documented testing package, this also generates an added value for the pharmaceutical industry and ultimately patient-safety." says Maximilian Mittelviefhaus, Research Manager, SKAN AG.

CONCEPTION

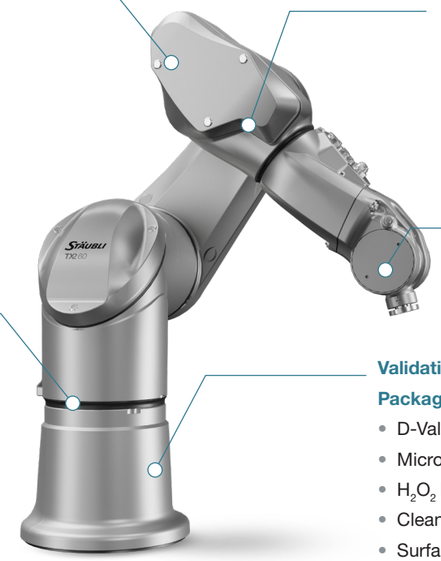
Unique hygienic design

Hygienic design

- FDA Compliant coating
- VHP compatible
- Hygienic covers with FDA Compliant Static Gaskets - USP Grade VI
- NSF H1 oil
- ISO 5 - Grade A

Smart design

- Encapsulated 6-axis arm enabled by hollow shaft drives, no external cables
- Vertical connection for integration through the base
- Attachement methods: 360° mounting possibility
- Patented JCS smart gearbox
- Unique and modular SIL3-PLe safety functionalities



Improved tightness and cleanability

- FDA Compliant Dynamic Joint Sealing on all axis - USP Grade VI
- IP65

Hygienic wrist

- FDA Compliant coating wrist

Validation & Documentation Package includes

- D-Value
- Microbiological resistance
- H_2O_2 Desorption / Absorption test
- Cleanability Test with Riboflavin
- Surface roughness
- Chemical resistance with 13 cleaning media

tested by skan

stericlean +

MODEL	**TX2**-40 Stericlean+	**TX2**-60 Stericlean+	**TX2**-60L Stericlean+	**TX2**-90 Stericlean+
Load capacity	2 kg	4.5 kg	3.7kg	14 kg
Reach (between axis 1 and 6)	515 mm	670 mm	920 mm	1000 mm
Number of degrees	6	6	6	6
Repeatability - ISO 9283	± 0.02 mm	± 0.02 mm	± 0.03 mm	± 0.03 mm
Max cartesian speed	8.6 m/s	8.4 m/s	11.1 m/s	10.9 m/s
Weight	29 kg	52 kg	53kg	114 kg

Available options

- Stericlean H_2O_2 harness
- Hygienic box

Coming soon

- Hollow wrist
- Aseptic tool changer
- Anti sloshing

An Opportunity for a more complete Validation and Documentation Package

To stay in line with these new requirements, Stäubli partnered with SKAN, the world leader in manufacturing isolator systems, and specialized in pharma and aseptic environments, in August 2021. “SKAN’s analytical services (SKANalytix) are helping Stäubli improve its aseptic robot design. They also provide robots with the much-needed validation and documentation package that clients ask for. We’ve done our homework,” smiles Rudolf M. Weiss, Stäubli’s Global Head of Pharma & Medical.

“Through our SKANalytix service, we provide our customers with analytical support for their questions and concerns around aseptic processing,” continues Gregor Hommes, Head of Research and Strategic Business Development at SKAN. “We offer studies around all aspects of isolators, and run tests regarding product, process and operator safety with regard to isolator and cleanroom technology.”

Stäubli and SKAN’s collaboration has resulted in the development of new features for the Stericlean+ package that ensure that the robots are suitable for aseptic manufacturing conditions.

Pharma Industry Requirements for Robots in an Aseptic Environment

Hygienic design is a central aspect of a robot, establishing that it is suitable for working in an aseptic environment. Design specifics cover a wide range.

“There are two primary factors,“ states Richard Denk, Senior Consultant Aseptic Processing and Containment at SKAN, and Chairman of the ISPE (International Society for Pharmaceutical Engineering). “First is the entire outer surface of the robot. If this cannot be adequately cleaned and decontaminated, then there is a risk that the aseptic processing conditions cannot be maintained. The materials need to be selected appropriately and the design should allow for easy access.

And secondly, of course, moving parts represent the greatest risk of generating particles, so special attention needs to go into the design and sealing of joints.”

More specifically, there can be no gaps in joints in the robot’s outer shell, where micro-organisms could accumulate and grow.

Surface roughness can have an Ra of no more than 0.8µm, again to not harbor fungi or bacteria and enable efficient cleaning. The surface must resist all cleaning and surface decontamination procedures, in particular vaporized hydrogen peroxide (H2O2) which is used for surface decontamination inside isolators.

“A robot should not generate turbulence in the laminar air flow as it moves,” Richard goes on. “Particles released during movement must remain at a low threshold, to guarantee that ISO 5 standards are met. And finally, a robot must be easy to clean and decontaminate: all areas have to be accessible and easy to clean.

There should be no areas where substances, particles or microorganisms can build up or pool.”

Stäubli Stericlean TS2-60 and TX2-40, -60 and -90 robots were run through SKANalytix’s intensive tests to determine what improvements could be made to make them even more fit for a clean room or isolator environment.

Intensive Tests for Robot Cleanability, Resistance and Movement in an Isolator

Individually, each test gives information about one aspect of a robot’s design. Altogether, they provide a complete picture about a robot and how suitable it is for use in an isolator. Depending on the type of test, each lasts from a few hours to few weeks. Maximilian Mittelviefhaus, Research Manager at SKAN, details the procedure behind each test.

1/ Equipment Cleanability

“We spray the robot with a fluorescent tracer substance, such as riboflavin,” he outlines, “before carrying out a cleaning procedure. After cleaning, any residual fluorescence helps identify weaknesses in design, where accessibility is too low and where contamination is hard to remove and/or likely to build up.” Testing can go further by a precise spiking of surrogate contaminations, and detecting them down to the nanogram-level after the cleaning procedure.

2/ Chemical and Microbiological Resistance

“These tests focus on ensuring that all materials resist a panel of commonly used cleaning and decontamination agents, including H2O2,” Maximilian continues.

All materials must also be inert to bacteria and molds. A standardized set of micro-organisms is inoculated on the construction material, and their growth is monitored over four weeks.

3/ Adsorption/Desorption

Materials should not adsorb H2O2 during decontamination procedures. “When adsorption is strong, or outgassing is slow, it can result in H2O2 concentrations inside an isolator that can be harmful to the product being handled,” reveals Maximilian. “The decontamination process can also become unnecessarily long. We practice standardized testing of H2O2 adsorption and desorption kinetics.”

4/ D-Value Tests

A D-value in microbiology gives the time required to achieve a 1(log)10 reduction (90% inactivation) in bacteria under a given set of conditions. A low D-value equates to faster and easier decontamination. The efficiency of H2O2 decontamination can vary according to the material. Different finishings on a robot may influence how contamination is deposited on a surface, or how easily H2O2 neutralizes that contamination.

“With this test, we artificially contaminate pieces of sample materials, then decontaminate them and compare the results with stainless steel. Making up most surfaces in an isolator, stainless steel serves as the reference,” Maximilian explains.

5/ Particle Emissions

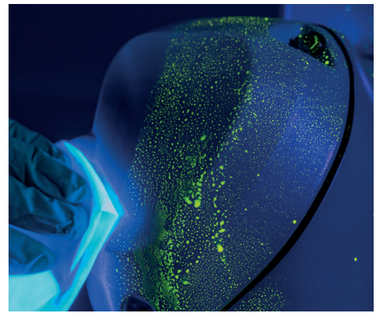
During kinematic movement, the robot should not produce any particles that could contaminate the drug being handled inside the isolator. “This test ensures compliance with ISO 5 requirements for a robot used inside an isolator,” Maximilian relates.

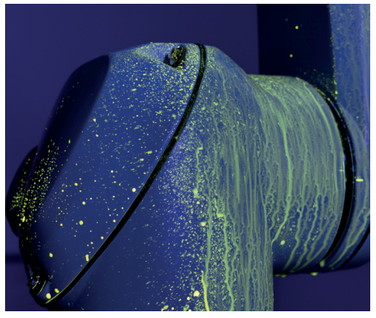
6/ Surface Roughness

“Finally,” he concludes, “we evaluate the surface roughness of different spare part materials, as a component of hygienic design.” Parameters for both profile roughness and area roughness are determined, “and we compare these values with those according to EHEDG guidelines, and SKAN’s internal specifications.”

7/ Seal tightness

“In addition to SKAN’s tests, we perform our own seal tightness test,” adds Renaud Doen, Stäubli’s R&D Pharma leader. In keeping with IP65 requirements, seal tightness is measured during dynamic and static movement.





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● Stäubli Units ○ Representatives / Agents

Global presence of the Stäubli Group

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robot.mkg@staubli.com | Photocredits: Stäubli - Semaphore - Winpix

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