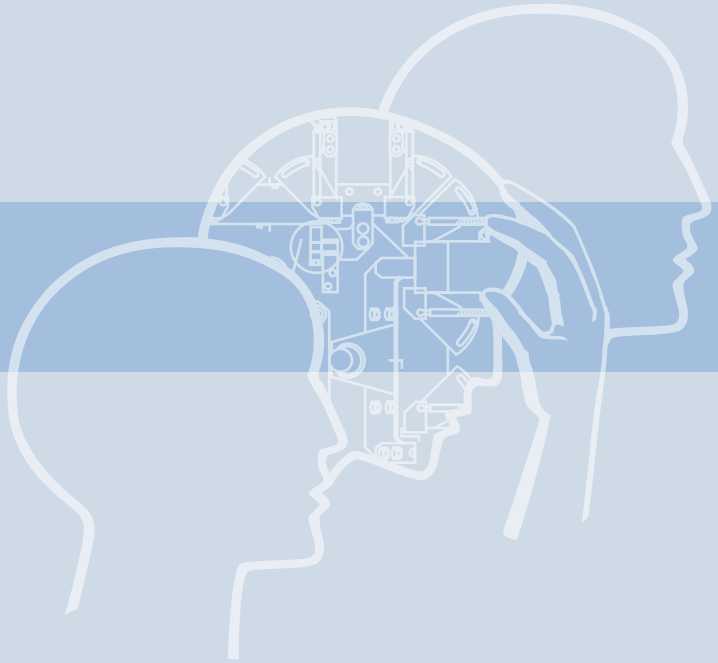
Harro Höfliger

[ALL YOU NEED]



Pharma and Medical

Production platforms for web processing systems

A member of Excellence United

New ideas require new methods – expertise from design to validation.

Innovative products and new dosage forms define current trends in the pharmaceuticals market. As a result, the complexity of required tasks is constantly increasing, with an immediate effect on production and manufacturing processes.

In response, we create technologies for all-inclusive concepts – from design to installation of the finished production lines. With individualized solutions for today's products and systems.

As early as the idea and design stage, our development center enters into close contact with our customers.
Our customers value our knowledge about processes and techniques, which we apply in the manufacturing of pharmaceutical products.

This enables a constructive dialog – the foundation for building high-tech systems on the very highest level.

We view our role as that of a development partner. Rather than offering off-the-shelf concepts, we bring to each project and system – from planning to delivery – the highest level of experience, expertise and production skills, and apply them in a customer-oriented manner.

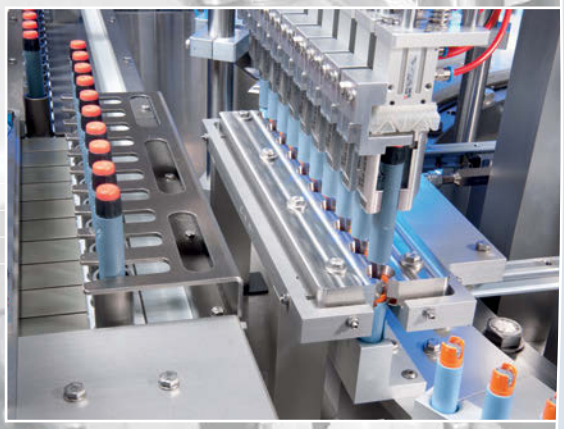
Simultaneously, our qualification management system supports customers in the validation of their systems.

We offer a completely new service as part of our pharmaceuticals service concept by using our own in-house Clean Rooms. This enables us to carry out trials of new systems under pharmaceutical conditions with original product – all the way to manufacturing stability samples.

pharmaceutical and

medical technology

competence



clean rooms

Harro Höfliger

Pharma Solutions [Pharma Services]

Advanced technologies for pharmaceutical production – product experience, skills and knowledge in technology and control systems.

For many years, we have worked hand-in-hand with leading international pharmaceutical companies as a well-respected partner company.

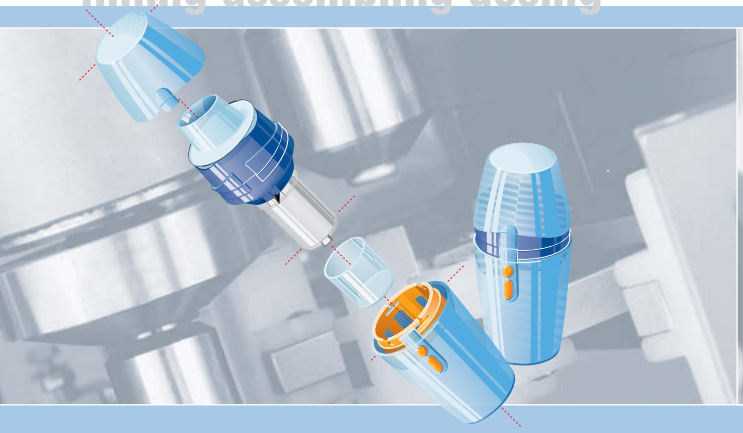
Whatever the task you place before us, we are always ready and willing to take on new challenges. As a specialist for efficient manufacturing, assembly and packaging concepts, we are your one source for customized solutions.

We combine our experience in pharmaceutical products with our knowledge of process flows and system electronics.

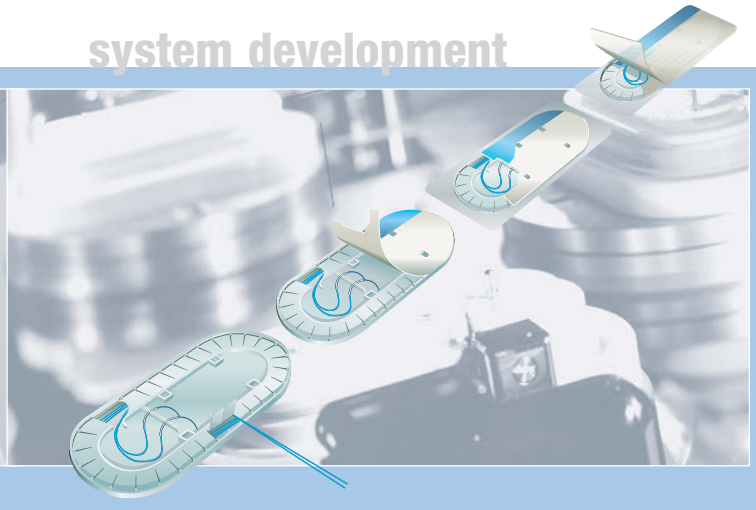
With our many years of experience in developing, designing and installing complex production lines, we have earned international prestige in an extremely wide variety of fields.

Our core competence extends from foil processing and manufacturing multiple-layer laminates, to dosing, weighing and checking systems, to assembly and handling technology, to processing syringes or inhalers in the cleanroom.

fillling assembling dosing



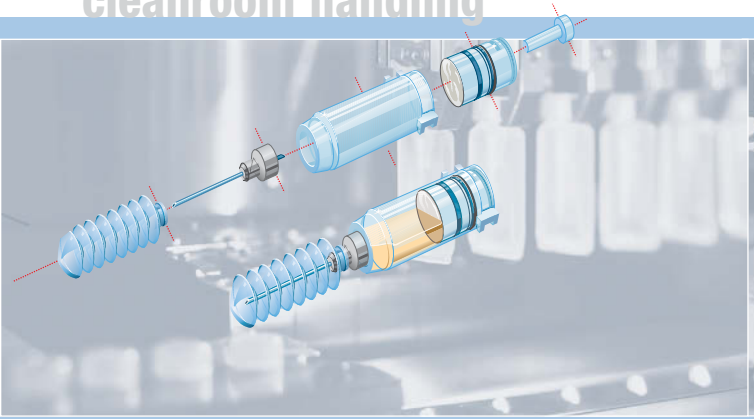
system development



Pharmaceutical Technology

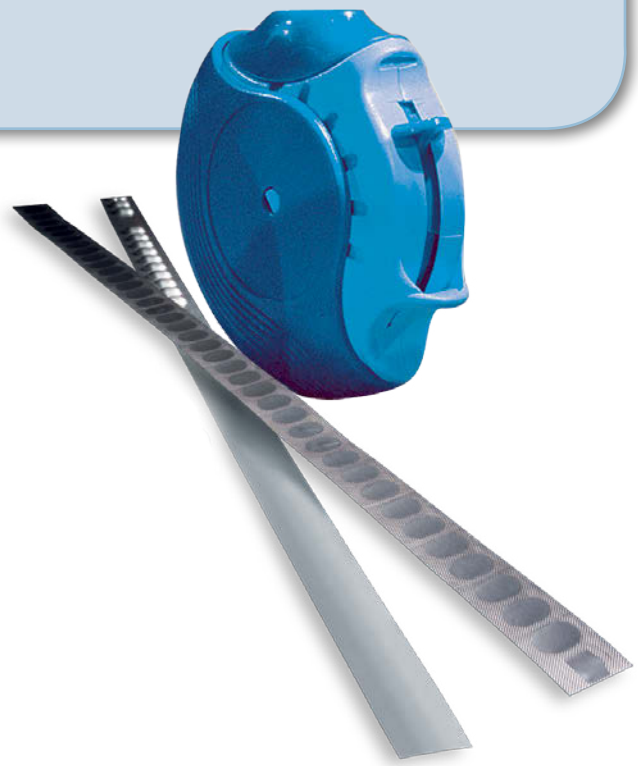
Contents

cleanroom handling

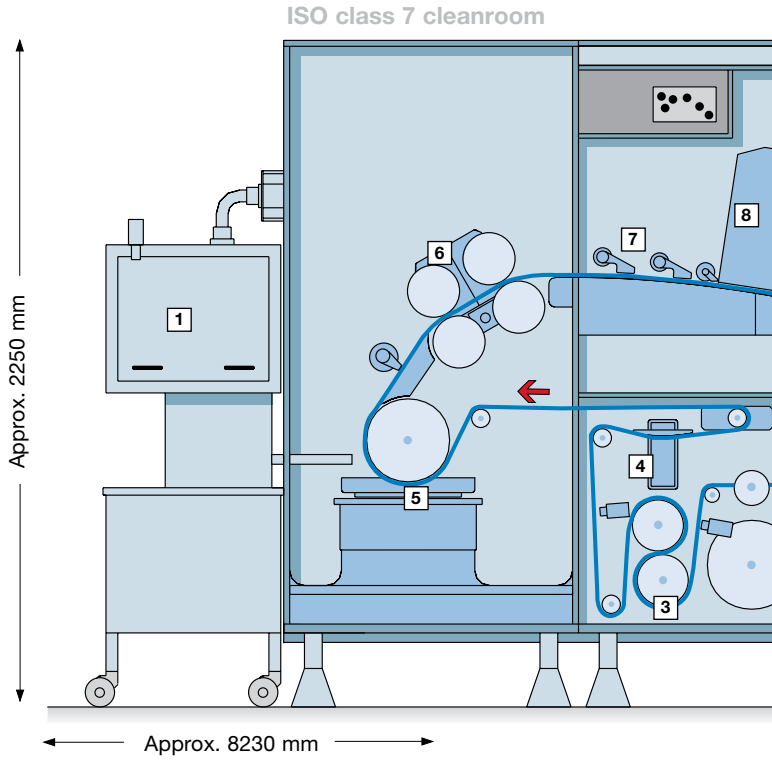


web processing

Filling and packaging micronized powder – exemplary technology for the production line.



When asthma medications are ingested using an inhaler, precise, accurate dosing must be guaranteed at all times. This places the highest demands on the mechanical engineering components of the machine, particularly for processing tiny quantities of micronized powder. Furthermore, the blister cups must be filled completely to guarantee an exact dosing quantity.



Process flow:

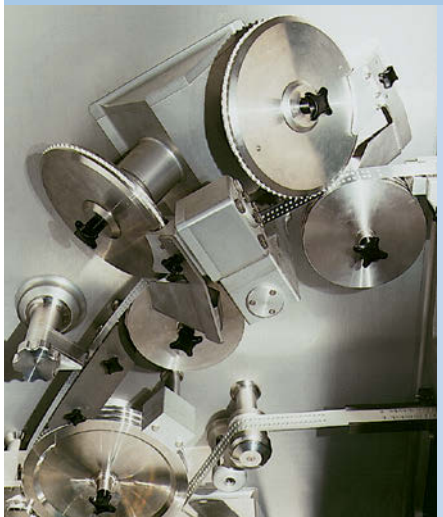
The blisters are manufactured with the greatest precision and filled to 100% with micronized powder. For optimum sealing, the foil surface is cleaned and checked. The sealing process requires that the bottom foil and lidding foil are synchronized accurately.

After the sealing process, the blister web, which is produced in a continuous web, is imprinted and wound.

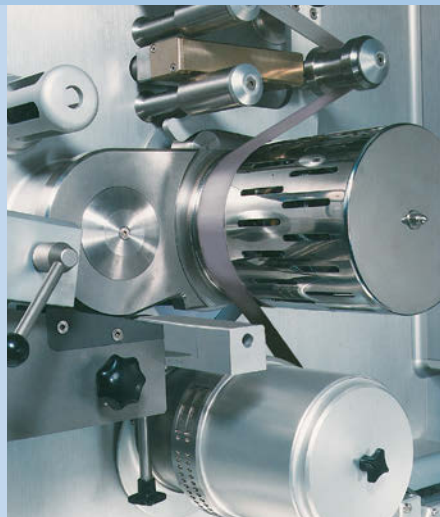
Specifications:

Output:	3,600 cavities/min.
Dosing:	13.3 mg
Accuracy:	+/- 0.5 mg

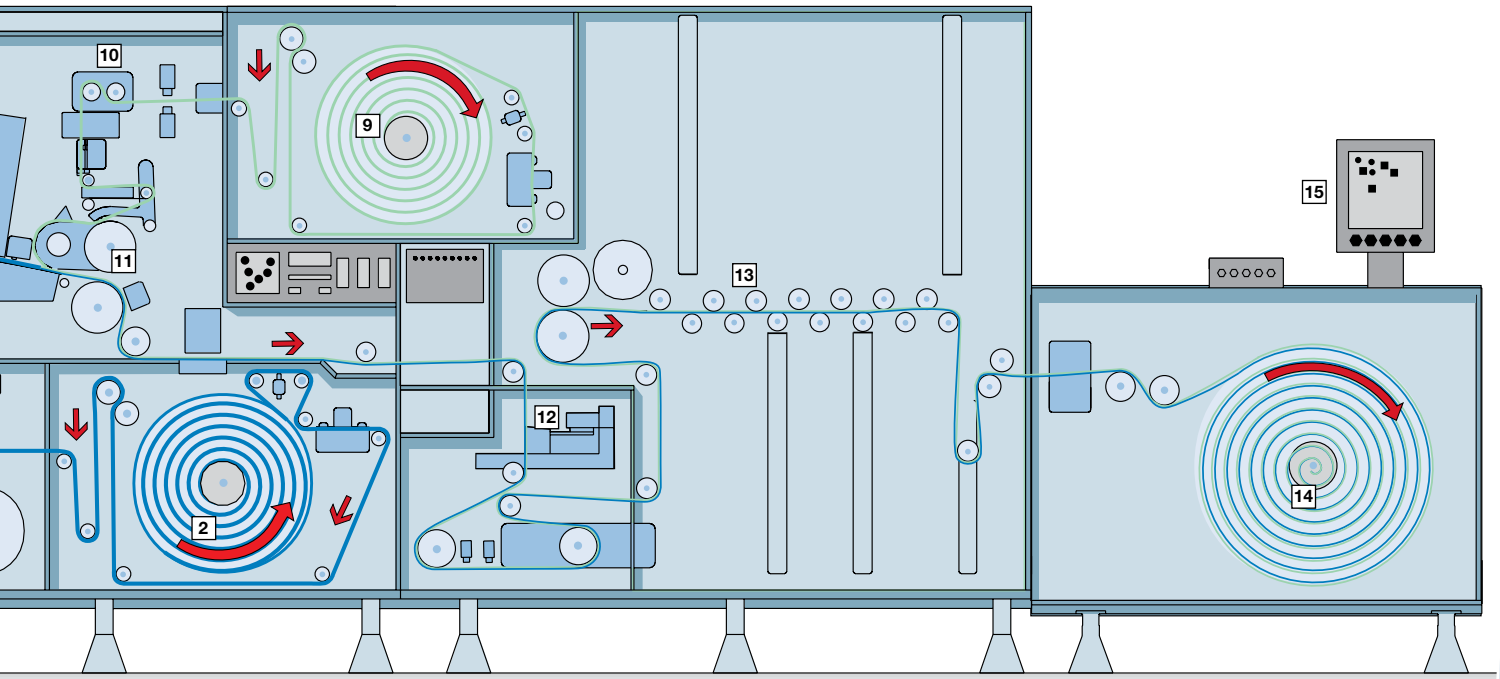
Filled to 100%:
Filling the cups with micronized powder and cleaning the sealing surface



Hot sealing:
The blister foil with the filled cavities is sealed

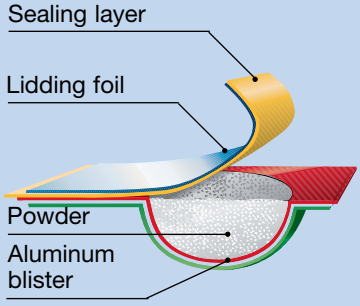


Smooth production:
While the reel is changed, the buffer system holds the blister web



Line for forming and filling inhaler blisters

Structure of a filled blister cup:



Process flow

1. *Powder supply*
2. *Bottom foil unwinder*
3. *Molding the bottom foil*
4. *Pin hole detection and checking the cups*
5. *Powder dosing system*
6. *Removing excess powder by doctor blade*
7. *Cleaning the bottom foil*
8. *Video inspection*
9. *Lidding foil unwinder*
10. *Web edge tracking control*
11. *Heat sealing*
12. *Printing*
13. *Buffer system for changing reels*
14. *Take-up of the continuous blister*
15. *Screen for video inspection*

Production line for filling blisters with powder – a system cooperation by Uhlmann Pac-Systeme / Harro Höfliger.

By means of inhalation, a substance can be directly administered either nasally or via the lungs. Inhalation is extremely well suited to the trend towards increasingly smaller active ingredient quantities of highly active substances.
For this purpose, a system solution has been created for filling blisters with inhalant powder.

The powder-in-blister platform is the efficient link between automated small-volume production in Phase III and a large-scale facility. All processes and parameters of this technology can be scaled up to high-output principles. The system also features an exceptionally small footprint.

The barrier concept allows it to be used in production rooms without a regulated atmosphere.

The system consists of two parts and forms a closed production cycle. The cold-formed blister is filled with powder in the Omnidose, checked and returned to the blister machine.
During this process, the blister is processed in a protected atmosphere on the filling line through to the sealing station.

This prevents cross-contamination of the product from the outside and protects the operating personnel from the effects of active ingredient emissions. The machine can fill blister strips with a length of up to 800 mm with active inhalant ingredients or pharmaceutical powders; the machine can be equipped with up to three dosing stations.

The dosing system can be easily changed by replacing modular dosing trolleys.

Specifications:

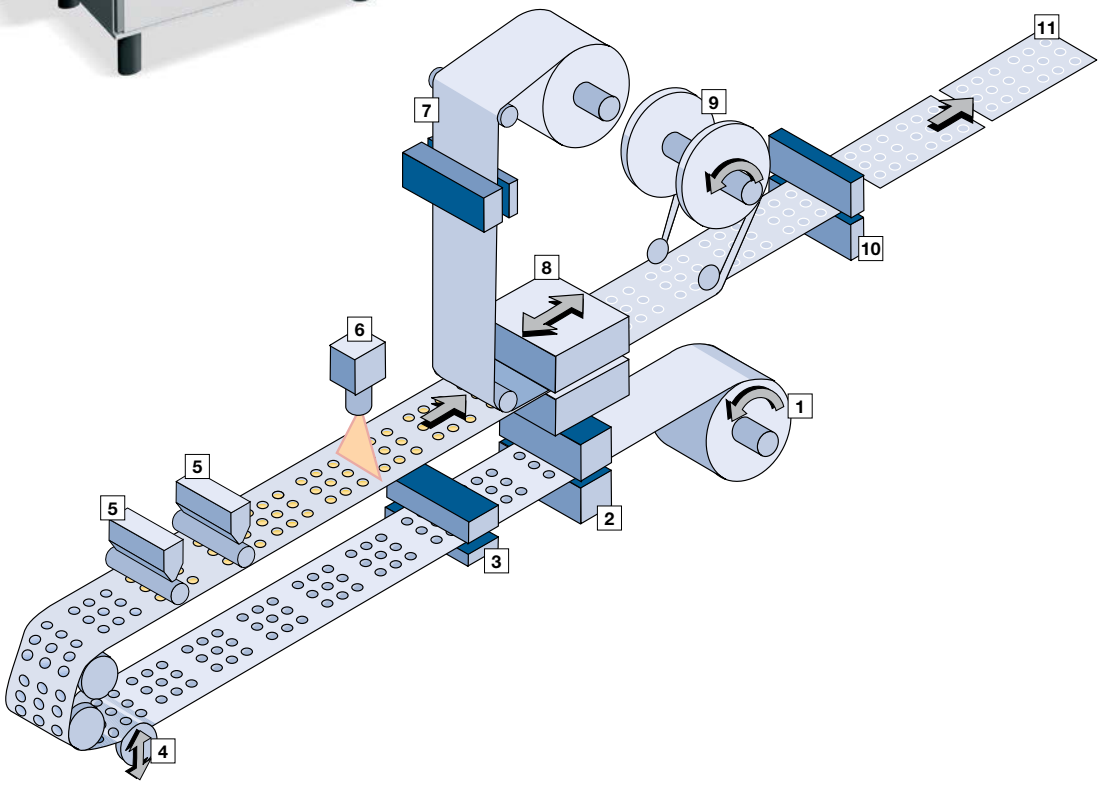
Dosing systems:

Drum filler:	Filling range from 1 – 35 mg, up to 16 bores per cylinder, output up to 75 cycles/min.
Dosator:	Filling range from 15 – 750 mg, output up to 75 cycles/min.
Tamping pin:	Filling range from 30 – 1.000 mg, output up to 140 cycles/min.

Accurately and precisely filled:
Cylinder filler for precision dosing of powder quantities of 1µm or more

Complete control:
Quality control during production using an inline video inspection system

Blister manufacturing in a system:
A self-contained system solution for filling aluminum blisters with inhalant powder



Process flow

1. *Forming foil unwinder*
2. *Cold forming of blister cavities*
3. *Pin hole and pore detection for forming foil*
4. *Dancing roller*
5. *Twin dosing unit for micronized powder*
6. *Camera/filling control*
7. *Lidding foil unwinder/pin hole and pore detection for lidding foil*
8. *Sealing station*
9. *Longitudinal cutter and strip waste winder*
10. *Blister strip crosscutter*
11. *Discharge belt*

Liquid filling and assembly of inhalers – intelligent process technology at every level.

A propellant-free aerosol vaporizer has been developed for inhalation of liquids. Combined with a cartridge that enables the entire dose of active ingredient to be withdrawn, it provides very high utilization of the product.

Process flow:

The cartridges are sorted into transport shuttles in lots of 24. These shuttles are driven to the function stations of the filling and closing line with perfect positional accuracy.

The entire process takes place in the ISO class 5 cleanroom:

- Testing for leaks
- Filling, closing and checking the cartridges
- Unloading the cartridges from the transport shuttles and feeding them to the drying unit

Checking filled inhaler cartridges with integrated puck transport:

- Transferring the inhaler cartridges into a puck transport
- Testing for leaks after filling
- When the test is finished, an elevator transports the cartridges to the level underneath

Creasing and crimping inhaler cartridges:

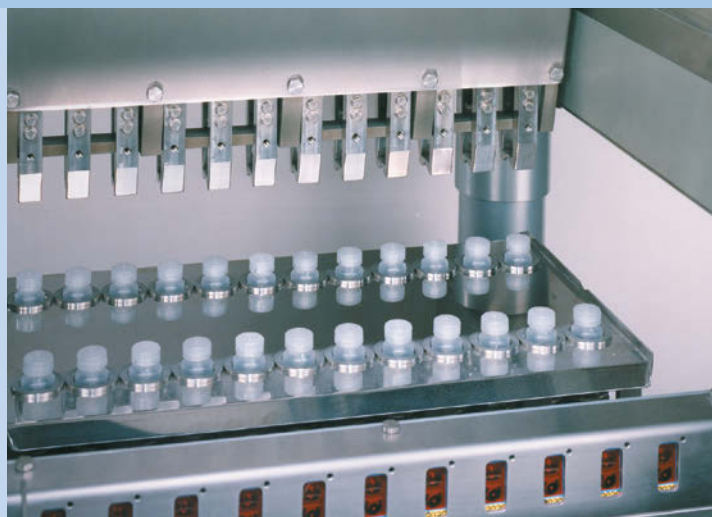
- Sealing the filled cartridges with a fine membrane
- Feeding, creasing and crimping the aluminum sleeve
- After the weight check, the finished product is unloaded into a container via feed belts

Specifications:

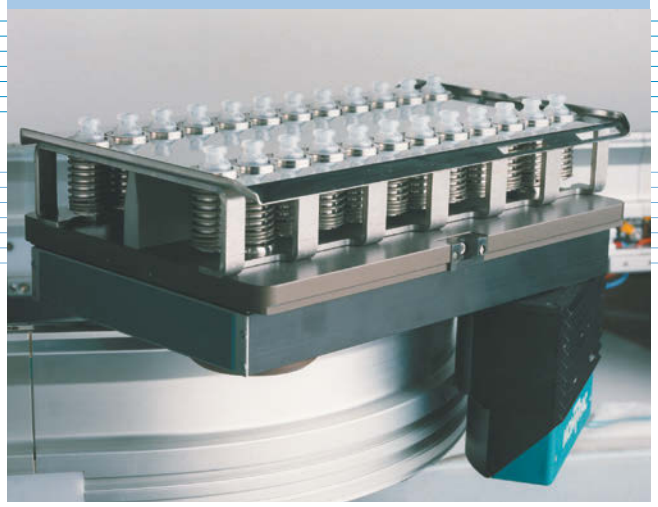
Output:	150 cartridges/min.
Dosing:	4.5 ml

12 at a time:
Filling cartridges using CIP/SIP-capable filling heads

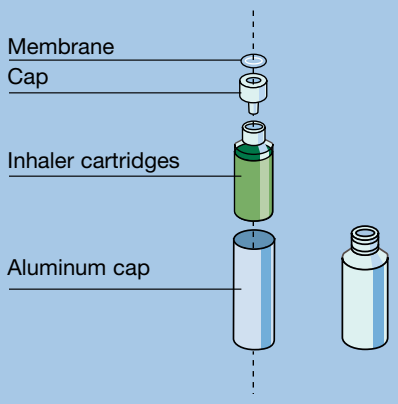
The right fit:
Checking the lids for correct fit



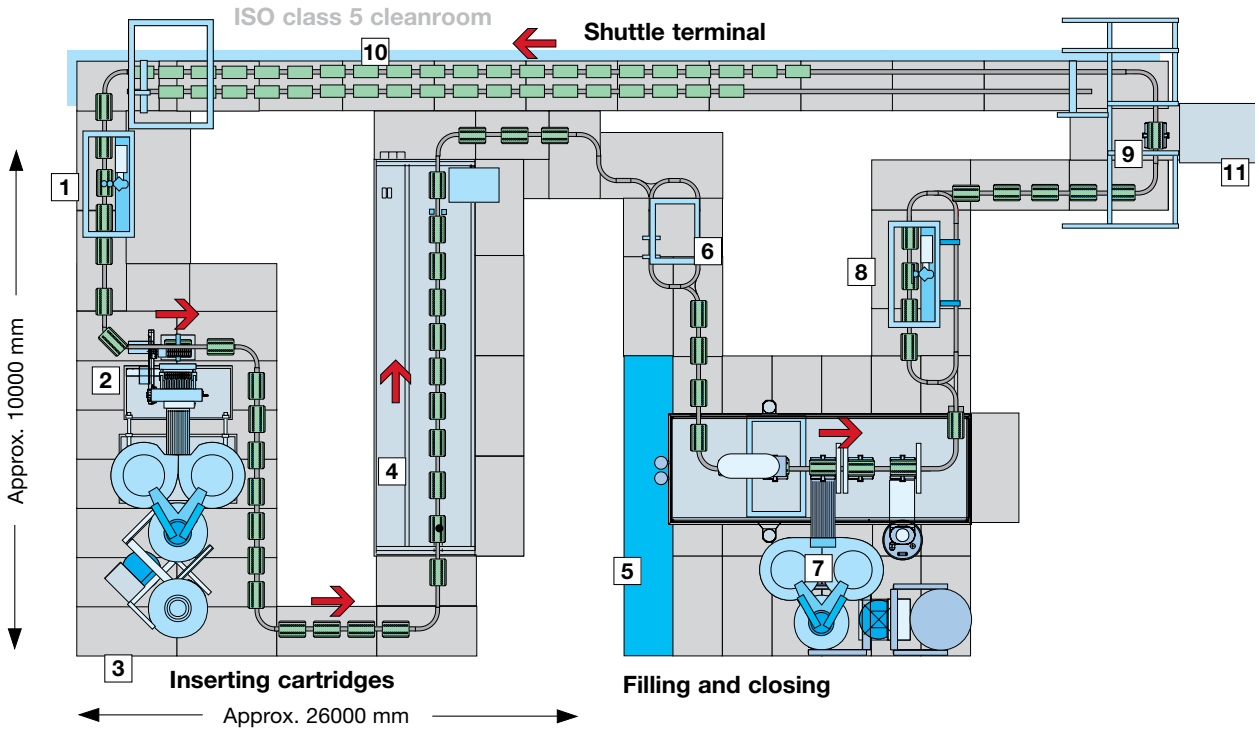
Transport shuttle:
Transporting the cartridges in a shuttle using a rail system



Structure of the inhaler:



Line for filling inhaler cartridges



Process flow

Filling, closing and checking

- ***1 Elevator system for transporting the shuttles from top to bottom***
- ***2 Sorting and inserting the inhaler cartridges into transport shuttles***
- ***3 LF area***
- ***4 Leak test before filling***
- ***5 Aseptic system***
- ***6 Ejection of transport shuttles***
- ***7 Filling, closing and closure check of the inhaler cartridges***
- ***8 Elevator system for transporting the shuttles from bottom to top***
- ***9 Discharging cartridges***
- ***10 Shuttle terminal at 2 m height***
- ***11 Drying and inserting into puck transport***

Testing liquid inhalers – because safety is everything.

On this machine, the inhalers undergo extensive function tests. The spray from the inhaler must shoot into an exactly specified “corridor”. The inhaler‘s dosing mechanism is triggered several times at the specified dose quantity to verify that it will work properly for the patient. In addition, the distribution and intensity of the spray are checked.

Process flow:

The inhalers are taken from trays, transferred into a transport system and equipped with test cartridges. These test cartridges are filled with a test liquid (ethanol).

A 12-point function test in the rotary machine, and a spray check by laser after exiting the rotary machine, are the central features of the machine. Next, the ethanol is extracted and the test cartridges are returned.

The inhalers themselves are completely emptied, then IPC samples and fail parts are discharged.

In the last step, the good parts are loaded onto trays.

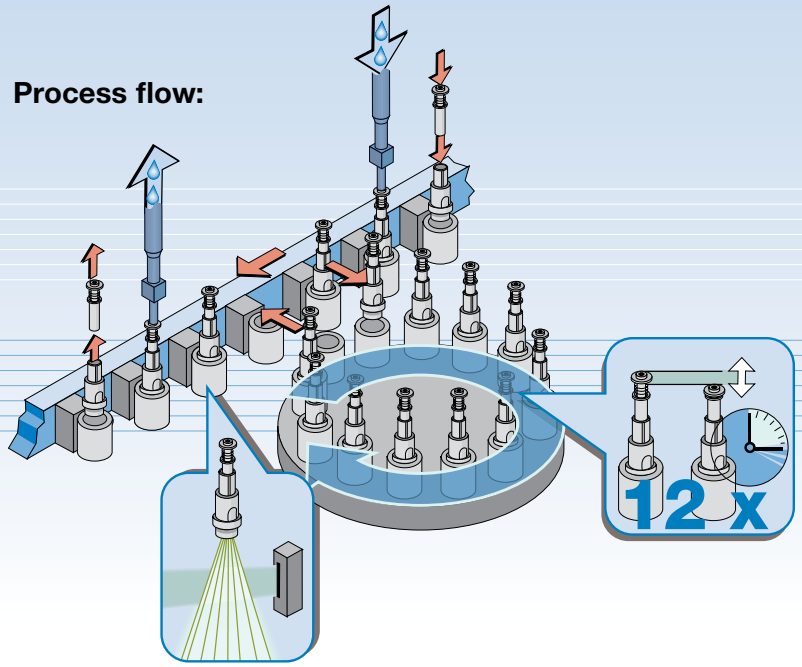
Specifications:

Output:	45 inhalers/min. Infeed and discharge in stacked trays 96 inhalers/tray
Checking:	- Spray durance - Particle distribution - Spray intensity

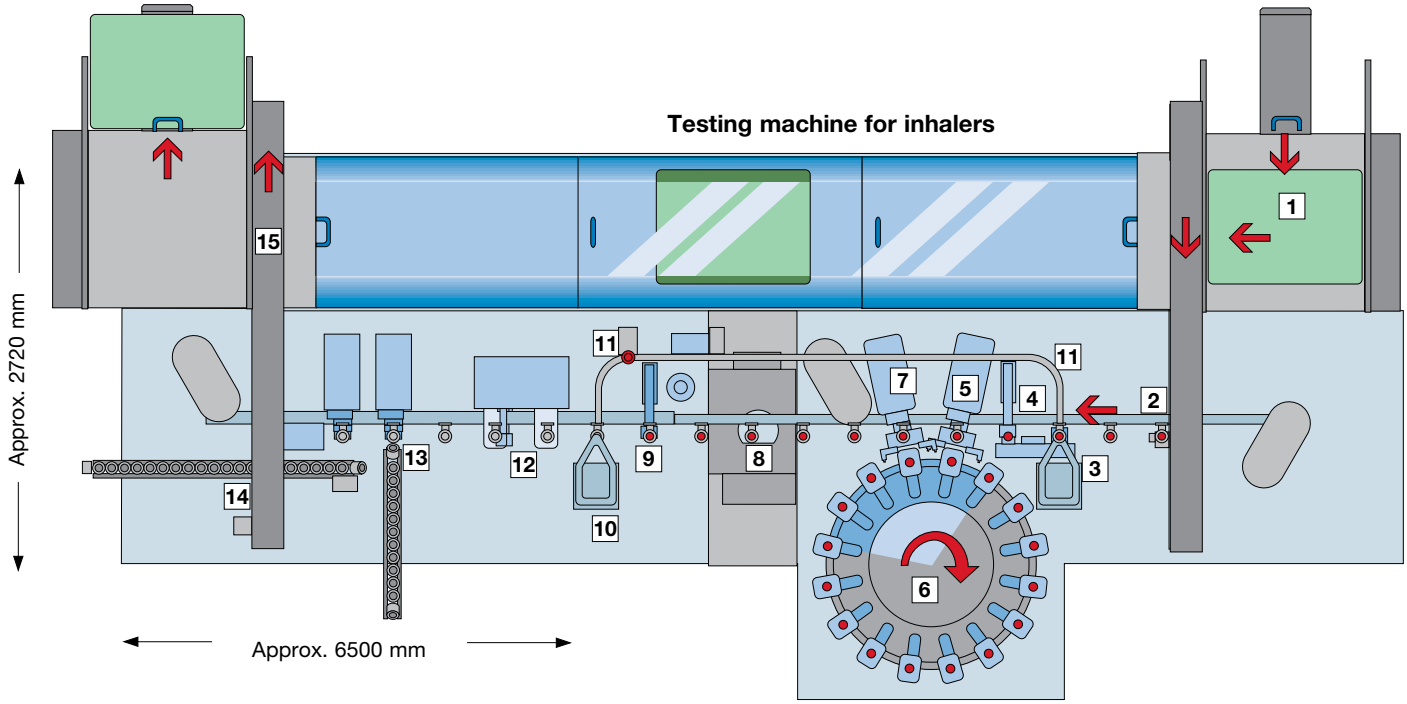
Around and around:
Transport of the inhalers being tested in the rotary machine

Complete detection:
The laser checks the spray in a defined tolerance range

Process flow:



Testing machine for inhalers



In neat rows:
Transfer of tested inhalers to the product outlet

Process flow

1. *Tray unloading*
2. *Inserting the inhalers in the transport system*
3. *Inserting the test cartridges*
4. *Dosing the test medium*
5. *Inserting into rotary machine*
6. *12-point function test*
7. *Ejection from rotary machine*
8. *Laser check of spray*
9. *Ethanol extraction*
10. *Test cartridge removal*
11. *Returning the test cartridges*
12. *Complete emptying of inhalers*
13. *Ejection of IPC samples*
14. *Ejection of fail parts*
15. *Loading trays with good parts*

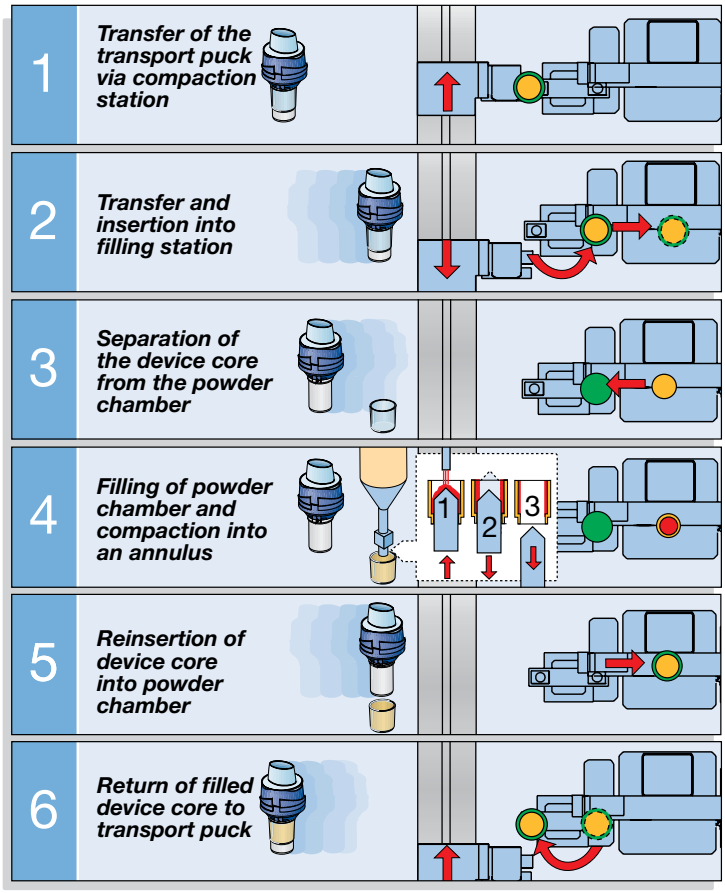
Filling and assembling multidose powder inhalers (MDPI).

Inhalers for micronized powder are dosing units with a complex design that are manufactured with high precision. The many components of the inhaler, all exactly matched to each other, are joined in a complex assembly process.

Process flow:

The upper section and drum arrive separately in trays. After being removed from the tray, the upper section is fed to the filling and compressing station. The tare weight is determined before the filling. The powder chamber is removed, filled and the powder is compressed. The chamber is then reattached. The filled upper sections then pass through a gross weigh station and then, if the fill weight is correct, through the assembly machine. From an alignment station, the drums are transferred to the assembly rotary machine. The upper section is inserted into the drum and checked by a camera.

This is followed by the check of a test spray. After the cap is attached, the finished inhalers are inserted into a tray.



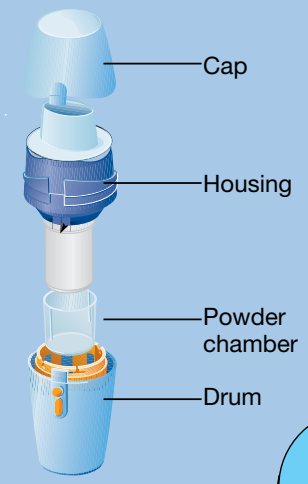
System technology features:

- Individual powder dosing
- Special compressing station for defined powder density
- Safety zones stop in case of fault only partial areas of the complete system
- Elimination of electrostatic field interference in the weighing area
- Upper section is laser-marked with the number of the compressing station
- Sample removal and function test of the inhaler
- Compact construction
- Decoupled load cells

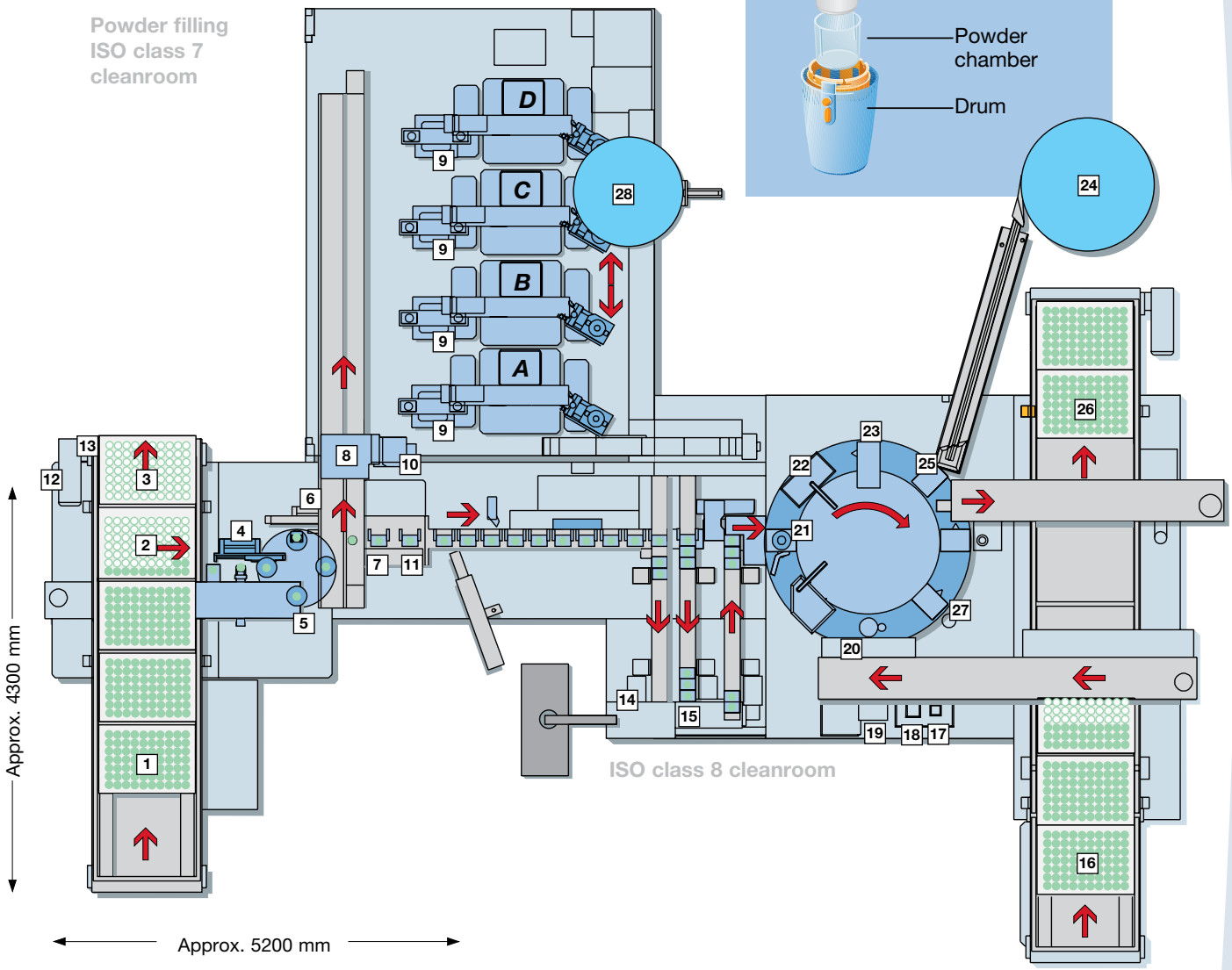
Specifications:

Output:	8 product/min.
Dosing:	up to 200 sprays/product
Accuracy:	+/- 0.05 mg

Structure of the inhaler:



Line for filling and assembling inhalers



Process flow

1 *Upper section infeed housing with powder chamber*
2 *Tray unloading*
3 *Empty tray outfeed*
4 *Transfer and rotate 180°*
5 *Align upper section*
6 *Transfer to puck transport*
7 *Tare weighing*
8 *Puck transport to filling station A, B, C or D*
9 *Powder filling (see flowchart)*
10 *„Filled pucks“ return conveyor*
11 *Gross weighing*
12 *Laser coding of upper section*
13 *Fail part rejection*
14 *Samples for in-process control*
15 *Storage*
16 *Drum spray unit infeed*
17 *Inkjet printing*
18 *Video inspection*
19 *Angle alignment of the drums*
20 *Transfer of drums to assembly rotary machine*
21 *Inhaler assembly*
22 *Inhaler testing*
23 *Test spray checking station*
24 *Cap infeed*
25 *Attaching caps*
26 *Good part outfeed*
27 *Fail part rejection*
28 *Powder supply hopper*

Filling powder into inhaler refill cartridges with inline packaging.

The Novolizer® aerosol inhaler is designed with cost-effectiveness and environmental considerations in mind, allowing it to be used over a longer period. The inhaler is supplied with the active ingredient by a refill cartridge. Because air humidity that penetrates the inhaler can, over time, change the composition of the powder and thus the dosing accuracy and output quantity of the inhaler, the unused cartridges are packaged and stored in airtight and moisture-proof canisters.

Dosing gates are inserted into the fed cartridges. After a slide force check, the counter strip is inserted; then, the number reading of the counter strip is checked at the next station.

The cartridge, which is assembled from several components, is then labeled on both sides and a pharmaceutical code is printed on it. The special requirements are due to the need to print on the convex side surfaces of the cartridge.

The downline checks the print layout for any deviations so that faulty parts are ejected before filling.

Next, the tare scale determines the tare weight of the container.

In order to attain the required output, a micro auger filler in duplex configuration has been integrated into the system. The tendency-controlled gross checkweigher adjusts to the correct fill weight. The filled cartridge is closed with a lid and conveyed to the packaging unit. The canister is positioned and loaded with a desiccant and the cartridge. An inline-punched foil pad is sealed on to protect the cartridge from harmful environmental influences.

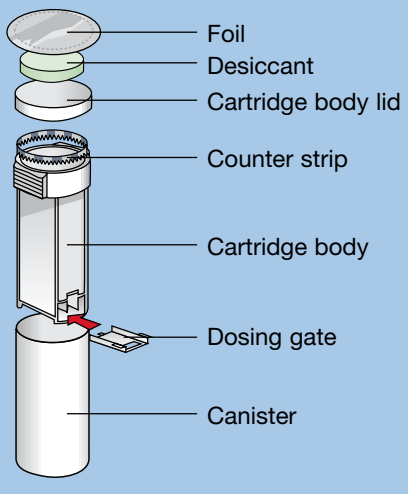
Output data:

Output:	up to 50 cartridges/min.
Dose quantity	300 to 4,000 mg
Dosing accuracy	+/- 70 mg

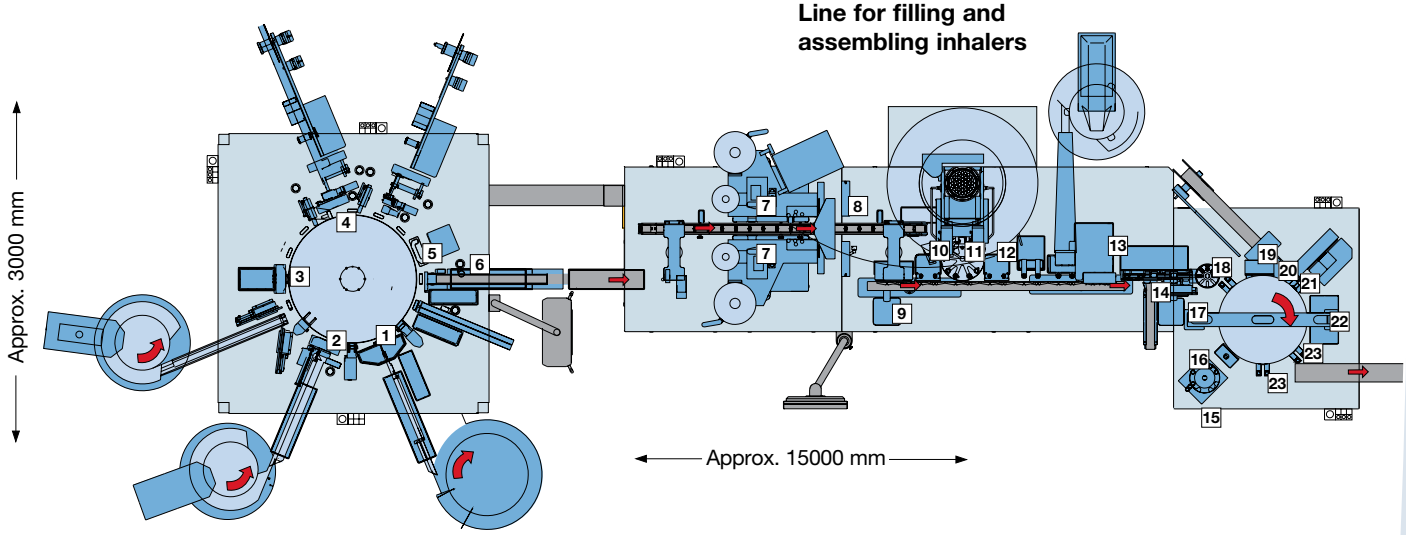
Gentle transfer:
Feeding and transfer of the cartridge body into the process

Impressive:
Bilateral labelling of the cartridge body

Structure of the inhaler refill cartridge:



Line for filling and assembling inhalers



Process flow

1 *2-up infeed of cartridge bodies*
2 *Slide-in of dosing slider*
3 *Slide force check*
4 *Insertion of counter strip*
5 *Count position check*
6 *Transfer of good parts*
7 *Labeling of left & right side*
8 *Camera check*
9 *Reject*
10 *Tare weighing*
11 *Powder dosing*
12 *Gross weighing*
13 *Placement of cover*
14 *Reject*
15 *Infeed of cans*
16 *Infeed and insertion of dry agent*
17 *Presence check of dry agent and cartridge*
18 *Insertion of cartridge body into can*
19 *Foil punching, winding waste grid*
20 *Tack sealing of foil*
21 *Camera check tack sealing*
22 *Placing and sealing of foil*
23 *Outfeed good & fail parts*

Assembling and checking liquida inhalers.

This cartridge for an inhaler has been designed such that for dosage, it is pressed into the inhaler unit as a fixed unit joined to the counter. The counter unit simultaneously serves as the bottom closure of the device.

In an assembly solution specially developed for this interchangeable unit, the
filled cartridges are taken from a test system and inserted into the counter bottom sections using a revolving machine.

To do so, robot gripper arms are used that position the components in intermediate storage trays in groups of 4.

There, the product holders are separated, so that the distance between the center points of the components is adapted to the spacing of the revolving machine.

The bottom sections are turned by 180°.

After being transferred to the rotary machine, the bottom sections reach the transfer station for cartridges.

Two sequential duplex pressing stations firmly press the cartridges into the bottom sections.

A downline check ensures that the assembled products have the correct press-in dimension.

Another pick-and-place unit lifts the good parts onto the discharge belt.

At the next station, faulty parts are unloaded and the emptied holders checked.

Output data:

30 cycles/min.

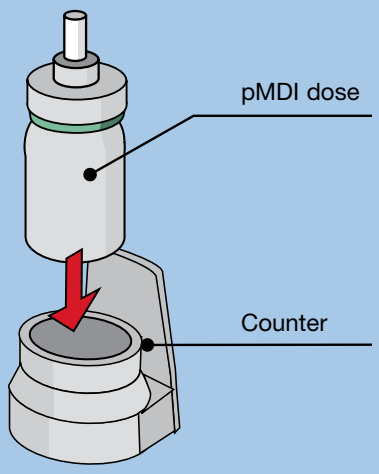
4-compartment product holders

120 products/min.

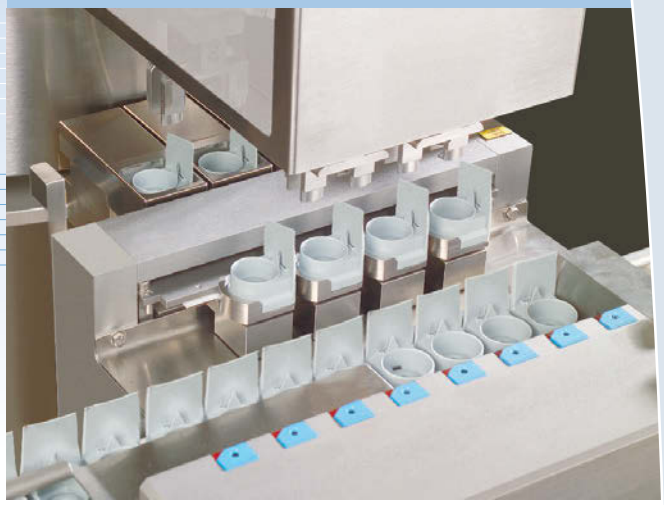
A perfect fit:
Pressing the cartridges into the counter bottom sections

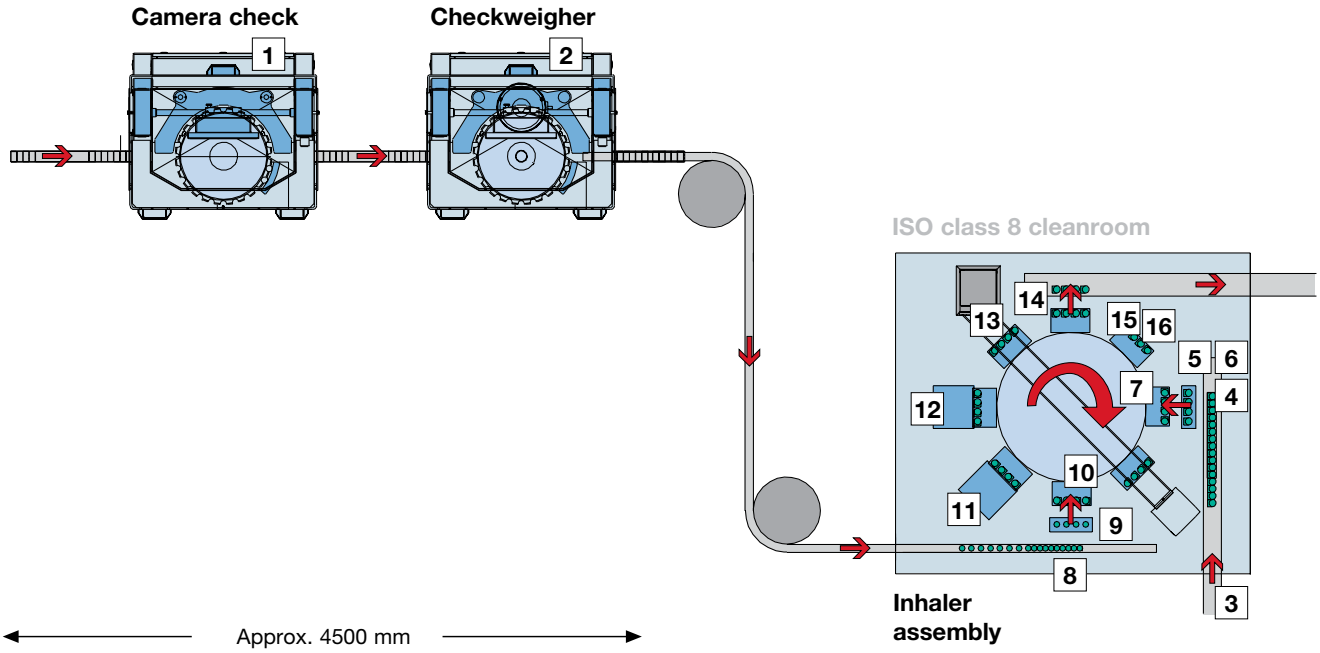
Very careful:
Checking the installed products for the correct press-in dimension

Structure of the liquida inhaler:



Gripping technology:
4-compartment transfer of the bottom sections into the turret





Process flow

1. *Imprint video inspection*
2. *Weighing canister*
3. *Counter infeed*
4. *Gripper transfer to intermediate storage tray*
5. *Increasing the distance between the center points*
6. *Turning the intermediate storage tray*
7. *Transfer to product holders*
8. *Canister transfer to inter-mediate storage tray*
9. *Increasing the distance between the center points*
10. *Positioning canisters in counters*
11. *Pressing in canisters, duplex*
12. *Pressing in canisters, duplex*
13. *In-process control*
14. *Product transfer on discharge belt*
15. *Fail part ejection with countercheck*
16. *“Product holder empty” check*

Assembling, filling and packaging depot syringes – precision and safety in sterile production.

Assembling depot syringes requires precise process flows and, at the same time, careful handling that will not damage the sensitive products. In addition, this project reflected market demands for safe syringe handling after use.

Process flow:

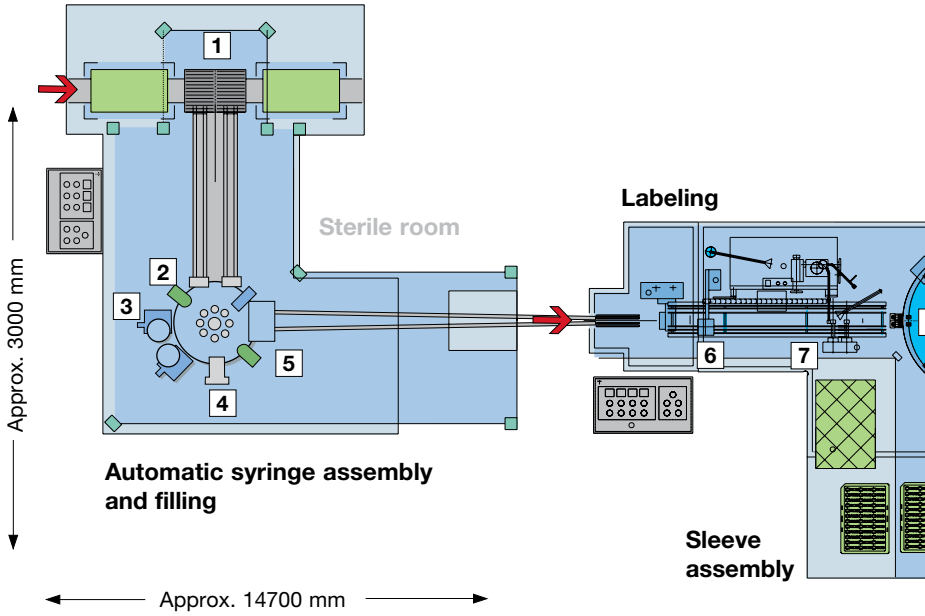
Preassembled syringes are unloaded from trays using an elevator system and inserted into the rotary machine. There, the syringe is disassembled and a solid implant inserted. After a check for the presence of the active ingredient, the syringes are closed and turned from a vertical to a flat position.

Before labeling, the product is checked for correct closure. In an additional assembly unit, the finished syringes are inserted into protective sleeves. In the downline system part, the syringes are packed into prefabricated pillow packs. These, in turn, are stacked in trays.

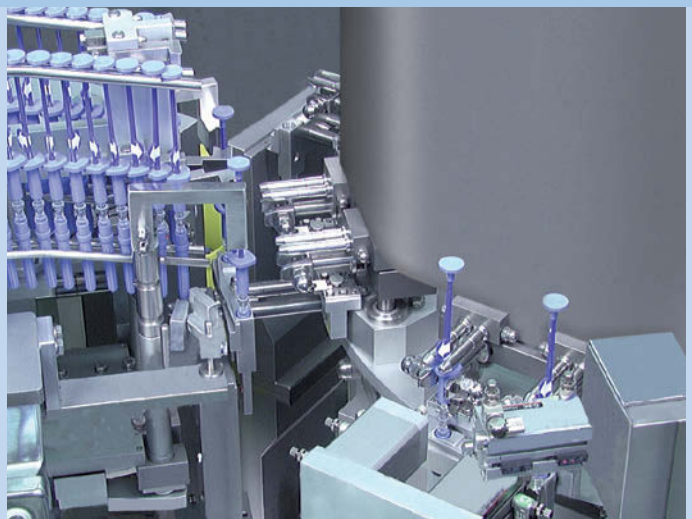
Specifications:

Output: 60 syringes/min.

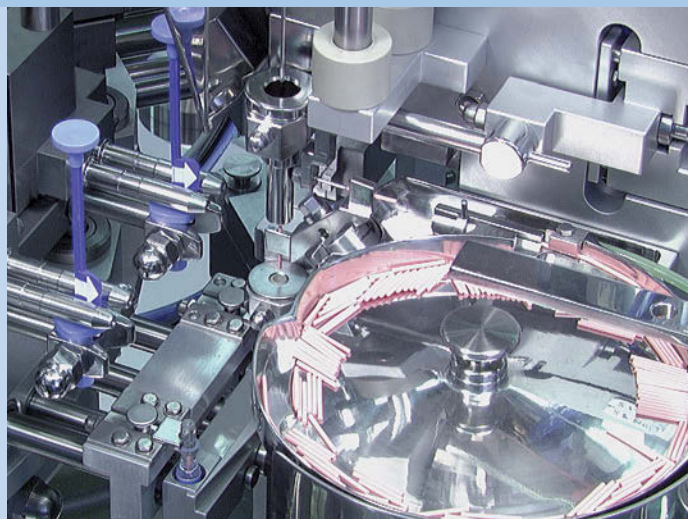
The fully automatic syringe assembly takes place in the ISO class 5 clean-room.



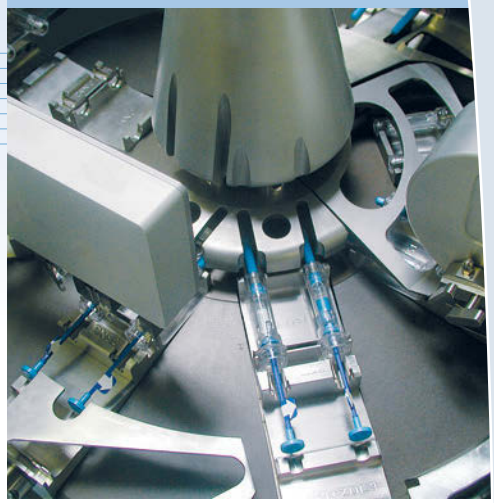
Smooth transfer:
Transferring the syringes from the elevator system to the rotary machine



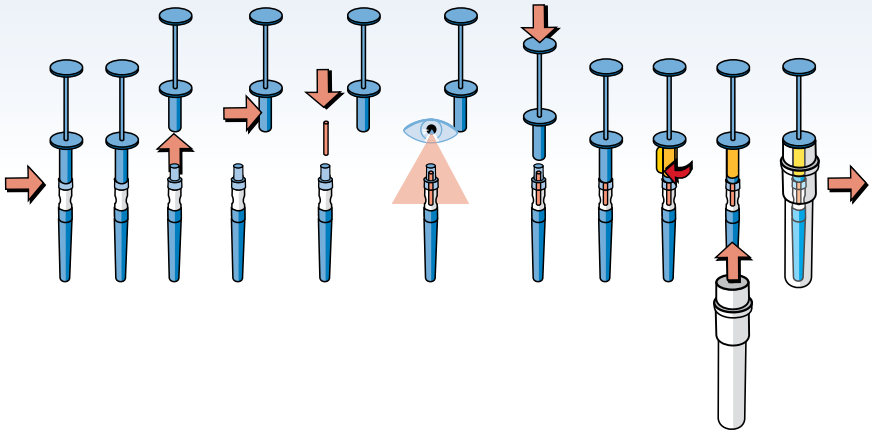
Neatly separated:
Separating the implants and inserting them into the syringes

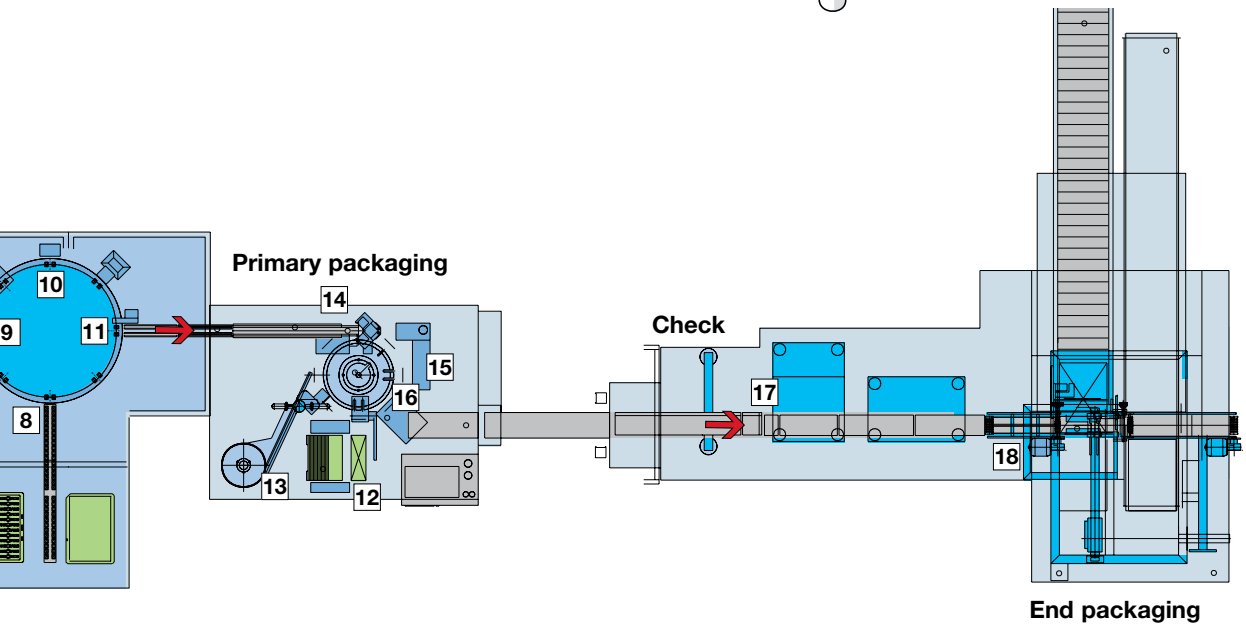


On the safe side:
Inserting the syringes into protective sleeves



Process flow (excerpt):





Process flow

1 *Syringe infeed*
2 *Opening syringe*
3 *Inserting the implant*
4 *Implant presence check*
5 *Opening syringe*
6 *Video inspection for syringe closure*
7 *Labeling syringe*
8 *Inserting sleeve*
9 *Inserting syringe*
10 *Joining and check*
11 *Syringe transfer into separator rake*
12 *Sachet infeed*
13 *Desiccant infeed*
14 *Syringe infeed*
15 *Sachet sealing*
16 *Sachet transfer*
17 *Weight check*
18 *End packaging*

Assembling multi-chamber injectors – complex process technology for highly sensitive products.

The design of these filling and assembly machines for multi-chamber injectors had to fulfill the requirements for ISO class 5 cleanrooms.
The fill product of the multi-chamber autoinjectors is composed of two separately filled active ingredients that are mixed during application.

Process flow:

The stopper, disc and needle are pre-assembled in the puck transport system. This preassembly is then transported to the filling unit. Injector barrels are fed, separating stoppers are added and the barrels are filled with the first active ingredient.

Then, the pre-assembly is inserted into the syringe barrel. Unloaded pucks are returned.

After the injectors are closed, these are used for the dosing of the second liquid. The filled active ingredient chambers are closed by inserting stoppers on the bottom. The finished injectors are then discharged.

The highest product quality is ensured by extensive quality control measures and an integrated in-process control (IPC) station.

System technology features:

- 100% check for completeness and fill quantity during assembly and filling operation
- Compact processes in the least space
- Complex, perfectly tuned product transport systems
- Handling systems for feeding and inserting difficult-to-handle product components
- Dosing separate liquid substances under cleanroom conditions

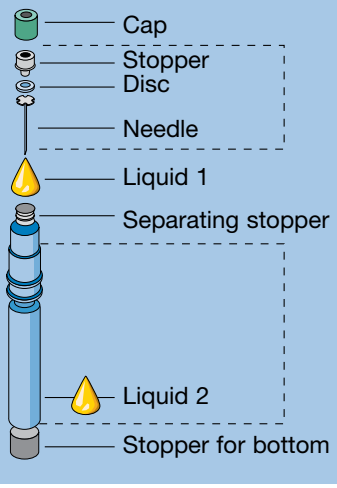
Specifications:

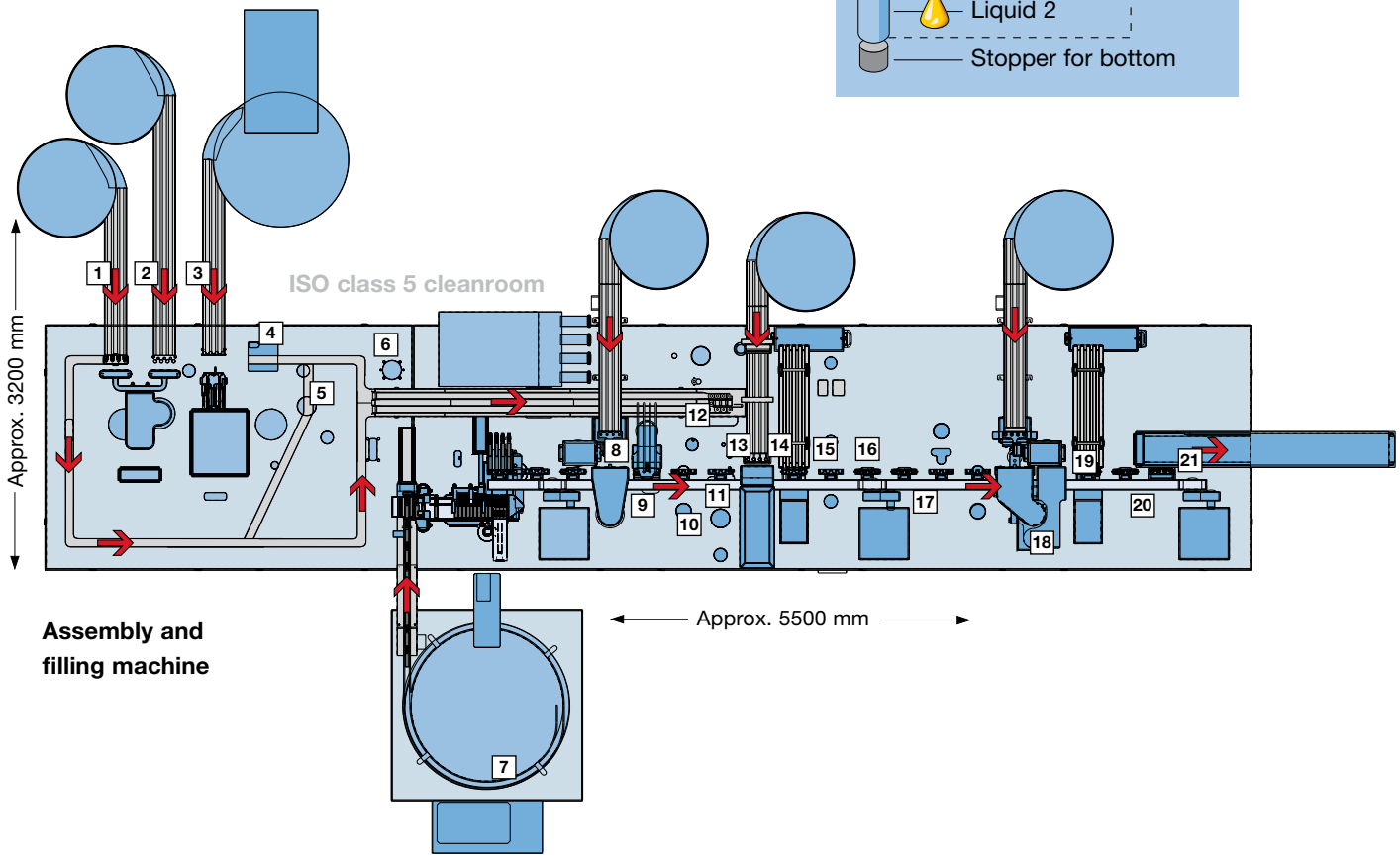
Design:	4-compartment holder
Output:	120 pieces/min.
Dosing:	Active ingredient 1: 0.73 ml Active ingredient 2: 3.18 ml

Extremely accurate:
Inserting the injector barrels for assembly and filling

Right on target:
Inserting the needles into the plungers and discs

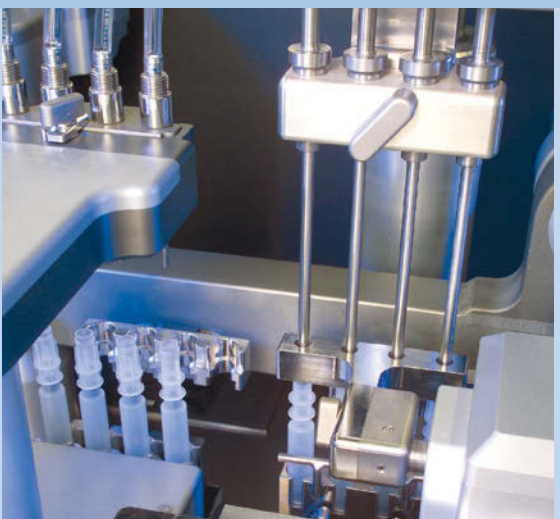
Structure of the multi-chamber injector:





Assembly and filling machine

Well filled:
Filling the active ingredient into the turned injectors



Process flow

1. *Inserting plug into puck transport*
2. *Inserting disc in stopper*
3. *Needle assembly*
4. *Fail part ejection NSD assembly*
5. *Discharge of individual emptied pucks*
6. *Discharge of pre-assembly*
7. *Injector barrel infeed*
8. *Insertion of separating stopper*
9. *Dosing active ingredient 1*
10. *In-process control*
11. *Inserting pre-assembly*
12. *Returning empty pucks*
13. *Attaching cap*
14. *Fail part ejection*
15. *Turning the injector*
16. *Dosing active ingredient 2*
17. *In-process control*
18. *Inserting stopper for bottom*
19. *Fail part ejection*
20. *In-process control*
21. *Discharging injectors*

Assembling needle-free injectors – bringing production to the point.

Needle-free injectors are a very advanced product, primarily for self-medication, due to its painfree application method. The injector is applied, and the active ingredient reservoir is emptied by pressing a button. The liquid is shot through the skin with high pressure.

The needle-free injector is assembled and filled in an ISO class 5 cleanroom. This requires exacting process steps for assembly. The capsules are filled in the downline machine.

Process flow:

Capsules are inserted into a puck transport system so that plugs can be assembled there. Simultaneously, capsule sleeves are inserted into the 5-compartment product transport. Gaskets are fed and positioned in the capsule sleeves. After a video inspection, the capsules are placed in the capsule sleeves and pressed in. The plungers are inserted into the sleeves, followed by the laser check of the plunger position and the discharging of fail parts.

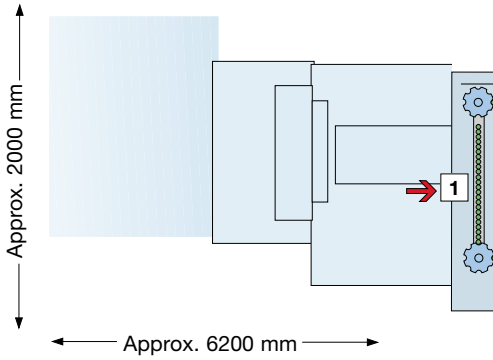
The assembled parts are turned by 180° and transferred to the filler. Alternatively, the products can be fed to an external filler using a tray system.

Our expertise in this application:

- Cleanroom technology
- Isolator technology
- Complex processes for handling and transport of products
- Each production step covers 5 products thanks to 5-compartment workpiece holder
- High-precision assembly of parts and components
- Modern control technologies

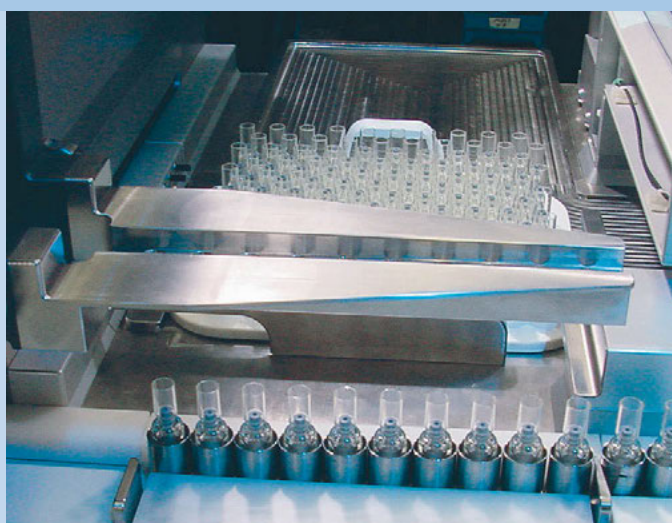
Specifications:

Output: 120 cartridges/min.



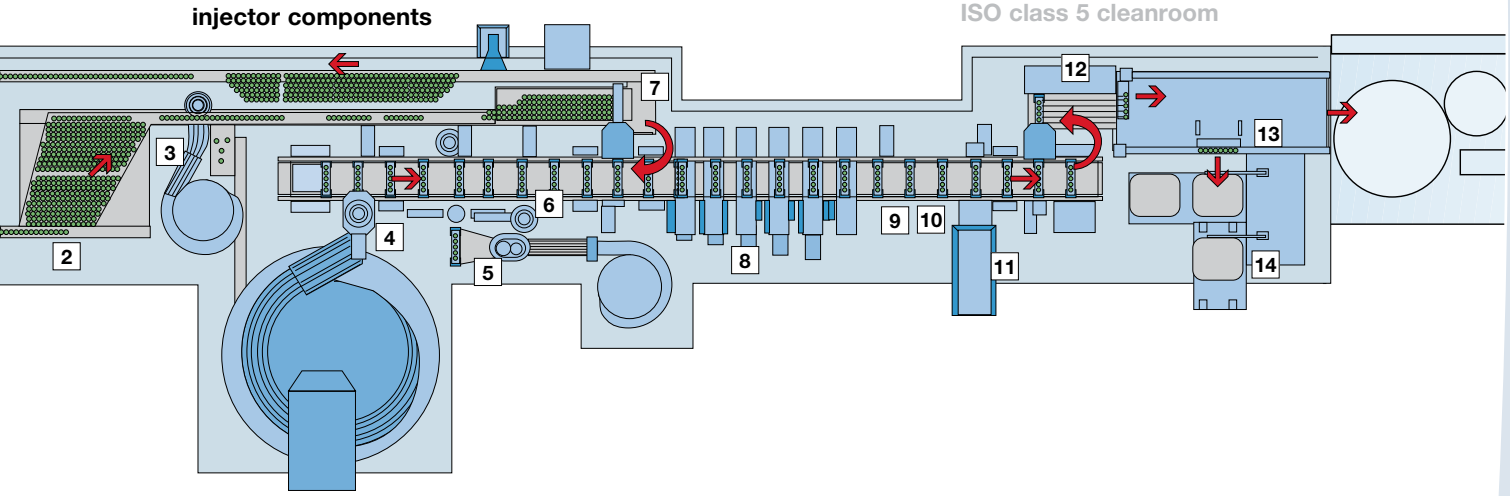
Complex cleanroom technology:
Assembly line for completing the injector components

Neatly in trays:
Unloading the preassembled products from the puck transport system



5-fold process:
Transferring the injector components using gripper

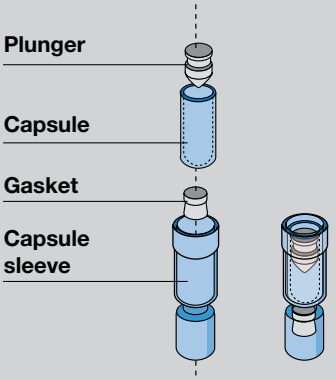
Assembly machine for injector components



Process flow

1. *Inserting capsules into puck transport*
2. *Puck transport and storage*
3. *Feeding and inserting plunger*
4. *Feeding and inserting capsule sleeve*
5. *Feeding and pressing in the gasket*
6. *Gasket video inspection*
7. *Inserting capsule into sleeve*
8. *Pressing the capsule into the sleeve*
9. *Positioning plunger in sleeve*
10. *Laser check of plunger position*
11. *Fail part ejection*
12. *Turning and unloading into pucks*
13. *Transferring assembly parts to filler*
14. *Tray loading for external filler*

Product components



Filling and sealing cartridges with diagnostic products – process technology with perfect dosing.

This machine fills cartridges with two different analytical liquids, then seals them with foil. One of these suspension liquids contains tiny particles enclosed in glass.
To generate a homogenous mass from this, the liquid is constantly agitated. In addition, accurate and variable filling of the widest variety of cup combinations places the most stringent requirements on the machine design.

Process flow:

Cartridges are fed and transferred to the rotary machine. If necessary, the position of the cartridges is corrected at this stage. At the first station, liquid is dosed into the first chamber using peristaltic pumps. The next station then fills the empty chambers using the same process. Pipetting is used to dose the suspension solution into the chambers of the cartridges.

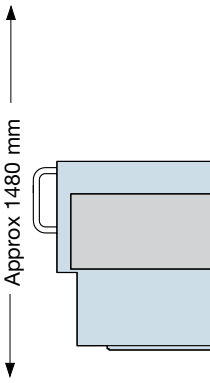
Lidding foil is unwound, crosscut, attached to the cartridges and sealed. Then, the cartridges are removed from the rotary machine and any fail parts are ejected. The cartridges are then turned again by 180° and discharged.

System technology features:

- Three primary manufacturing processes within a minimal footprint:
  - Individual product transport and alignment of the cartridges for insertion into the rotary machine
  - Extremely accurate dosing of analytical liquids
  - Accurate processing of a sealing foil
- „Laminar flow“ for a sterile production environment

Specifications:

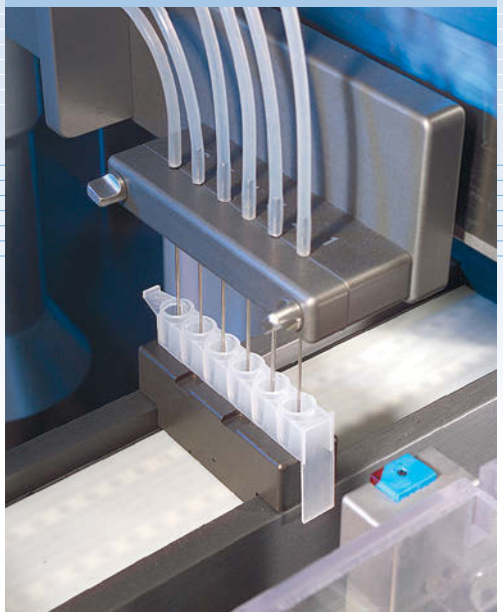
Output: 15 – 20 cartridges/min.
Filling of up to
12 cavities possible



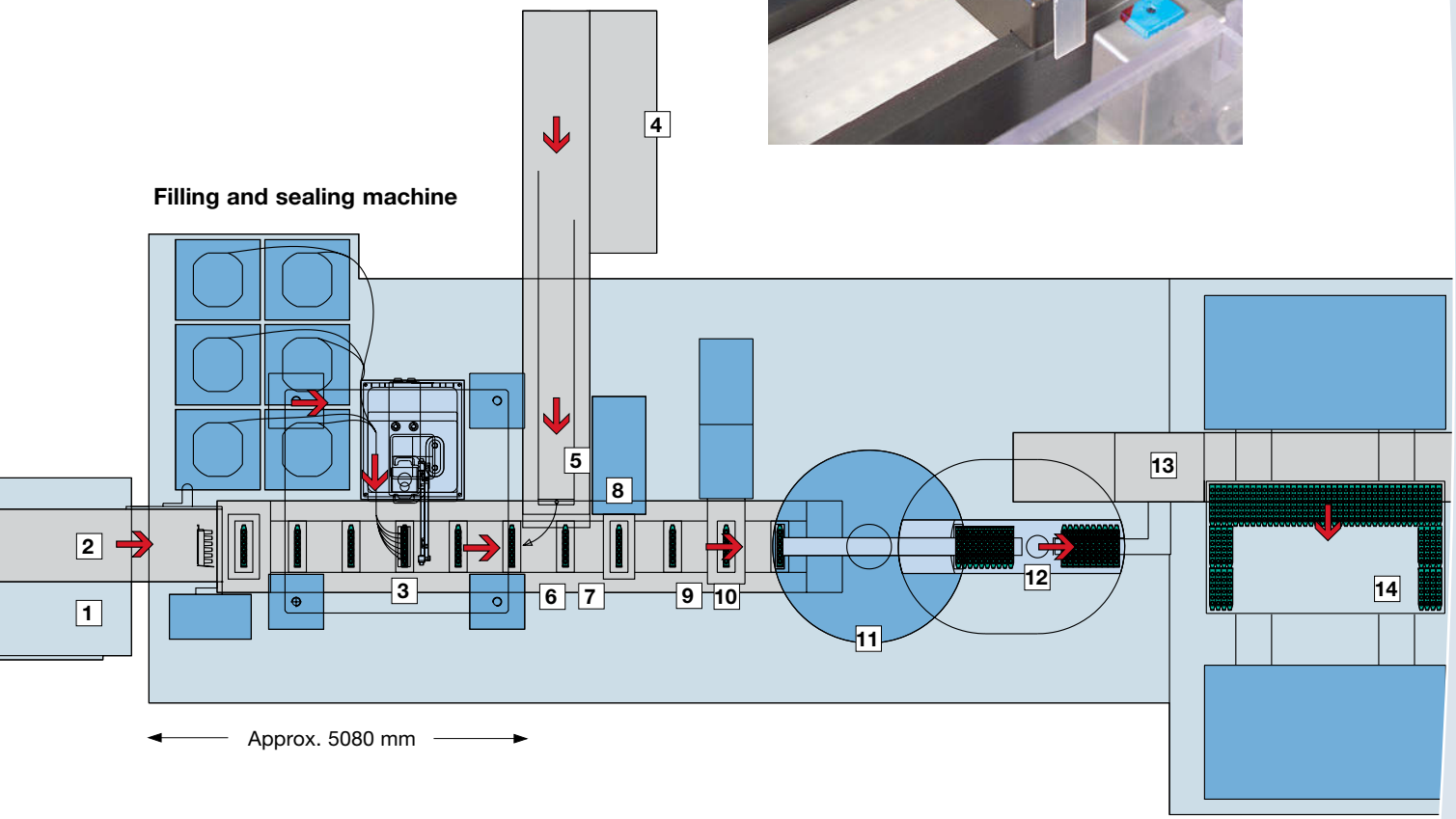
Agile:
Feeding and transferring the cartridges into the process

Precise fit:
Placing and sealing on the lid foil

Maximum precision:
Dosing of the suspension



Filling and sealing machine



Process flow

1. *Feeding strip panel*
2. *Separating strips*
3. *Reference weighing and dosing of the liquid*
4. *Foil unwinder*
5. *Foil crosscutting*
6. *Foil sealing*
7. *Foil presence detection*
8. *Foil sealing*
9. *Inkjet station*
10. *Fail part ejection*
11. *Discharging good parts*
12. *Bundling the strip*
13. *Strip turning and tray loading*
14. *Moving the tray*

Winding and packaging surgical suture material – customized technology for a wide range of product variants.

The extremely wide variety of needle shapes and sizes, as well as of thread materials and lengths, necessarily results in an equally wide range of product variants. Thus the machine designs must guarantee quick format and batch changes, both for manufacturing of the surgical suture material and for foil packaging.

Process flow for foil packaging:

The fabricated suture material is fed to the machine, packaged, checked and inserted into transport and sterilization boxes.
By sealing on a Tyvek® strip, the packaged product can be sterilized at a later stage.

Specifications for foil packaging:

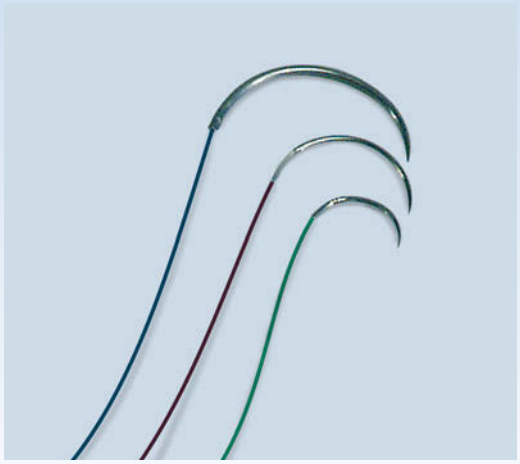
Output: 30 sheets or
240 zippers/minute

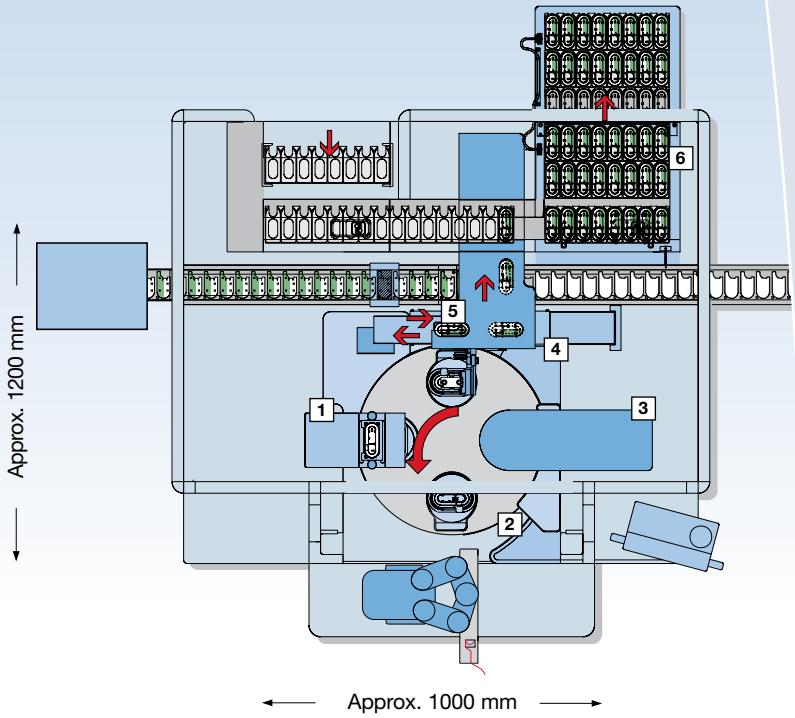
The machine design is suited to an extremely wide variety of production parameters:

- Quick tool changes enable quick adaptation to different package sizes
- Integrated control concept – from the machine controls to complex in-process controls and vision inspection systems
- Handling techniques using robot systems for flexible loading and unloading without harming the product
- Recipe management
- Three robot systems for the greatest possible flexibility
- Code readers for automatic batch change
- Inline imprinting with specific product data and direct transfer from the higher-level control system

Melting:
Heat sealing the Tyvek® strip

Illuminating:
Video inspection of the deep-drawn forms for pin holes





The efficient solution for automatic processing of suture materials within a sterile package design with Tyvek® vent.

Process flow for fully automatic winding:

Using the needle, a robot gripper arm places the thread material into the carrier holder. Then, the flexible side flaps of the zipper are mechanically opened, and then the thread, depending on the length, is wound in the zipper up to 4 revolutions.

Then, a cover sheet, which has been imprinted inline, is attached to the zipper and the fabricated product is stacked in magazines.

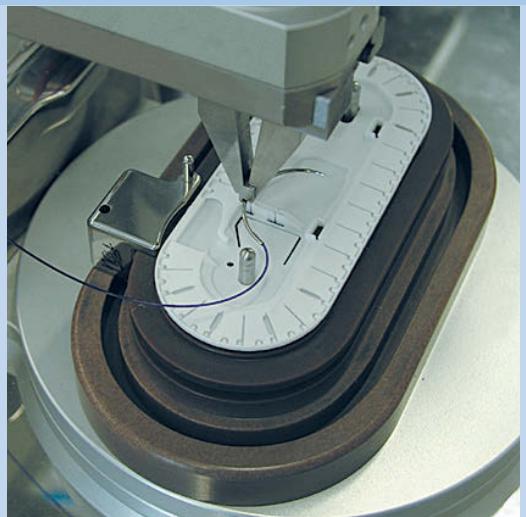
The magazines are removed manually for transfer to the sterile end packaging.

Specifications for winding:

Thread lengths:	Various lengths possible
Output:	With automatic filler, up to 25 threads/min.

Synchronized perfection:
Winding of the suture material onto the carrier

Threading the needle:
Inserting the needles and thread using a robot



Process flow for winding:

1. ***Inserting the empty zipper***
2. ***Inserting the needle and thread***
3. ***Winding the thread***
4. ***Unloading and transferring the zipper***
5. ***Feeding and attaching cover sheet***
6. ***Stacking in trays for further processing***

Packing pharmaceutical powders and bulk materials in sachets with downline cartoning.

Dosing and filling these pharmaceutical powders and bulk products take place in a Clean Room area of ISO Class 5.
A new machine concept was realised in compliance with these strict regulatory directives and regulations.

Höfliger has thus developed a new machine platform for the inline production and filling of sachets, in full compliance with the pharmaceutical requirements under Clean Room conditions.

The following features make the concept perfectly suited to expanding the product range by adding patient-specific active ingredient quantities and size variants:

- Ability to vary the setting of the dose quantity
- Processing different fill media from different dosing systems
- Integrating two dosing units (two active ingredient components, with different compositions can be combined in a single sachet and 100% completely checked)

System technology features:

- Complex handling and joining processes
- Online imprinting
- Clean Rooms-compliant technology
- 100% complete weighing/checking of the powder quantity

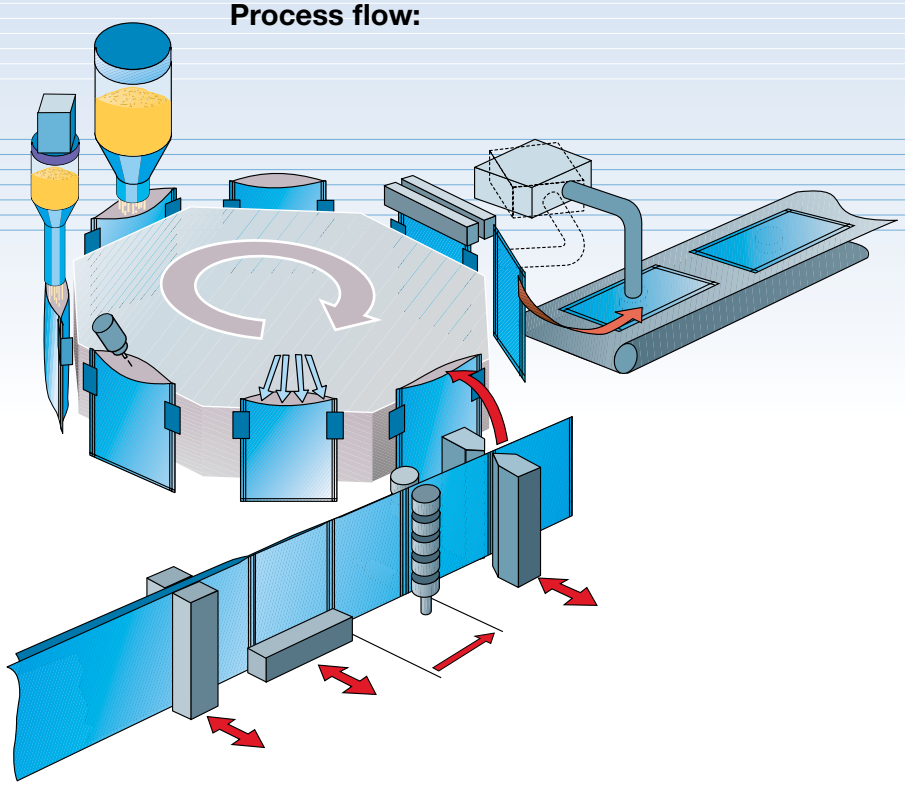
Specifications:

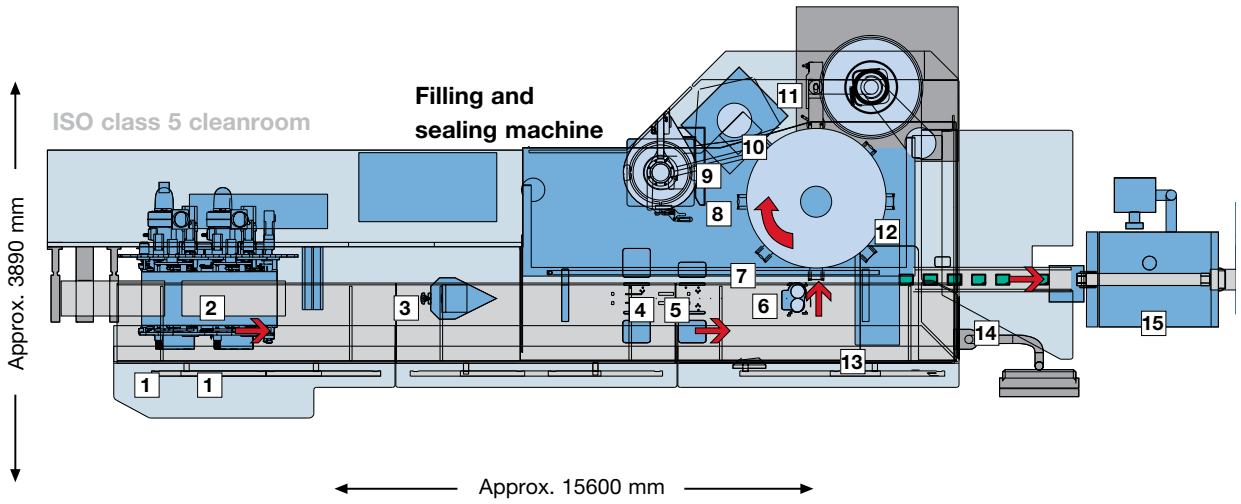
Output: 80 to 300 sachets/min.

Clean cut:
Cutting the sealed foil into sachets and inserting them into the rotary machine

An all-around success:
All of the most important process steps, such as dosing, take place in the rotary machine

Process flow:

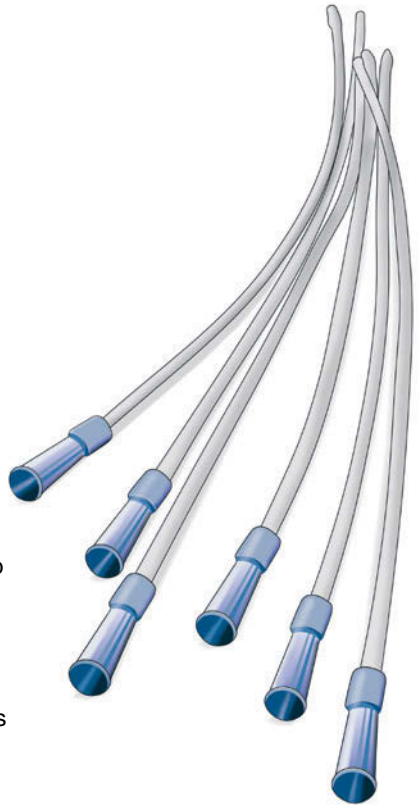




Process flow

1 *Packaging material unwinder*
2 *Foil imprinting*
3 *Foil web folding*
4 *Contour sealing*
5 *Cooling, cutting the easy-tear notch and stamping*
6 *Web advance and cutting*
7 *Opening the sachets using air*
8 *Opening check*
9 *Product dosing 1*
10 *Checkweigher*
11 *Product dosing 2*
12 *Top sealing*
13 *Fail sachet rejection*
14 *Good sachet discharge*
15 *Leveling*

System platform for manufacturing contoured foil packages for medical products.



This catheter, in a perforated single-product pack, is used in everyday medical applications. Based on a modular production line platform, Höfliger engineers have designed a line tailored to the customer's production peripherals for manufacturing contoured aluminum packages for catheters.

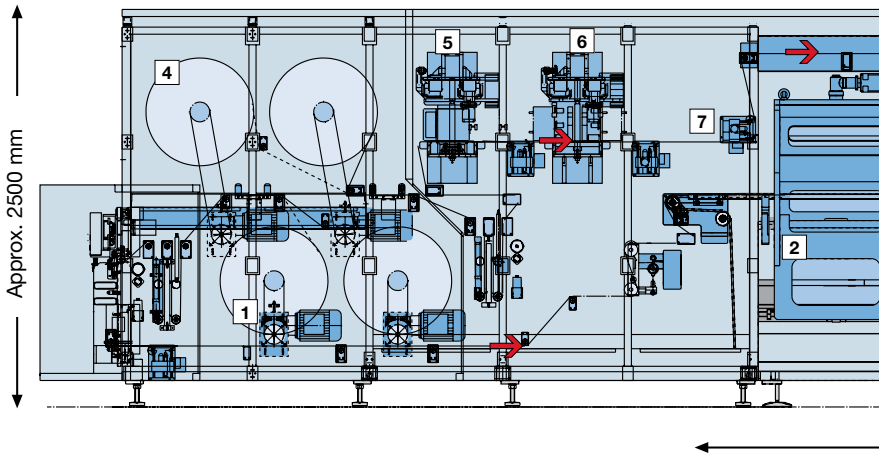
Processing different tube diameters and lengths places high demands on the flexibility of the line, as the packages come in a variety of sizes, which must be labeled accordingly. Cold forming gives the bottom foil its contoured shape.

The separately unwound lidding foil is labeled inline by hot embossing and a thermal transfer print.

After the sealing process an opening is cut into the package by means of specific cross-section. The catheters are transferred from production using a pick-and-place unit and inserted into the package.

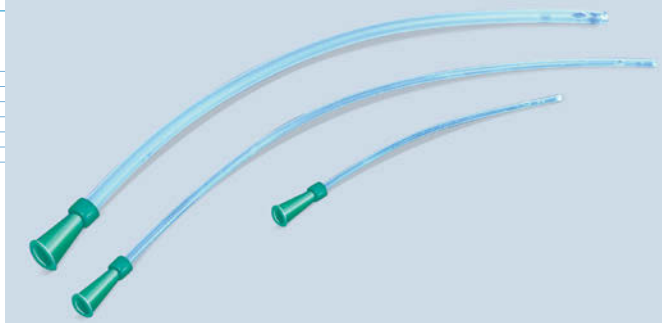
After the rest of the packaging seams are sealed, labels are applied to the top of the package for easier opening.

Then, the foil web is separated into customer packs. In addition, the packages are also perforated longitudinally to allow individually packaged catheters to be torn off.

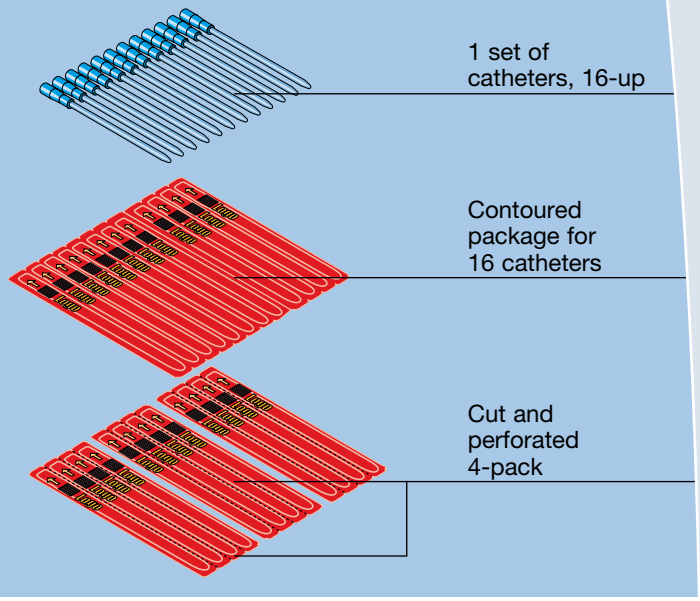


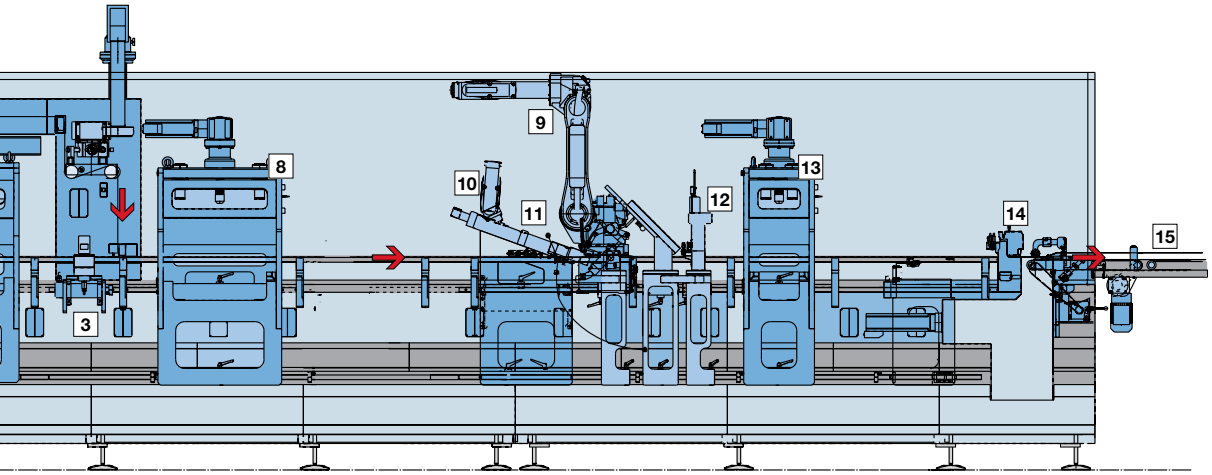
Cool indeed:
Cold forming of the catheter package

Wide variety:
Catheters are produced in an extremely wide variety of sizes



Structure of the contoured package:





Process flow

1. *Bottom foil unwinder*
2. *Molding the bottom foil*
3. *Hole detection*
4. *Lidding foil unwinder*
5. *Hot embossing of company emblem and logo*
6. *Imprinting of product data*
7. *Video inspection*
8. *Partial sealing of bottom and lidding foil*
9. *Pick-and-place infeed*
10. *Catheter infeed*
11. *Catheter transfer to contoured package*
12. *Catheter presence detection*
13. *Heat sealing*
14. *Longitudinal cutting and perforation*
15. *Product outlet*

Pharma Services – Over 450 m² of laboratory space for tests under controlled climatic conditions.

Today, innovative companies use strategic alliances to keep development costs and time to market to a minimum. Harro Höfliger is the ideal development partner for product and process-specific systems. For example, as a starting point for a joint powder project, Harro Höfliger offers a comprehensive analysis of the products; based on this, a preliminary selection of the dosing system can be made. Then, in our in-house laboratory, under controlled conditions – together with the customer – the selected system can be further optimized with original product.

At the end of several development stages from the pilot system to the production line, it is possible to save time by using the qualified machine at Harro Höfliger to create stability samples and to operate the entire system with verum under production conditions.

Service & Consulting:

- ➜ Analysis and classification of powder preparations
- ➜ Process development and optimization
- ➜ Support in recipe and packaging material development
- ➜ Qualification and Clean Rooms training sessions

Tests under controlled climatic conditions:

- ➜ Testing customer-specific experimental setups (POPs)
- ➜ „Breaking in“ systems using real product (verum) instead of placebo
- ➜ Optimizing process parameters and machine settings
- ➜ FAT and qualification runs in the same conditions as later production conditions

The customer benefits of comprehensive service:

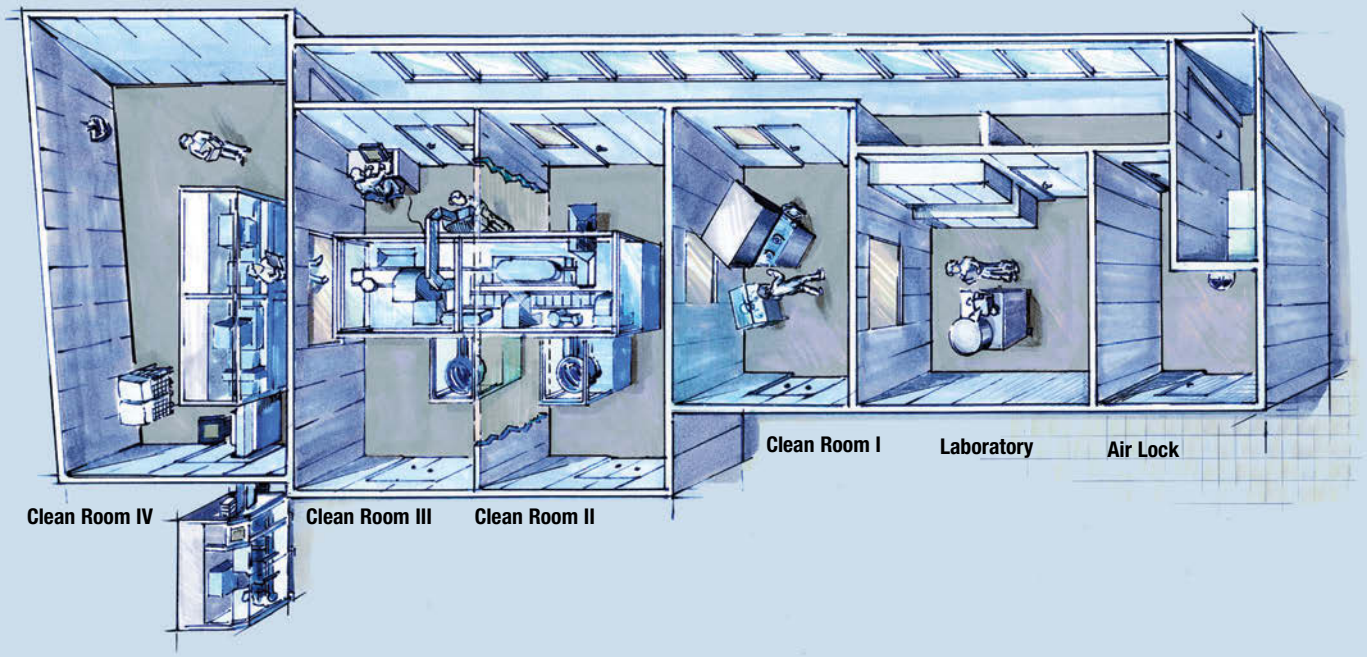
- ➜ High efficiency thanks to direct availability of development and production departments
- ➜ Time savings, for example by creating initial stability samples onsite
- ➜ Well-trained team with technical pharmaceutical skills and knowledge:
  - Pharmacists with many years of industry experience
  - Engineers in our in-house development department
  - Specialists in the qualification department
  - Experienced assembly and service personnel
- ➜ Availability of machine modules and test equipment for:
  - Dosing tiny powder quantities
  - Forming/sealing of innovative foils
  - Feeding/dosing of solid and liquid components
  - Laminating and delaminating
  - Punching and cutting
  - Molding

Ideal conditions:
Production trial runs in the climate-controlled chamber

Specifications production suite:

Area:	42 m²
	L x W x H (mm)
	8000 5250 3400
Ambient conditions:	17 – 22°C
	15 – 40% relative humidity

The 4 Clean Rooms and the pharmaceutical laboratory open up new possibilities.



Specifications Clean Rooms:

Space:	approx. 300 m^2 4 Clean rooms 1 Laboratory
Environmental conditions:	18 – 22°C 20 – 60% relative humidity
HVAC:	- Approx. 10 x air exchange - Final air filtration (H14) - Control of air pressure difference - Individual regulation/control of the clean rooms - Central monitoring of temperature, relative humidity and air pressure difference

Highly frequented:
Many of our customers already use the Clean Rooms and have voiced their complete satisfaction

Harro Höfliger

[ALL YOU NEED]

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