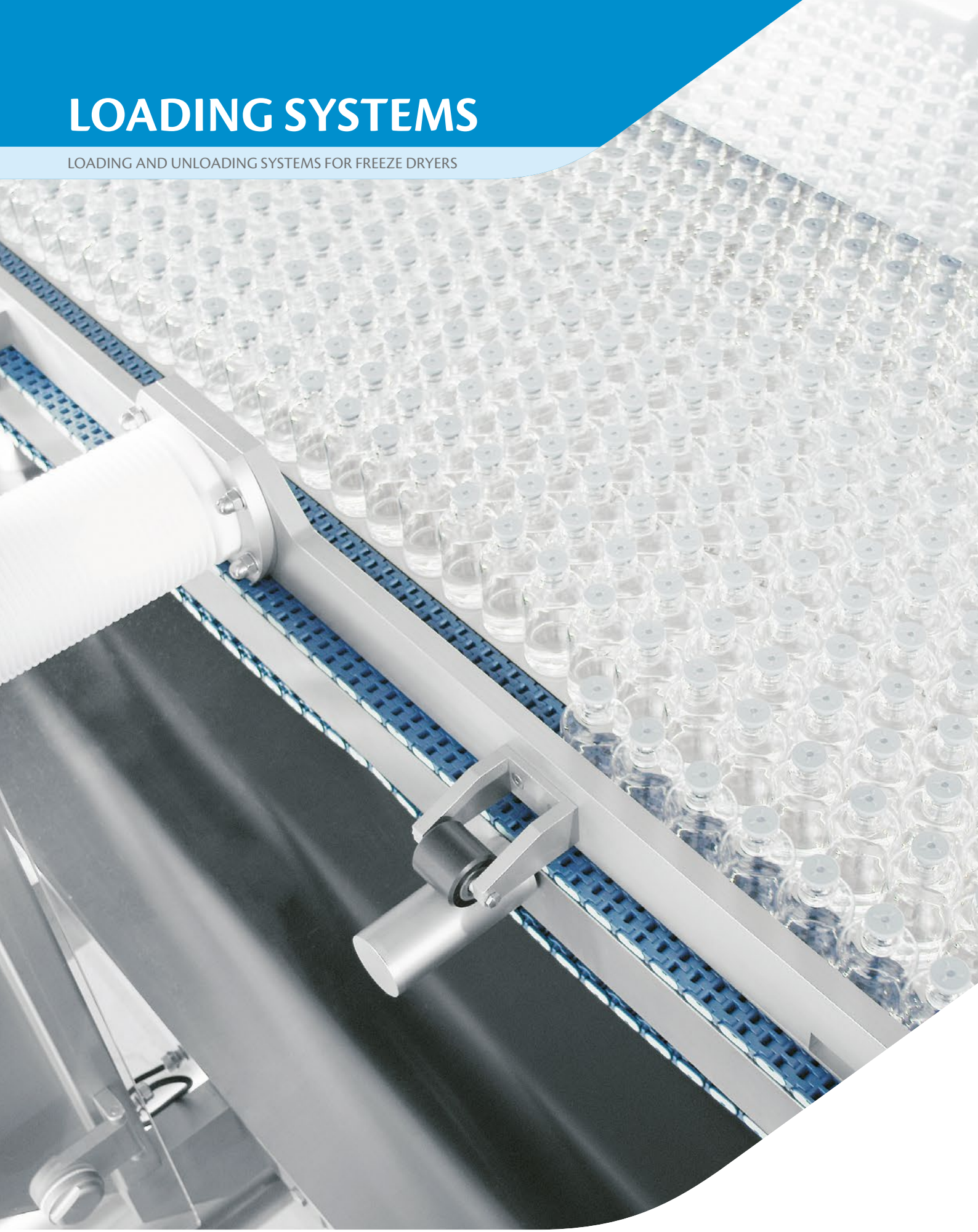
LOADING SYSTEMS

LOADING AND UNLOADING SYSTEMS FOR FREEZE DRYERS



IMA LIFE

Aseptic Processing & Freeze Drying Solutions

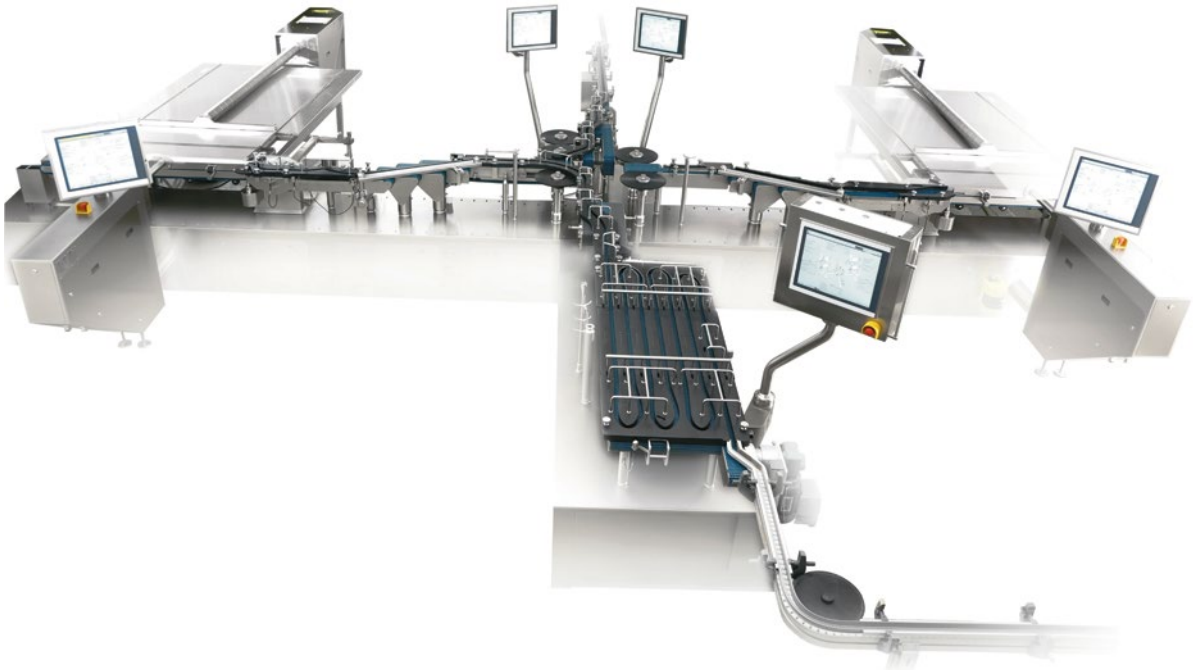
LOADING/UNLOADING SYSTEM SOLUTIONS

Automatic loading and unloading systems minimize the risk of contamination through human intervention in the loading and unloading of freeze dryers. The amount of product handled when using an automated loading and unloading process is increased since the time spent for the loading/unloading operation is, of course, much shorter if compared to manual loading.
Operational costs are also reduced since these state-of-the-art systems drastically decrease the number of operators needed to assist the freeze drying process. In some cases, the machine can be left unattended, as well. As a consequence, the SAL (Sterility Assurance Level) levels are greater while contemporarily reducing the operating costs.
The protection of operators also when handling potent compounds can be achieved with these automated systems, since they can be installed either under closed RABS or isolation technology.

KEY FEATURES

The IMA LIFE automatic loaders ensure efficient, safe and reliable performance thanks to the following key features:

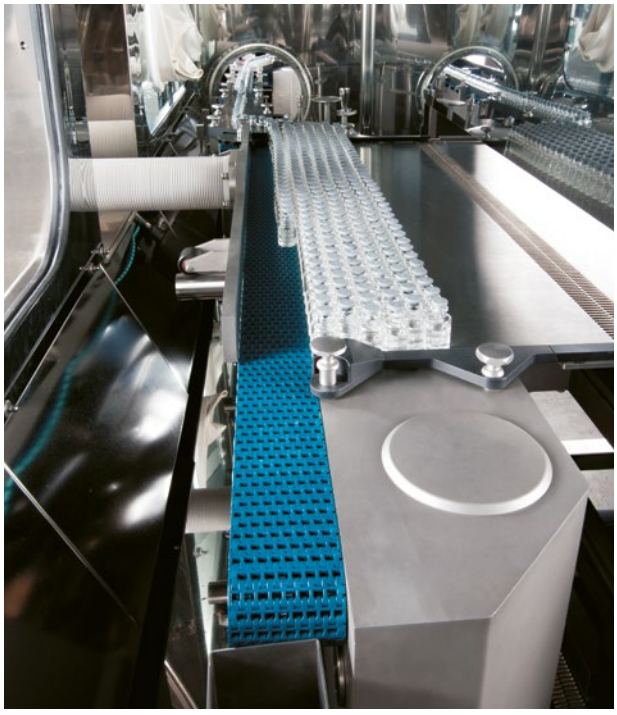
- Extremely compact footprint
- High throughput with loading speed up to 600 vpm
- High flexibility to handle different vial size parts
- Quality sanitary design - VPHP (Vaporized Hydrogen Peroxide) compliant
- Pre-arranged for UAF (Unidirectional Air Flow)
- Closed RABS and isolation technology



In supporting customers and addressing ever-changing market requirements, IMA LIFE has consistently led the development of automatic loading and unloading systems for minimising human intervention in clean rooms, thereby reducing contamination exposures.

AUTOMATION DRIVERS

- Greater SAL (Sterility Assurance Level)
- Bio-burden reduction
- Increased output
- Reduced operating costs
- Higher product & operator protection
- Repeatable standards
- Reduction in room air classification
- Process time drastically reduced



Fixed system integrated with an aseptic filling line under isolator.

A major driver of our design are the performance criteria of the application. Productivity is vital and so speed of operation is key. Short lead-times between batches are a must. We have proven systems which can load up to 600 vials per minute and unload up to 900 vials per minute. Flexibility for the application is also a big influence with IMA Life systems supporting various vial formats. We offer **fixed, flexible and mixed systems**, compact designs, single or multiple-row loading, and on to complete shelves across multiple handling requirements.

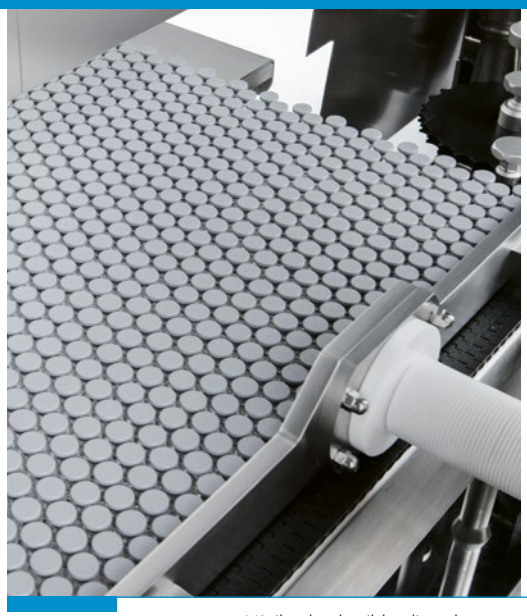
PROCESS ENVIRONMENT

The production environment being served at the customer facility means we develop flexible sequencing programmes to meet diverse process requirements. From ambient to cold-shelf loading, even via a cryogenically pre-frozen product.
From conventional UAF (Unidirectional Air Flow) to closed RABS or isolator systems with designs optimising unidirectional airflow at the vial level to ensure there are no static or moving objects above the vials.

LOADING/UNLOADING SYSTEM SOLUTIONS

NATURE OF LOADING

The freeze dryer is loaded or unloaded one shelf, or one row or several rows at a time, with vials at constant level. All systems are frameless and can be **FLEXIBLE** (TCAR, LAT, LUAT, UAT), **FIXED** (CLU or Miniloader) or **MIXED** (combination of fixed and flexible systems).



Miniloader detail: loading phase

CLU detail: unloading phase

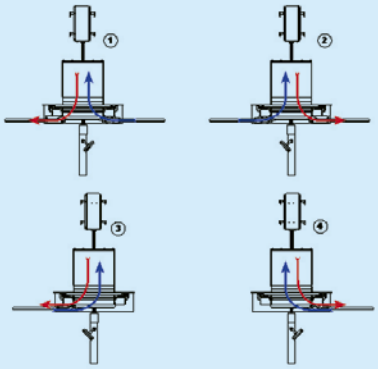
Numerous design criteria have been used as the basis for our system solutions, including the following:

- Full Modular Design Technology (MDT) approach
- Minimal footprint with compact solution and optimum ergonomics
- Different sizes available according to freeze dryer shelves
- Shelves based on sunken rail principle
- Ambient and cold shelf loading
- High level error recovery system (via SCADA or manual intervention) and fully GMP compliant
- Different pusher configurations available
- Compact footprint with dedicated loading and unloading pusher.

FIXED SYSTEMS: CLU AND MINILOADER

CLU (Compact Loading Unloading) and MINILOADER (loading and unloading system designed for small-sized freeze dryers) are systems which are built for individual freeze dryers and can load each shelf one row at a time or in packages of several rows at a time.

- Operating speed: up to 500 vials/min.
- Fixed loading configurations for one or more freeze dryers, depending on cycle times, logistics and process environment.
- Choice of type of loading pusher.
- Mainly loading and unloading from the same side.
- Isolator or cRABS



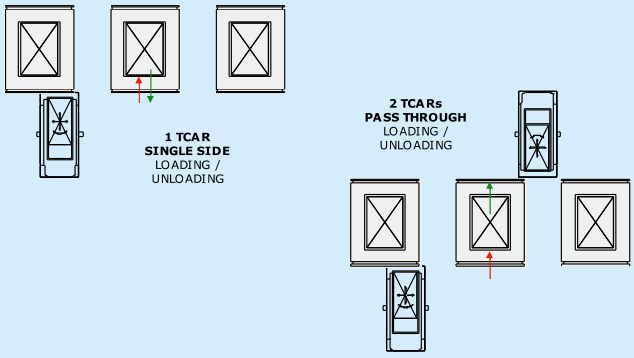
LOADING CONFIGURATIONS: FIXED SYSTEMS

The fixed automated loading and unloading system is available in the below-mentioned standard configurations:

1. Loading from right & unloading to left
2. Loading from left & unloading to right
3. Loading from left & unloading to left
4. Loading form right & unloading to right

Flexible loading system in production area

LOADING/UNLOADING CONFIGURATIONS: FLEXIBLE SYSTEMS



FLEXIBLE SYSTEMS: TCAR, LAT, LUAT AND UAT

The flexible systems use "transporters" (TCAR) to serve multiple freeze dryers one shelf at a time. They are normally composed of:

- LAT (Loading Accumulation Table) which assembles a pack of vials to the shelf dimension;
- TCAR (Transfer and Loading Cart) which carries one pack of vials to and from the freeze dryers (one or two transporters in system);
- LUAT: (Loading & Unloading Accumulation Table) which is a combined system;
- UAT (Unloading Table) disassembling pack of vials.

LAT

Loading systems consist of a loading accumulation table, integrated with the out-feed of the filling line, which collects and moves vials in a vial pack equivalent in shape and size to each freeze dryer shelf. LAT system is designed to automatically create a hexagonal package from vials collected from the filling line. Loading times depend on vial sizes.

TCAR

Once a vial pack is created on the LAT, a Transfer Cart (TCAR) collects the vial pack from LAT and automatically transfers the pack onto the designated freeze dryer shelves. It is designed for the automatic transfer of a package of vials from FD to UAT, as well. TCAR recent improvements include:

- Wireless communication
- Positioning on rails (absolute encoder principle)
- Process Integration with FD (i.e. flexible docking plate, vertical sliding slot door, cleanable backside, fast acting design etc.).

LAT Overview

TCAR vial pack pick up from LAT

LOADING/UNLOADING SYSTEM SOLUTIONS

UAT Overview

TCAR overview

LUAT

A combined Loading & Unloading Accumulation Table is also possible for assembling and disassembling a pack of vials to the shelf dimension.

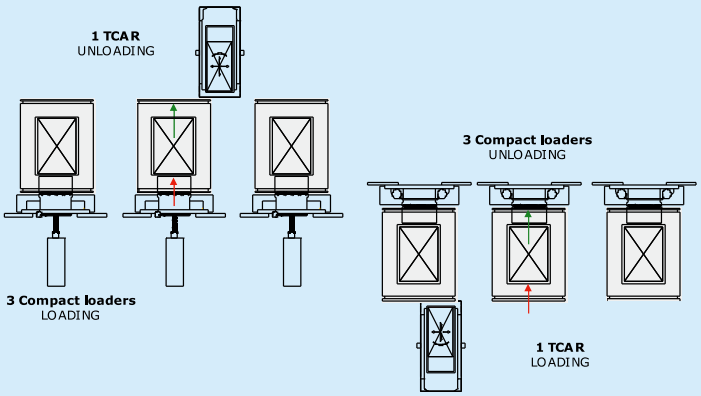
UAT

The TCAR collects the vial packs from the designated freeze dryer shelf and transfers the vial pack to an unloading accumulation table (UAT) where the vials are de-scrambled for unloading and single lining to the alu-capper. Unloading times depend on the vial sizes.

FLEXIBLE SYSTEMS MAIN FEATURES:

- Fully modular design (LAT + UAT/LUAT+TCAR)
- It can be used with two and more freeze dryers;
- Flexible docking with FD shelves;
- Mainly loading and unloading from same side or from different sides, i.e. loading by CLU system (front side) and unloading by TCAR configuration (rear side);
- It can load and unload individual shelves sequentially;
- Expansion easily accommodated;
- Fast unloading possible by using multiple UATs;
- Suitable for pass-through system configurations;
- Primarily used for multiple freeze dryers;
- Operating speed:
  - Loading Accumulation Tables (LAT): up to 600 vials/min.
  - TCAR: up to 900 vials/min.
  - Unloading Accumulation Tables (UAT): up to 600 vials/min.
- Ideal solution for any type of RABS .
- High-speed, single liner system integrated with unloading table.

LOADING/UNLOADING CONFIGURATIONS: MIXED SYSTEMS



High-speed single liner

MIXED SYSTEMS

- These systems offer a combination of fixed and flexible solutions:
- Only pass-through configurations
- Operating speed:
  - Loading: up to 500 vials/min.
  - Unloading: up to 600 vials/min.
- Fixed loading and flexible unloading
- Flexible loading and fixed unloading.

HIGH SPEED SINGLE LINER

Suitable for integration with both fixed and flexible loaders for unloading speeds above 250 vials/min up to 450 vials/min.

- Compact footprint: 1000mm x 600 mm

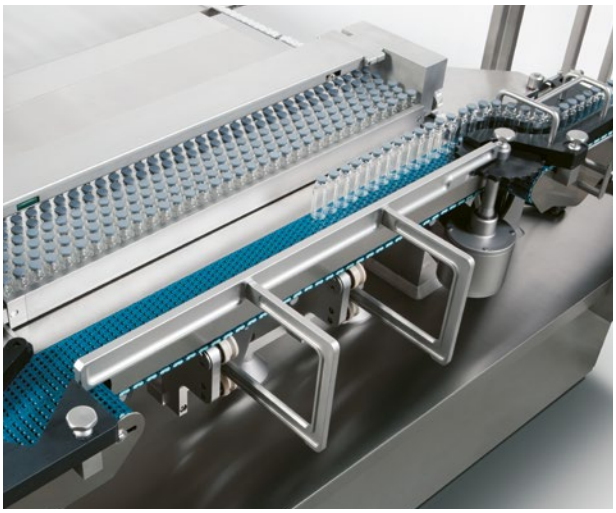
Optimum design for Isolator application:

- Low friction conveyor belts-optimised for stable transport of unstable vials
- Individual driven conveyor belts + vial guiding belt
- Speed difference between belts free to set
- Absence of friction between vials during single lining process.
- It can be combined or integrated with CLU/UAT and LUAT.

HIGHLY COMPACT LOADING/UNLOADING SYSTEM:

- Extremely compact footprint with integrated loading and unloading module
- High throughput with speeds up to 600 vpm
- Quality sanitary design - VPHP - compliant
- Pre-arranged for isolator application
- Excellent integration with freeze dryers

Self-driven transfer module

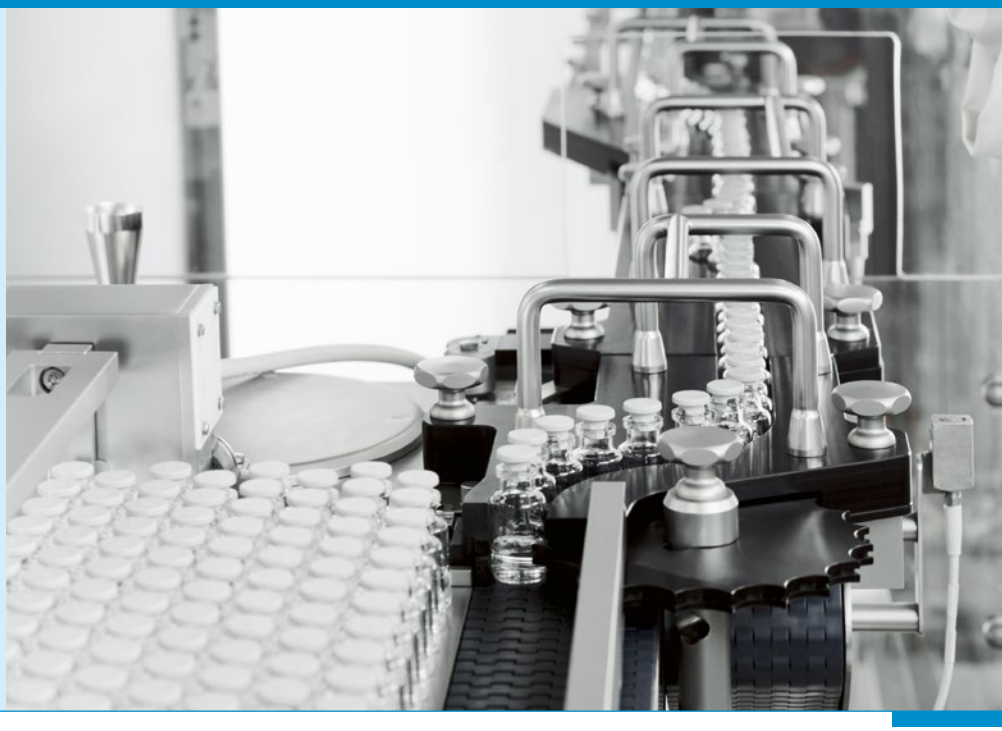


State of the art design coupled with innovative wireless technology makes the DA VINCI the latest cutting-edge breakthrough in the field of loading system automation.
DA VINCI is the latest example of IMA LIFE's ability to capitalise on in-depth application experience to deliver simple design concepts for improved automation resulting in enhanced performance and lower operating costs for the end user.

- Pass-through loading and unloading of freeze-dryer
- Complete absence of front and back pusher
- One-sided loading and unloading of freeze dryer
- Self-driven module installed on a transfer bar

DA VINCI

THE EXTREMELY CLEAN AND NEAT DESIGN OF THE NEW LOADER IS BASED ON THE COMPLETE ABSENCE OF AN ACTUATING MECHANISM INSTALLED IN FRONT OR ON THE BACK OF THE SYSTEM, RESULTING IN AN EXTREMELY COMPACT FOOTPRINT.



DA VINCI loading detail

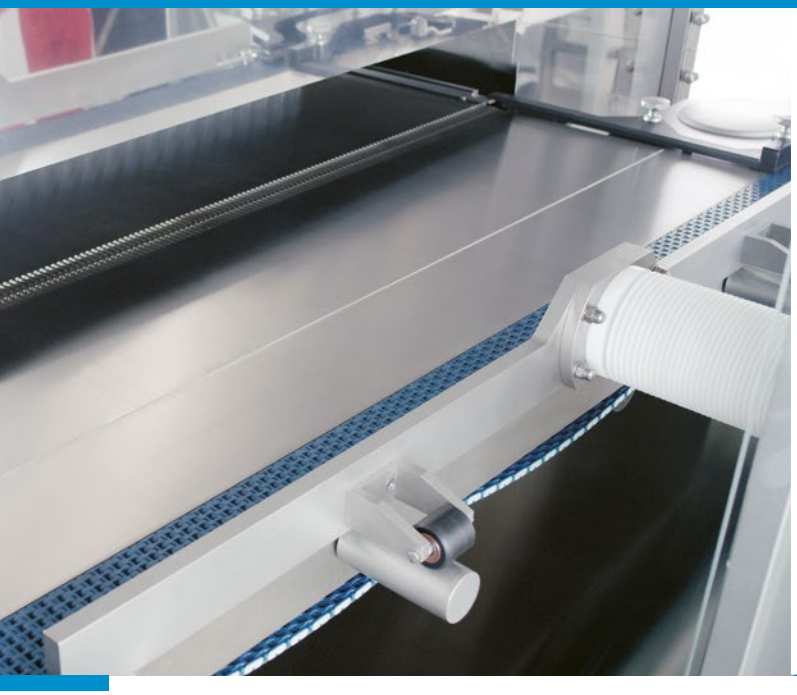
The design of the new DA VINCI loader is based on the complete absence of any overhanging actuating mechanism installed in front of or at the back of the freeze dryer. This mechanism used to move vial packs into and out of the freeze dryer is based on the unique concept of a stand-alone battery driven transfer module. Communication with the machine is wireless.
Designed according to the latest international guidelines, DA VINCI loaders can be configured under RABS or fully isolated working environments.
DA VINCI's revolutionary technology results in an extremely compact footprint, which considerably increases the level of flexibility for possible lyo configurations and cleanroom layout. DA VINCI can be used with lyos which are loaded and unloaded on same side or opposite sides in a pass-through configuration.
The new system combines cutting-edge technology and innovation with IMA LIFE's proven ability to meet the latest market demands for class-leading aseptic processing. Speed and efficiency are matched with reliability and control to provide a winning combination for the customer.

DA VINCI KEY FEATURES

- Rechargeable battery
- Short stroke pusher with or without bellows
- The system never stops during unloading process
- Minimum need for FIFO

DA VINCI unloading top view

LOADING SYSTEMS INTEGRATION



SYSTEM INTEGRATION

- More than 25 years' experience successfully integrating freeze dryers with fixed and flexible automated loading and unloading systems in aseptic applications
- Excellent in-depth project management of integration projects
- Scada systems designed for integrated systems
- Design, documentation and test built from an integrated foundation
- Conveyors up and downstream always part of loading system supply
- Conveyors based on FIFO principle with single conveyor or serpentine designs
- Manage all interfacing with filling and capping equipment

IMA LIFE HAS ALL THE NECESSARY EXPERTISE AND FACILITIES IN-HOUSE TO ENSURE THE HIGHEST QUALITY STANDARD ACROSS THE ENTIRE SOLUTION.

Aseptic filling line overview with CLU loading/unloading system

IMA LIFE LOADING SYSTEMS ARE DESIGNED TO BE FLEXIBLE SO AS MEET ANY INTEGRATION AND INTERFACE REQUIREMENTS.

INTEGRATION WITH FREEZE DRYERS

- Integrated design
- Flexible docking plate
- Vertical sliding slot door
  - Minimum opening
  - Two-seal (vacuum + steam) design
  Minimal access from outside (UAF or Isolator)
  - Cleanable backside
  - Fast acting design
- Sunken rail principle of freeze dryer shelves

INTEGRATION WITH FILLING & CAPPING MACHINE

- Upstream and downstream loading system conveyors are always part of system supply
- Conveyors based on FIFO (Fist In First Out) principle (single conveyors or serpentine system)

Loading system in-feed from filling machine

Conveyor length is determined by:

- Speed of filler & loading system (according to vial size): the loading system needs to run slightly faster than the filler
- Position of back-up switch at filler out-feed
- Type of IPC (In Process Control) on filler
- Loading sequence type on loader

Unloading system for vial transport to capping machine

Conveyor length is determined by:

- Position of in-feed switch on capper
- Speed of unloading system & capper (according to vial size)

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February 2024 - 991EK220101

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