

XTREMA PWD

ASEPTIC POWDER FILLING & STOPPERING MACHINE



XTREMA PWD ASEPTIC POWDER FILLING & STOPPERING MACHINE

THE CUTTING-EDGE SOLUTION IN POWDER MICRODOSING

More than 50 years of experience have made IMA LIFE the undisputed leader in powder microdosing.

The advanced technologies developed in the field have led to the latest innovative solution, XTREMA PWD, our new intermittent powder filling and stoppering machine for aseptic environments.

With positive in-line transport system, as per the Xtrema liquid filling series, this machine is conceived to process simultaneously different type of powders into the same vial, efficiently and reliably, preserving also all current safety and handling requirements.

The possibility to dispense at once two or three different powders inside a vial is, amongst other advantages, one of the keys for processing “new generation” of Antibiotics and powders drugs.

The XTREMA PWD design criteria and its geometry facilitating the unidirectional airflow make this machine the **ideal solution for installation inside conventional sterile rooms, or integration with any type of RABS or isolators, as well.**

The machine is completely tight sealed allowing the manual Cleaning in Place (CIP) of all parts in contact with the product. The sloped machine base helps collection of the washing media.

Its reduced size and weight of hoppers and discs allow very easy operations and access inside machine and isolator.





XTREMA PWD Overview with Closed RABS integration over the filling area

XTREMA PWD ASEPTIC POWDER FILLING & STOPPERING MACHINE

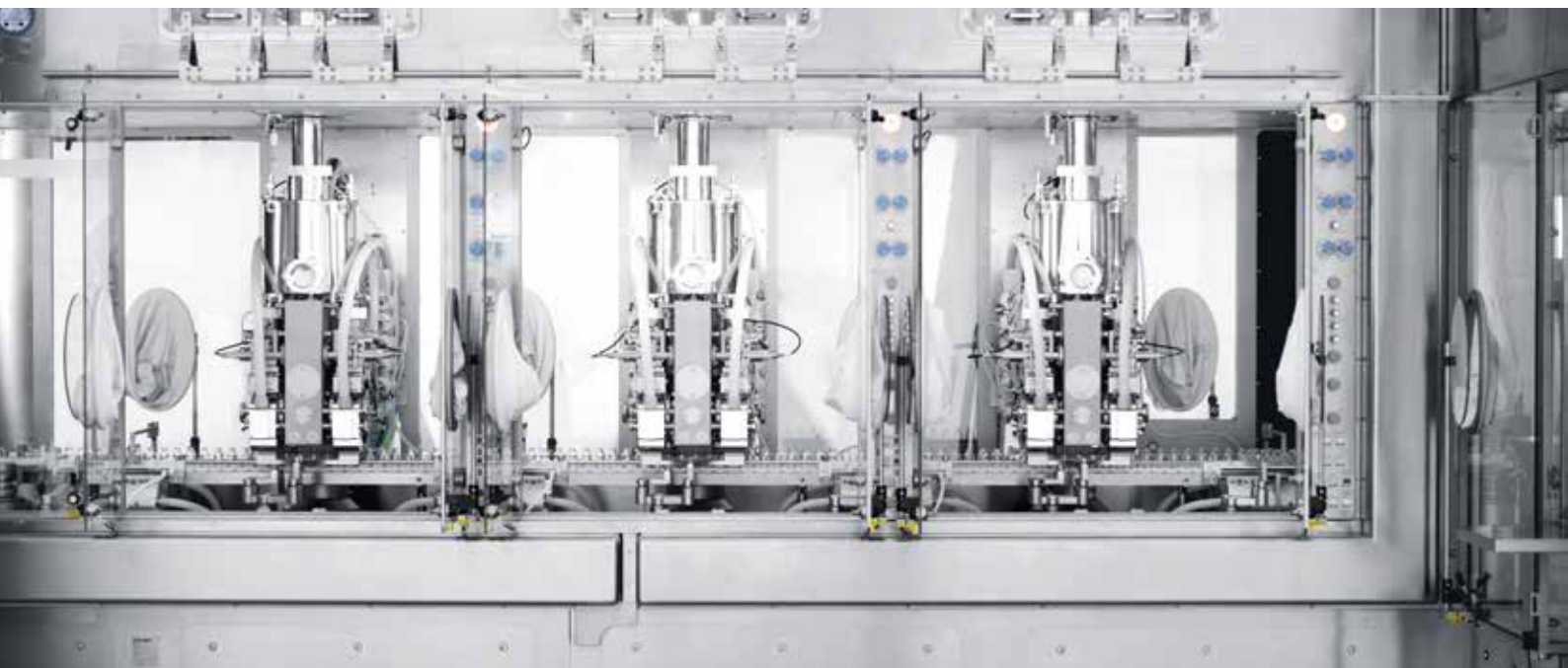


Vial infed continuous vs. intermittent motion

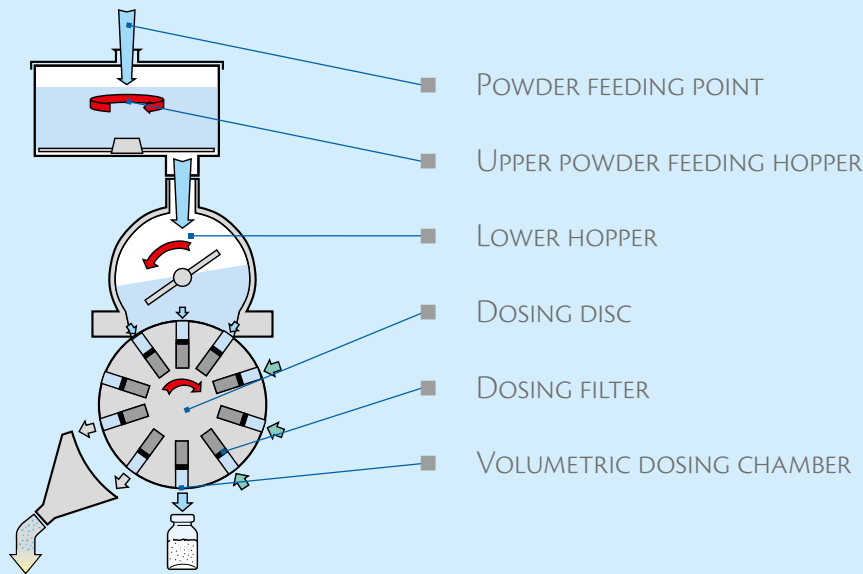
The vials are transferred through the machine by an initial continuous motion infeed which is switched to an intermittent motion by an infeed sector starwheel. The positive, linear transport system is granted by modular pucks with housing and controlled by brushless motors configured for each vial size.

Owing to intelligent servo technology, XTREMA PWD is extremely user-friendly and flexible in its application. Possibility to install up to three powder dosing units, powder filling is carried out by vacuum-pressure technology or auger system, with dosages starting from 0,50 mg. Suitable for integration with **100% check weighing system (IPC)**, the XTREMA PWD can perform an output **up to 400 vials/min**.

Example of a "Three-Powder dosing unit" configuration



XTREMA PWD DOSING SYSTEMS



"Vacuum- pressure" filling main components

EXTREME PRECISION COMBINED WITH HIGH VERSATILITY

"**Vacuum-pressure**" filling identifies the dosing system universally recognized for its extreme precision and high versatility. This dosing system is designed for any process requiring high-speed and high accuracy dosing and suitable to keep a very low particle generation level.

The Powder dosing unit consists of:

- One upper powder feeding hopper
- Two lower hoppers with stirrer and powder level sensors
- Four dosing discs complete with 10 chambers each, with dosing pistons
- Vacuum/Compressed air circuit for powder ejection into vial and dosing chamber cleaning
- Dust removing system with cyclone dust recovery unit and dust removing aspirator
- Powder feeding unit (various options are possible, such as Customers' bins or bags)

All hoppers are dismantable without tools.

The dosing discs are fitted with radial slots housing the dosing pistons. The powder is aspirated by vacuum from the lower hoppers and depressed during disc rotation. In its lower position, the disc discharges the powder into the vial by means of sterile air. After dosing, the slot which has ejected the powder is cleaned by sterile air jets.

All materials in contact with the product are constructed in AISI 316 L st. st., Teflon or silicone rubber and can be sterilized in autoclave.

- POSSIBILITY TO DOSE TWO DIFFERENT PRODUCTS INTO THE SAME VIAL (MACHINE SUITABLE FOR INSTALLATION OF TO THREE POWDER DOSING UNITS)
- EASY ADJUSTMENT OF VACUUM DIRECTLY MADE AT PUSHBUTTON PANEL FOR:
 - SLUG FORMATION
 - SLUG HOLDING & EJECTION
 - CHAMBER SLOT CLEANING
- IDEAL FOR cRABS INTEGRATION ABOVE FILLING AREA



XTREMA PWD DOSING SYSTEMS



Dosing unit detail: vial neck centering device



Dosing disc detail

AUTOMATIC SIMULTANEOUS REMOTE ADJUSTMENT OF DOSING DISC CHAMBER DEPTH.

By means of servomotors, activated through push-buttons located on HMI, this unit permits the simultaneous adjustment of the dosing chamber depth, with machine running separate for left and right disks.

A self-adjusting system of dosing chamber depth is supplied on request, only with 100% IPC.

Alternatively to the vacuum-pressure technology, **the auger dosing system** can be either assembled on the XTREMA PWD machine. By auger system, the product is supplied directly into the hopper via dedicated feeder. A motor actuates the stirrer that spreads the product homogeneously in the dosing hopper. The auger with servo-drive doses the product out of the hopper into the container. The presence of a filtering air hole permits to avoid any over pressure on the powder inside the hopper.

All product contact parts can be easily removed for cleaning purposes.

The internal design of the filling nozzle is dedicated to the flowing characteristic of the product.



SMARTPLATE: A SOLUTION FOR STERILITY ASSURANCE REQUIREMENTS



Smartplate connection



Dosing unit after removal of the dosing components

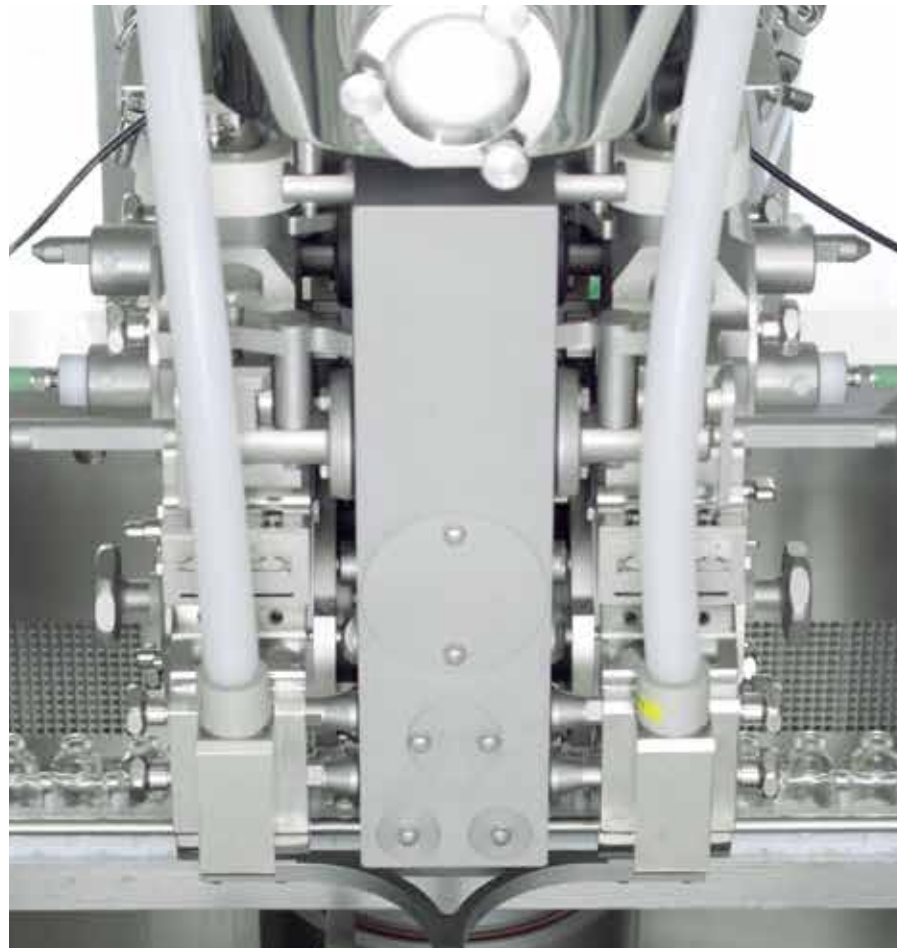
IMA LIFE SMARTPLATE: THE ULTIMATE SOLUTION FOR CLASS CONTINUITY REQUIREMENTS.

Innovative and customized **“Smartplate”** device for the assembly/disassembly of the dosing units without breaking the **Sterility Assurance Level (SAL)**. “Quick fit” revolutionary technique which allows a very easy fitting and dismantling of the filling units. After service connection undocking and removal of the upper hopper, the dosing unit is lifted up and rotated for Smartplate connection and consequent disassembly of the parts to be removed.

This system processes an extraordinarily broad spectrum of powders dust free and with great precision. Owing to the very small and easily manageable design a changeover operation is now child’s play. The dosing discs can be changed during a batch run while still maintaining sterility, without losing powder.

The Smartplate is equipped with “support plate” on a dedicated trolley for easy transportation, fulfilling Sterility Assurance Level requirements.

- 90% LEFT/RIGHT DOSING UNIT ROTATION FOR EASY ASSEMBLY OF DOSING COMPONENTS
- QUICK CONNECTIONS FOR UTILITIES (AIR, VACUUM, ETC.)



XTREMA PWD 100%IPC FOR HIGHLY PRECISE QUALITY AND



100% IPC tare sampling before dosing

SOPHISTICATED 100% IN PROCESS ADVANCED CHECK WEIGHING SYSTEM

The possibility to equip the XTREMA PWD machine with up to three Dosing Units, thus enabling the simultaneous filling of different type of powders into the same vial, efficiently and reliably, makes this machine the ideal answer to current Pharmaceutical safety and handling requirements for the processing of "new generation" of Antibiotics and powders drugs.

The XTREMA PWD sophisticated 100% check-weighing system is designed to automatically perform, during production process, **a net check-weighing of each different powder dosed into the vial for every Powder Dosing Unit installed on the machine (up to three), on the whole total number of vials produced, at a speed up to 400 vpm.**

To this aim, 4 loading cells are located before the first powder Dosing Unit, for tare measuring of the empty vials and data storage by PC Control System.

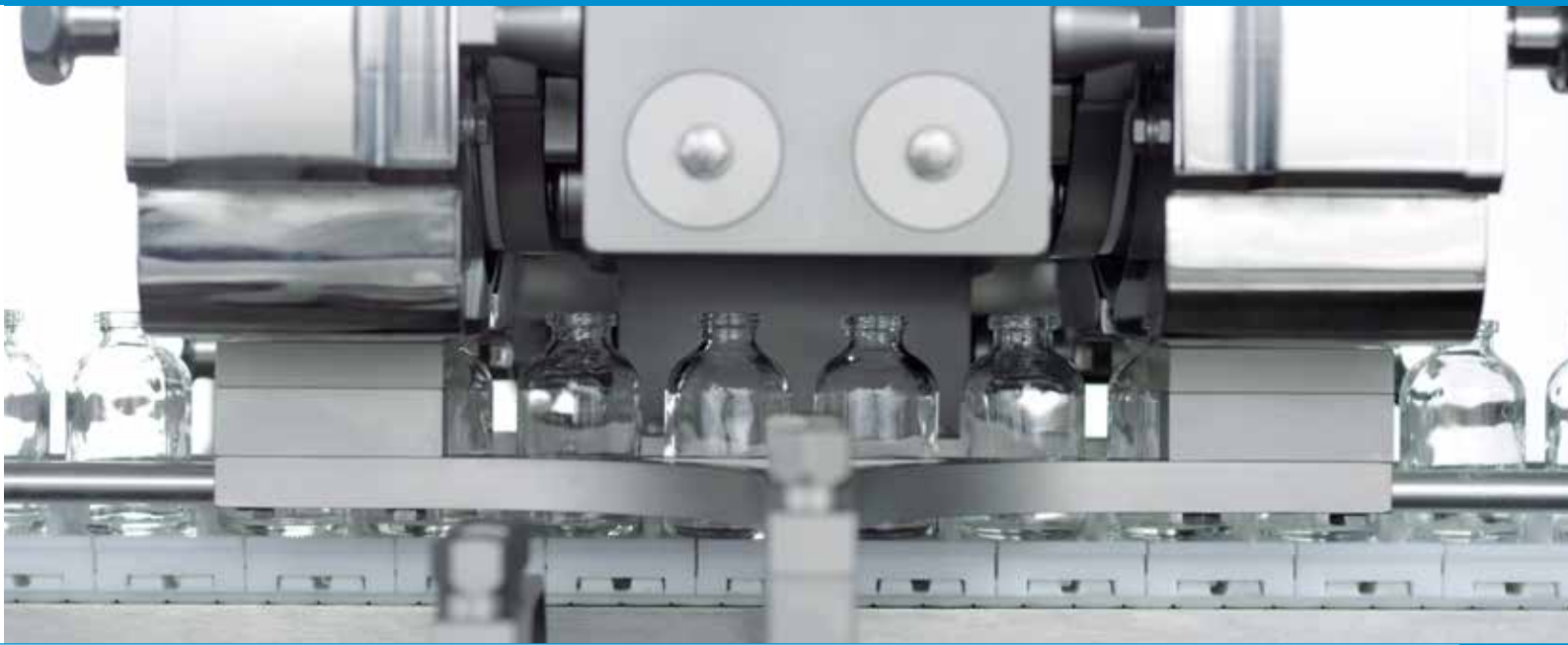
Additional 4 loading cells are then placed after each assembled Powder Dosing Unit, **measuring the gross weights** after each powder dosages inside the vial (up to three) and storing the detected data by Control System.



100% IPC gross weight sampling after first/second and/if present third dosing units



Detail of loading cell



self-adjustment system of dosing chamber depth allows automatic correction of powder delivery in case of incorrect dosage

A dedicated advanced SW determines the net weight of each different powder dosed into the vial.

A self-adjusting system of dosing chamber depth is available in case of 100% IPC system, so as to free the operator from carrying out weight corrections. The self-adjusting program provides to automatically change the dosing chamber depth during the production, thereby correcting possible trends to weight variations.

The system carries out also an "intelligent" correction in case of multiple dosages. The computer checks the current dosing chamber volume and processes the required correction to both dosing disks, so as to avoid or reduce at the minimum any possible differences in the dosing chambers of both dosing disks.

Combined with 100% IPC this function permits to reduce the waste of product.



ERGONOMIC, EFFICIENT AND USER FRIENDLY HMI FOR HIGHLY COMPLEX PROCESSES MONITORING

HMI friendly interface with very easy accessible location, complete with PC touch-screen and dedicated System software fully compliant to 21 CFR Pat 11 rules validated following GAMP5 guidelines approach. Direct management of all various machine operations and direct access to maintenance information, such as:

- Powder loading operations
- Check weighing system calibration and recording
- Alarm data recording
- Production parameters set-up
- Machine function checks and settings
- Recipes storage

XTREMA HIGH SPEED STOPPERING



Stopper feeding by vibrating bowl

STOPPERING STATION FOR HIGHEST PRODUCTION PROTECTION

The stoppering station includes a st.st. 316 L vibratory bowl feeding the stoppers directly onto a stoppering carousel with vacuum-operated heads.

Lifting platforms elevate vials up to the desired position for stoppering. The stoppering head is automatically height adjustable by means of servomotor.

This is the ideal solution for the processing of plug style stoppers and lyo stoppers, as well. The stopper feeding system ensures that the individual stopper travels only a very short distance before insertion into the vial, so as to reduce particle generation and distribution. Stopper placement on the vials is carried out by a horizontally operating vacuum wheel.



Stopper recovery in case of missing vial.

Stopper confirmation presence on carousel and stopper presence & height check on vial. >
Stoppering head by servomotors, without tools.



XTREMA HIGH SPEED STOPPERING



Automatic clamping of vibratory bowl to allow the minimization of operator intervention during change over operations

Rubber stoppers manual loading into pre-feeder by tilting unit. All operations are performed without entering the process area, under RABS execution.



Xtrema tilting unit device for class-continuity stopper loading



Xtrema gas purging station and powder cleaning device

Gas purging after filling station and up to the stoppering station. Gas flow can be set by machine's HMI and the value is automatically maintained.

XTREMA PWD is also provided with a dedicated system to clean each puck by filtered compressed air and dedicated vacuum unit.

Possibility to integrate a LIQUID DOSING UNIT for **media fill**, consisting of 4 coaxial peristaltic heads, driven by a stepping motor with dosage programs to be selected by HMI.

The system is controlled by a dedicated PLC.

XTREMA PWD VIAL TRANSPORT SYSTEM AND OUTFEED



The linear and positive transport system allows vial conditioning in multi-pocket dowels which are attached to the carrier system and are very easy to dismantle without tools, thus permitting a very quick and efficient size-change over and assuring particle generation minimization.

The dowels are made of special plastic material, suitable for direct exposure to the sterilization gas agent.



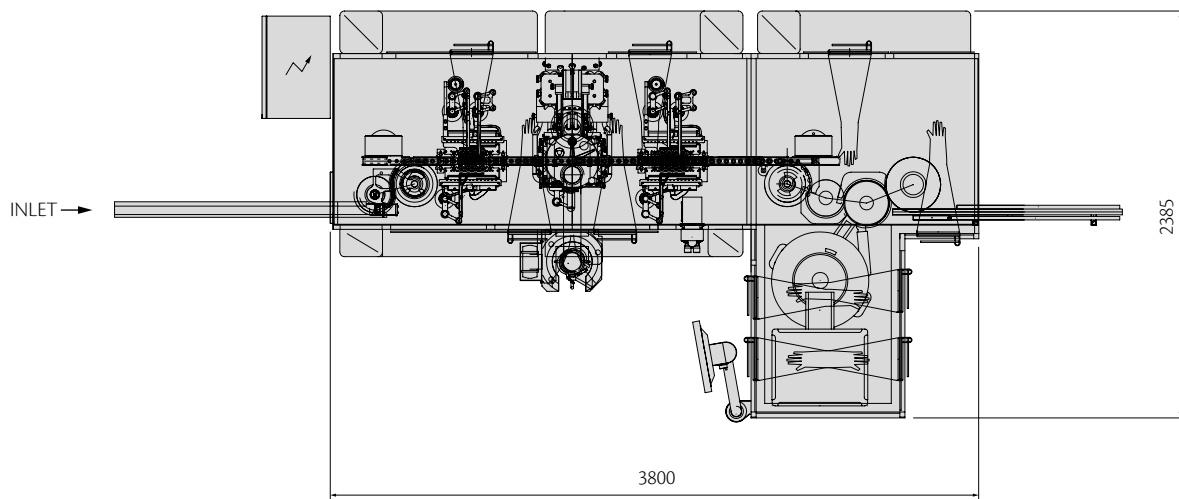
Vial rejection in case of incorrect first or second dosage

VIALS ARE AUTOMATICALLY REJECTED AND CONVEYED ONTO A DEDICATED OUT FEED BELT IN CASE OF:

- MISSING OR DISPLACED RUBBER STOPPER
- INCORRECT WEIGHT DUE TO THE FIRST OR SECOND OR THIRD DOSAGE (IF PRESENT)

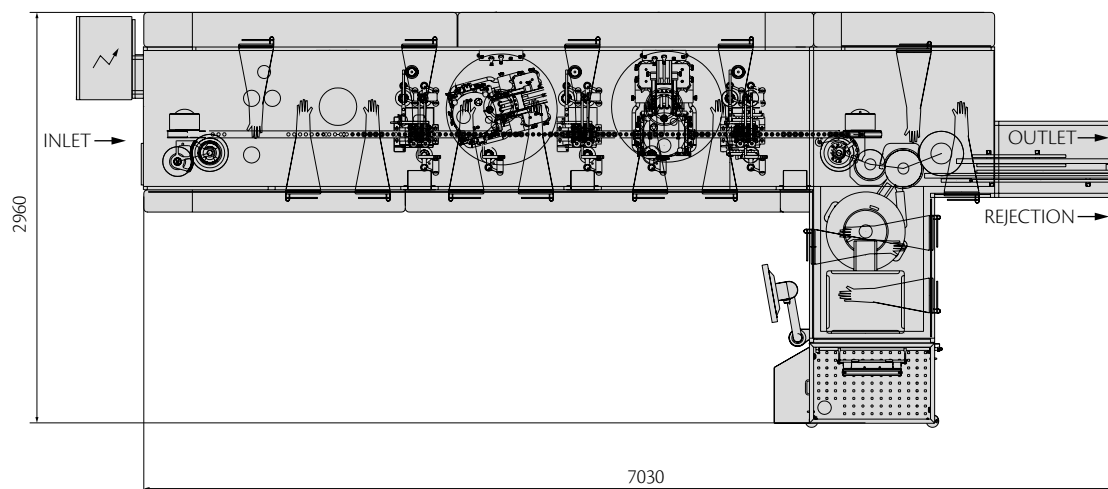
XTREMA PWD TECHNICAL DATA

XTREMA PWD WITH ONE POWDER DOSING UNIT



Example of machine layout

XTREMA PWD UP TO THREE POWDER DOSING UNITS



Example of machine layout

XTREMA PWD SERIES

	Min.	Max.
Vial diameter	22	56
Vial height	30	136
Stopper diameter	20	33
Stopper height	-	25
Powder dosing unit	Up to 3 dosing units	
Filling volume	From 0,50 mg	
Output with 100% IPC	Up to 400 vpm	
Transport system	Intermittent motion	

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