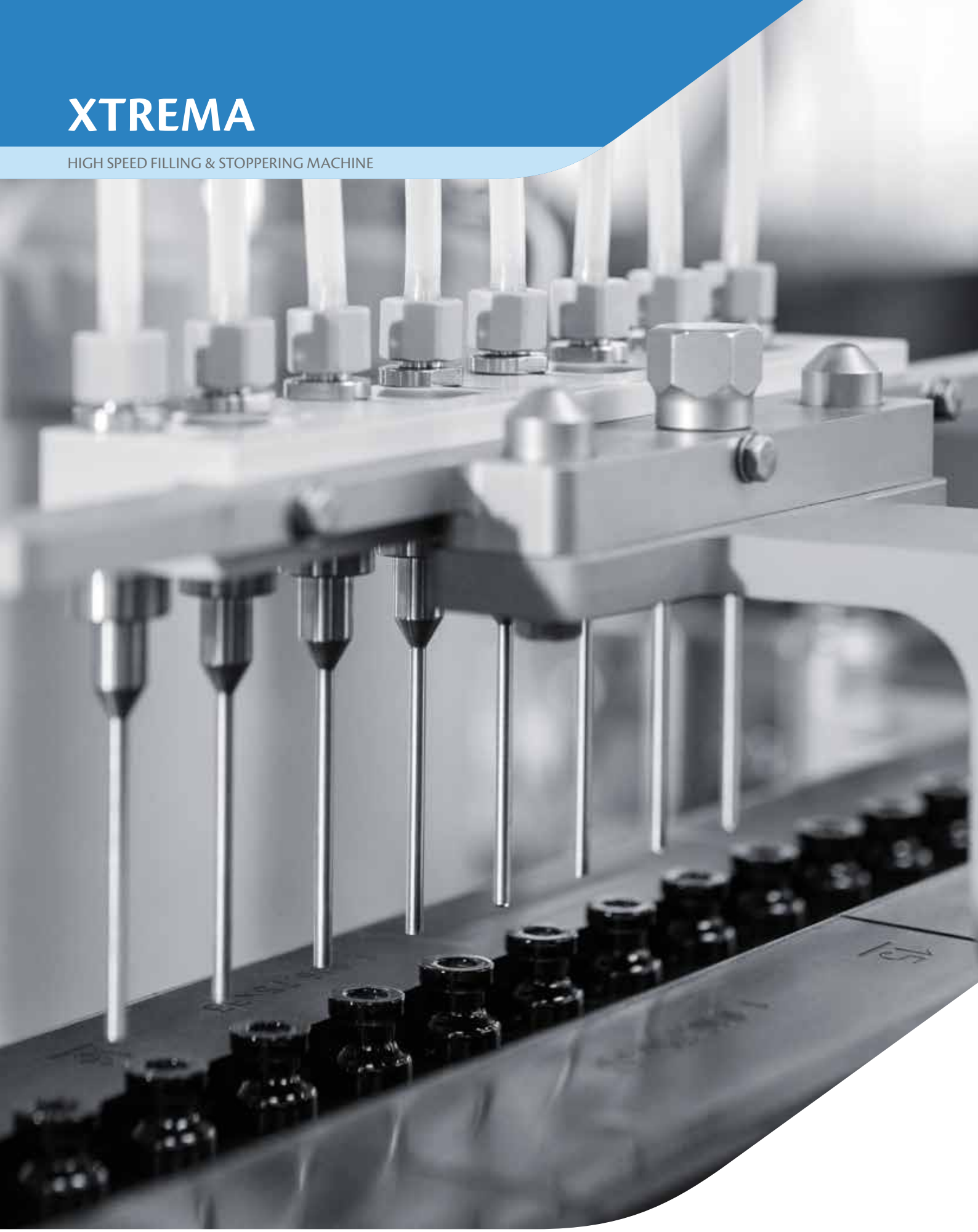
XTREMA

HIGH SPEED FILLING & STOPPERING MACHINE



IMA LIFE

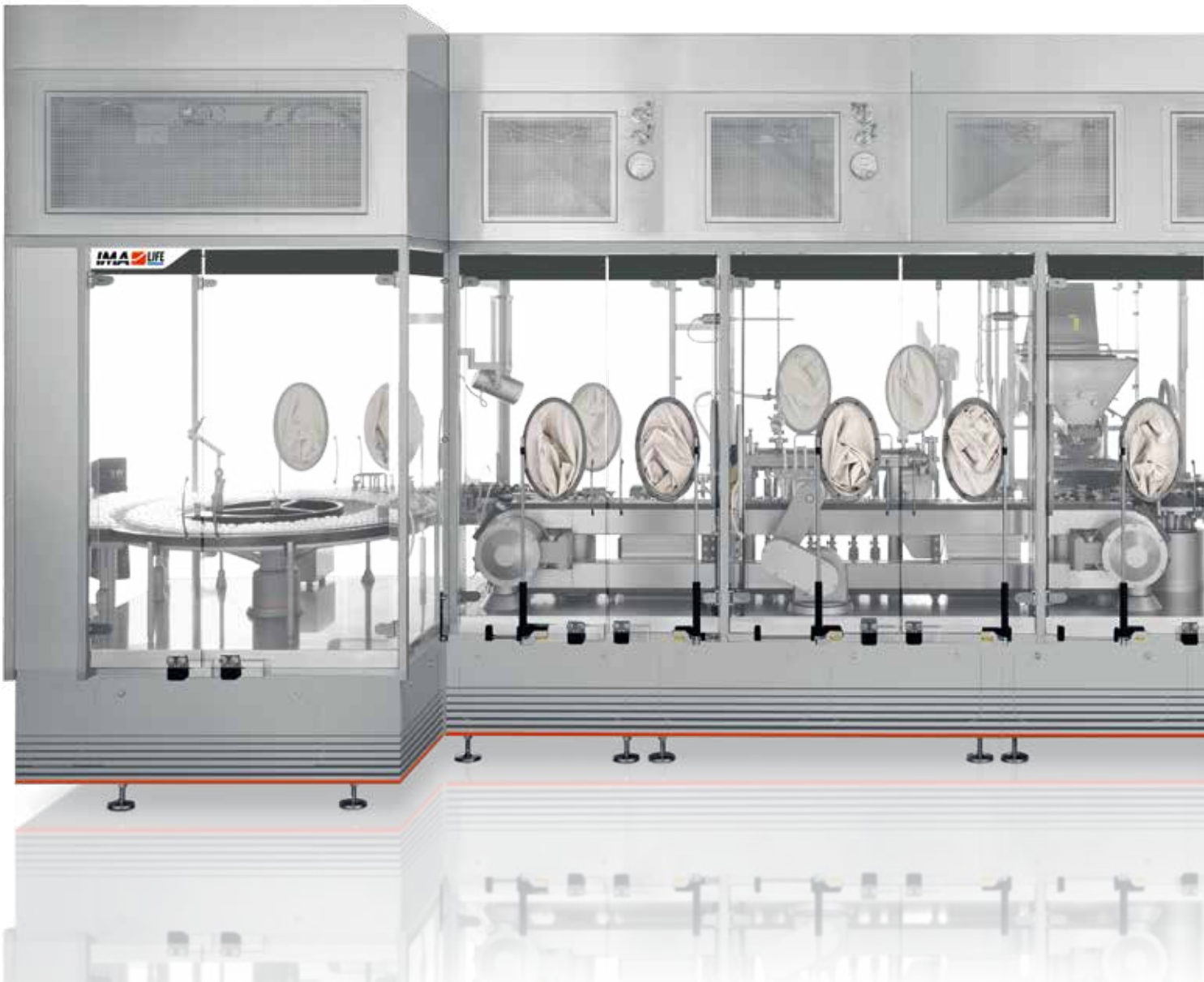
Aseptic Processing & Freeze Drying Solutions

XTREMA HIGH SPEED FILLING & STOPPERING MACHINE

TIME HAS COME TO TAKE CONTROL

This is the refrain that has driven IMA Life to further innovate. State-of-the-art construction details coupled with worldwide renowned filling technology make the XTREMA series the **latest technological breakthrough in aseptic filling**. Designed with a modern modular concept, XTREMA actively manages the production process by tailoring the different machine phases to the actual production needs.

XTREMA is an in-line filling & stoppering machine with a positive in-line transport system. The machine is suitable for filling liquid solutions into cylindrical vials and for the insertion of rubber stoppers, and can handle all vial sizes in the SVP range: from 0.10 to 100 ml and the LVP range up to 1000 ml.



FOR ASEPTIC ENVIRONMENTS

The full XTREMA series of machines offers flexibility, adaptability and modularity according to the production process.

From the top-of-the-range "full optional" machine to simpler versions to satisfy production needs.

XTREMA is available in the following versions:

- Continuous motion filler with or without statistical IPC for up to 600 vpm
- Intermittent motion filler with or without 100% IPC up to 600 vpm
- Continuous/intermittent motion filler, selectable from HMI, up to 600 vpm with 100% IPC.

Thanks to its modularity, the machine can be installed even in reduced space environments. Wall installation or right-to-left solutions are also available.
Different vial in-feed and out-feed options are available according to the speed and the dimension of the vials to be processed.

XTREMA INNOVATIVE DESIGN

Differential pumps

Peristaltic pumps

HIGHLY INNOVATIVE DESIGN DETAILS

Easy accessibility and improved cleanliness enhance XTREMA's ergonomics. An additional key focus of XTREMA's design is its great flexibility: the integration of modular equipment provides unlimited adaptability according to the most demanding customisation requirements.

ANTHROPOMORPHIC ROBOTIZED NOZZLE CARRIER

According to the cGMP guideline, no mechanical movements should come in and out of the grey area, to avoid product contamination and minimise the risk of leaks.
The IMA Life anthropomorphic robotized nozzle carrier fully responds to this requirement: similarly to the human movement, its smooth automatized movement ensures very gentle vial processing.
Nozzle carrier movement is driven by servo motor.

DOSING SYSTEMS

Mass flow dosign system

IMA LIFE DIFFERENTIAL PUMPS: NEW MATERIALS COMBINED WITH REVOLUTIONARY ASSEMBLY TECHNIQUES

Volumetric, differential dispensing pumps, suitable for CIP/SIP, based on a new design concept. The filling pumps are provided with a "QUICK FIT" revolutionary type of assembly technique, allowing easy fitting and dismantling of the pumps without the use of tools, and without touching the product contact parts. Thanks to the new cGMP design (exclusively for IMA Life) and the outer shell in plastic material, the pumps are also very light to handle and particularly ergonomic. XTREMA can be equipped with other filling systems typical of aseptic operations such as:

- time / pressure
- peristaltic pumps
- disposable filling units
- mass flow

All these systems can be assembled on the same support and changed according to the product to be handled and the stored recipes.

Simple changeover from a peristaltic to a volumetric filling system with a very quick lock/unlock assembly by HMI.

XTREMA CAN BE EQUIPPED WITH CIP/SIP SYSTEMS, PROVIDED WITH PROGRAMMABLE AUTOMATIC CYCLE, WITH NO COMPONENT REMOVAL.
IDEAL FOR APPLICATIONS IN ISOLATION TECHNOLOGY.

XTREMA VIAL TRANSPORT SYSTEM

POSITIVE VIAL TRANSPORT SYSTEM

XTREMA's vial transport system is linear and positive. The vials are moved by "multi-pocket dowels", handling several vials, thus reducing the number of dowels to be changed over.
The "multi-pocket dowels" are assembled on the carrier system and are easy to dismantle (no tools required) ensuring a **very quick size changeover and a clean transport mechanism**. The dowels are made of a special plastic material fit for direct exposure to the sterilisation agents.

Vial puck quick changeover

XTREMA's positive vial transport system avoids particle generation and its stainless steel belt gently carries the containers friction-free throughout the entire machine length. This new linear conveyor belt runs vertically, as well as all the other component movements, facilitating the unidirectional air flow over the vial mouth.

The round design of the anthropomorphic arm also ensures the absence of turbulence.

HIGH SPEED STOPPERING

Lifting platform

HIGH SPEED STOPPERING STATION

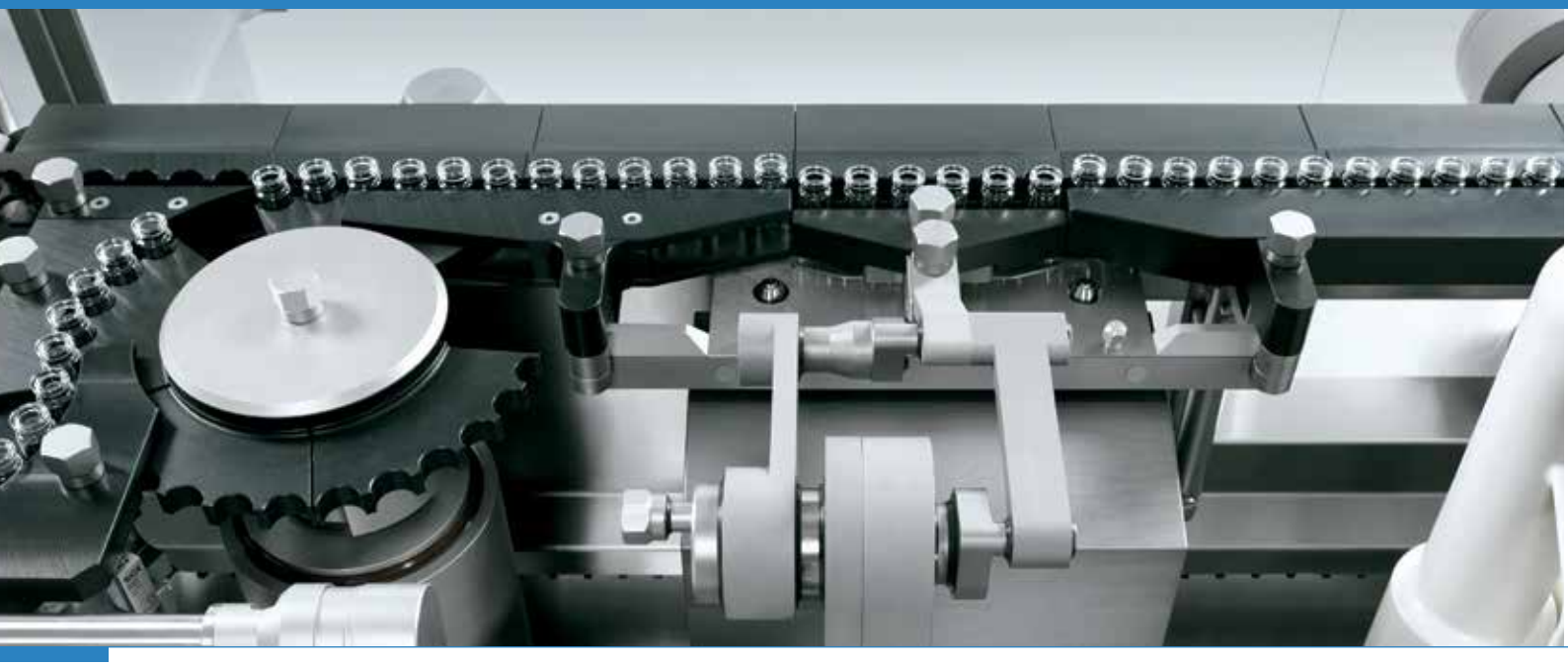
The stoppering station consists of a stainless steel 316L vibratory bowl feeding the stoppers directly onto a stoppering carrousel with vacuum-operated heads. The vacuum distributor is in stainless steel and Rulon 641and is easily removable and autoclavable. The stoppering head is automatically adjustable in height by a servo motor.
Ideal for the processing of conventional and lyo stoppers.
Pre-feeding of stoppers from the hopper to the vibrating bowl is performed smoothly so as to reduce particle generation and distribution. Stoppering is performed by a horizontally operating vacuum wheel.

AUTOMATIC HEIGHT ADJUSTMENT OF THE VIBRATING BOWL AND STOPPERING HEAD BY A SERVO MOTOR, WITH NO TOOLS.

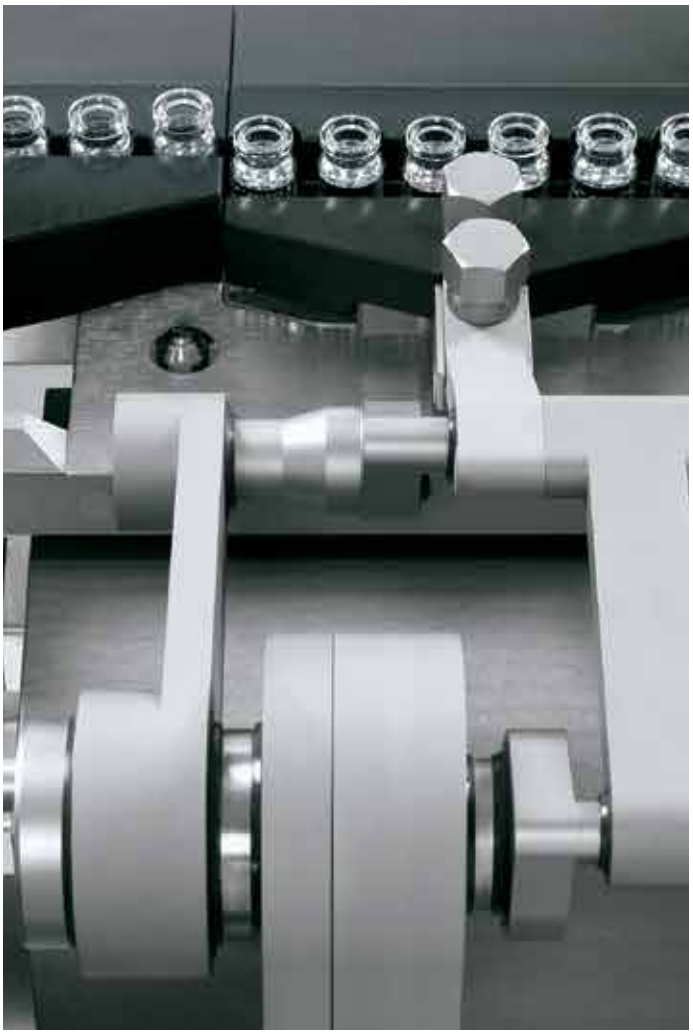
CONTINUOUS STOPPER FEEDING FROM VIBRATORY BOWL.
LIFTING PLATFORMS TO ELEVATE THE VIALS FOR STOPPER PICK-UP.

STOPPER CONFIRMATION PRESENCE ON CAROUSEL AND STOPPER PRESENCE & HEIGHT CHECK ON VIAL.

XTREMA IN PROCESS CONTROL OF FILLING VOLUME



100% IPC Check-Weighing System



Detail of load cell

BUILT-IN VERSATILITY WITH SOPHISTICATED IPC SYSTEM

XTREMA's **total In-Process Control (IPC)** system is based on the dual potentiality to select the vial transport motion according to the required production: high-speed at continuous motion and low to medium speed at intermittent motion. XTREMA can fill at high speed and simultaneously achieve 100% check-weighing sampling at 600 ppm, the highest speed available on the market. Selection from continuous to alternate motion is made automatically by HMI. The IPC system moves the vials from the conveyor system. After tare and gross check-weighing the vials are brought back to the empty dowels. In case of filling volume deviation, the machine's software automatically adjusts the dosing unit. The total In-Process Control (IPC) system is of course also available on the intermittent motion configurations at the same speed of 600 ppm.

- Available for the Intermittent motion or Intermittent/ Continuous configurations
- High speed: up to 600 ppm - Tare and Gross check with 8 loading cells at each station
- Time saving: reduced accumulation of vials at machine downstream.

A so-called **periodic check** can also be achieved on this version when checking only of a pre-defined number of vials is necessary (typically at batch start and at batch end). The number of vials to check is entered directly on the HMI. During the rest of production, the machine works at the highest speed.

CONTROL SYSTEM

Statistical IPC Tare Weight

Statistical IPC Gross Weight

A statistical In-Process Control system can also be featured on the continuous motion series. In this case, the machine carries out vial sampling by removing one vial at a time and feeding it back after check-weighing. During weight detection the machine moves at the highest speed. With statistically calculated frequency, the group automatically picks up the container before and after dosing and places it onto the loading cells for tare-gross weighing.

- Available for the continuous motion configuration
- High speed: up to 600 ppm - tare and gross check with 1 loading cell at each station
- Sampling plan up to 3%
- Settable sampling sequence.

OPERATOR FRIENDLY HMI

XTREMA is provided with a user-friendly touch-screen PC-based HMI. The control panel, fitted on a swinging arm, ensures easy graphic surfing among the various machine operations and direct access to maintenance information. Direct management of all machine motion controls via PC HMI. The software has been developed according to the GAMP4 guidelines and is 21 CFR Part 11-compliant. Multilevel configurable password system. Easy machine troubleshooting and teleservice.

HMI Scada client

XTREMA BARRIER TECHNOLOGY

XTREMA IS THE IDEAL SOLUTION FOR ISOLATED ASEPTIC PROCESSING LINES.

- Ergonomic displacement of operating groups
- Geometry facilitating unidirectional air flow (UAF)
- Completely sealed by inflatable gaskets
- Ideal for exposure to H2O2 (Hydrogen Peroxide in Vapour Phase)
- Easy-to-access user-friendly HMI interface

Thanks to the ergonomic positioning of the operating groups and the geometry facilitating unidirectional airflow, XTREMA is ideal for exposure to H_2O_2 decontamination.

XTREMA is particularly well-suited for any kind of installation or layout solution:

- traditional clean room
- RABS (Restricted Access Barrier System)
- Barrier Isolator
- Wall installation
- Left-to-right vial flow (standard version)
- Right-to-left vial flow (mirror version).

MATERIAL TRANSFER ISOLATOR

The Material Transfer Isolator (MTI) is recommended to decontaminate components, tools, or whatever unit that must be introduced inside the isolated filling line, without breaking the SAL. Even though the MTI is a section of the "main isolator" it can be decontaminated separately with respect to the other isolated sectors.

Isolated filling line

XTREMA FULLY INTEGRATED SOLUTIONS

Powder filling system

Liquid filling system

HIGH SPEED LINES WITH DOUBLE LOADING INTO FREEZE DRYERS

Xtrema is conceived for integration in complete aseptic processing lines from upstream vial washing equipment up to capping solutions and freeze drying with relevant vial loading & unloading systems.
Full harmonisation of electrical and mechanical components, conveyors, guarding, LAF units, RABS or isolators, gloves, RTP ports, and last but not least, the same control systems.
High speed double loading to freeze drying with line performance up to 600 ppm.
Combined testing & validation approach.
Total responsibility of the line lies with only one Project Manager, thus helping the project to stay on track.

COMBI VERSION FOR LIQUID & POWDER ALTERNATIVE FILLING

Multiple filling systems such as liquids and powder dosing units can be assembled on the same machine base frame for alternative use. Great flexibility and machine performance.

Synchronisation wheel to capping

SPRAY NOZZLE CONFIGURATION

Combining essential features and high quality standards and reliability, Xtrema can be pre-arranged for the processing of spray nozzle closures.
The integrated closing operation is performed by means of screwing pressure systems, kept on a segregated area from filling. This is an ergonomic and efficient solution when space constraints are an issue.

MONOBLOC CONFIGURATION WITH ALU-CAPPING

XTREMA's monobloc solution with the alu-capping unit are recommended in the case of an isolated line. Superior benefits in terms of:

- unique rejection zone for non-conformities
- positive vial transport system from the depyrogenating tunnel up to the alu-capping outlet.

High speed double loading to Freeze Drying with performances up to 600 pcs/min

Spray nozzle pump working area

Spray nozzle pump screwing detail

XTREMA LV LARGE VOLUME PARENTERALS

Mass flow dosing system – back view

XTREMA LV (LARGE VOLUME) SERIES

The XTREMA LV (Large Volume) series is conceived and designed to fulfil Large Volume Parenteral (LVP) requirements. Exactly like the standard version, this configuration can be integrated in complete filling lines, from vial washer up to (and including) the freeze-drying equipment and the alu-capping machine. Even this machine configuration is fit for integration under containment technology, such as cRABS and Isolation systems.

Based on a MASS FLOW measurement system, the machine is suitable for large volume filling from 100 ml up to 1000 ml. The mass flow dosing system (equipped with 8 mass flow meters) is designed for any process requiring high-speed and high-accuracy dosing. Other filling systems, like peristaltic pumps can be assembled on demand as an alternative.

Rapid changeover with easy-to-clean hygienic design facilitates CIP SIP operations thus contributing to minimise particle generation.

- 100% check-weighing
- Periodical check: numbers of vials directly entered on the HMI
- CIP-SIP System
- Mass flow dosing system with integrated-pinch valve-brushless control fills
- Peristaltic pumps

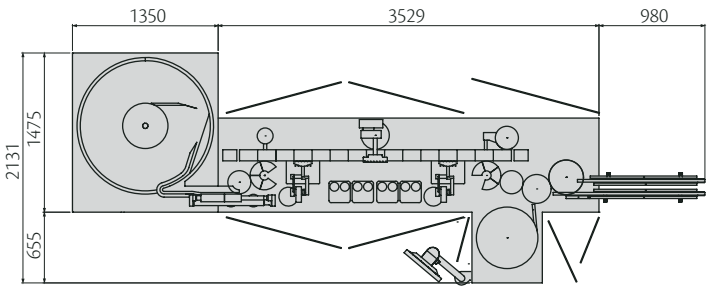
100% IPC – detail

100% IPC Check-weighing of all filled vials composed of:

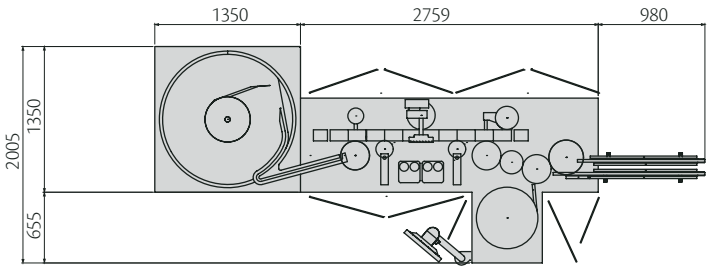
- 4 load cells for net weighing before filling;
- 4 load cells for gross weighing after filling;
- two anthropomorphic arms (one per cell) take care of vial positioning on the loading cells

TECHNICAL DATA

XTREMA



CONTINUOUS / INTERMITTENT MOTION - 8 PUMPS - TOTAL IPC

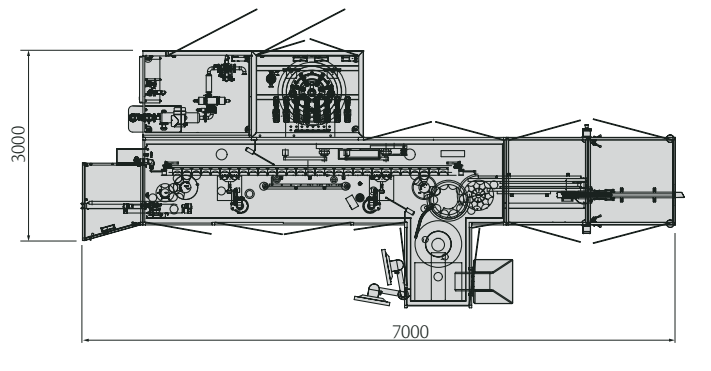


CONTINUOUS MOTION - 4 PUMPS - STATISTICAL IPC

Example of machines layout

XTREMA		
	Min.	Max.
Vial diameter	14 mm	54 mm
Vial height	30 mm	110 mm
Stopper diameter	13 mm	33 mm
Filling dosing unit	Up to 15	
Filling range	0,10 - 100 ml	
Output	Up to 600 vpm	
Output with 100% IPC	Max. 600 vpm	
Transport system	Intermittent motion Continuous motion Intermittent/Continuous motion	

XTREMA LV



Example of machine layout

XTREMA LV		
	Min.	Max.
Vial diameter	42,5 mm	101 mm
Vial height	73 mm	232 mm
Stopper diameter	20	32
Filling range	50 - 1000 ml	
Output	Up to 140 bpm	
Transport system	Intermittent motion	

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