

BABY PHILL

COMPACT ASEPTIC VIAL FILLING SYSTEM



ALL IN ONE | PLUG & PLAY



Simple installation



Compact dimensions



Easy to use



Optimal Cost/Quality



Fast changeover



PHARMA



CELL&GENE THERAPY
ATMP



COMECER

AN **ATS** COMPANY

The BABY PHILL is a full concept solution, for small batches liquid production.

The BABY PHILL concept is an **ALL IN ONE**, filling-stoppering & capping machine. Monoblock solution, including the Class A isolator and the no touch transfer section for opening of the trays bags.

BABY PHILL is conceived for any customer who need a Plug&Play technology who require a short product placement on the market.

The 100% IPC control of the dosing guarantee a high quality of the final product.

The newest model of BABY PHILL has seen a deep redesign, with increased speed up to 2,500 vial/h (based on 10ml/10R and 8ml filling volume)

BABY PHILL is designed for filling of RTU (ready to use) vials in trays.

BABY PHILL can also be connected with small vial washing machine and depyrogenation tunnel for bulk production.



KEY PERFORMANCE VALUES FOR FILL FINISHING



Short lead time
Pre-Designed
Fast manufacturing



Proven Technology
Best In Class - GMP Guidelines adherence
Robustness Isolators & Filling machine



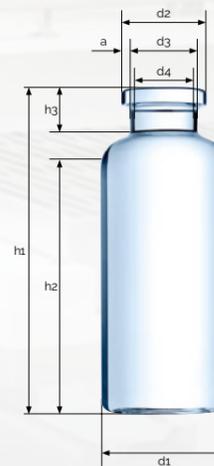
Small Footprint
Compact Modular design
Easy to replicate also in limited spaces



Flexibility
Suitable for different Products
Suitable for different Process

PRODUCT & PACKAGING MATERIAL

- The BABY PHILL has been specifically designed for Aseptic Liquid Filling
- It can be used for small batches, with RTU Vials in trays
- As alternative it can be linked to Washing machine & Depyrogenation tunnel, for medium size batches
- Automatic or semi automatic loading and accumulation of vials on rotating table
- Wide range of vials can be adopted, with minimum format changes and short time impact.



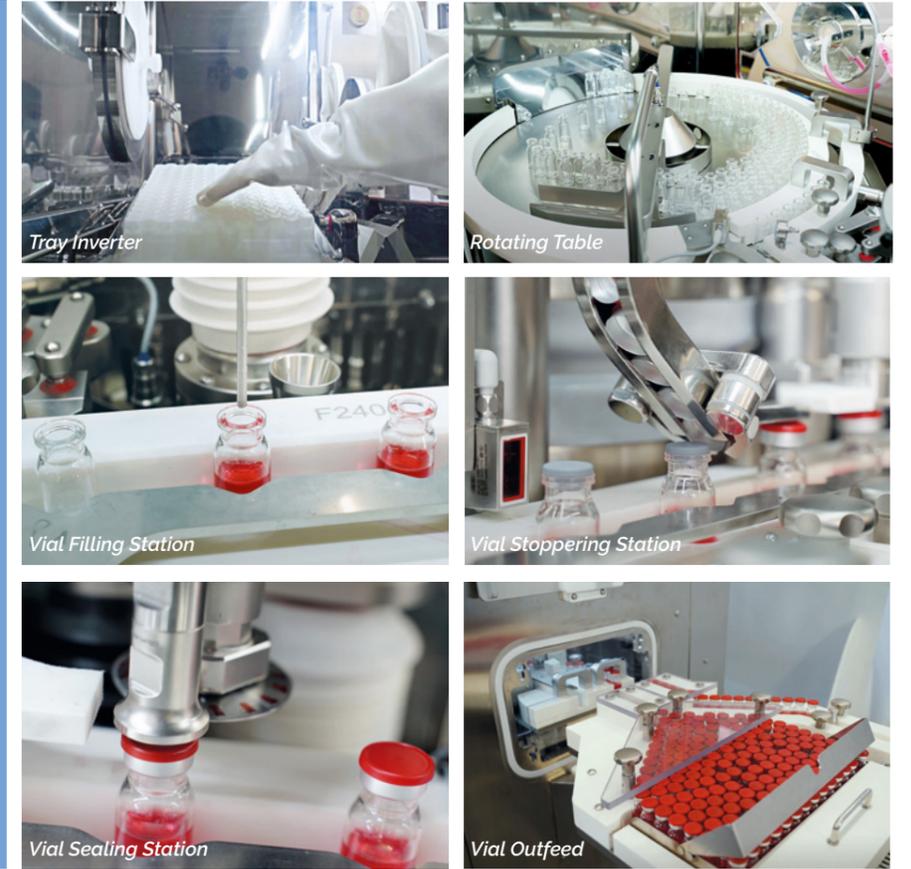
Vial size	Overflow capacity [ml]	a [mm]	d1 [mm]	d2 [mm]	d3 max [mm]	d4 [mm]	h1 [mm]	h2 min [mm]	h3 [mm]
2R	4	1	16	13	10.5	7	35	22	8
4R	6						45	32	
6R	10	1.2	22	20	16.5	12.6	40	26	8.5
8R	11.5						45	31	
10R	13.5						45	30	
15R	19	30	40	20	16.5	12.6	60	45	9
20R	26						55	35	
25R	32.5						65	45	
30R	37.5						75	55	
50R	62	40	40	20	16.5	12.6	73	49	10

BABY PHILL HIGHLIGHTS

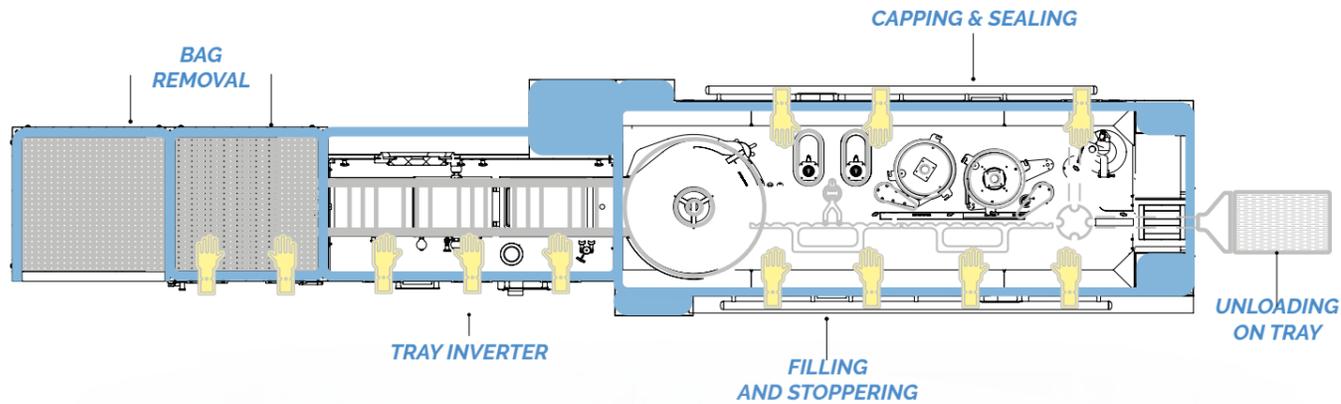
-  Modular platform for automatic filling of small batch
-  IPC 100% check weighing
-  Aseptic environment (Grade A) - ISO5
-  No Vial - No Fill system
-  Containment barrier for Highly Potent drugs
-  Flexible closure system compatible with Stopper / AluCap / PushFitCap
-  Filling speed: up to 40 pcs/min
-  Reject station (camera for stopper/caps)
-  Filling accuracy: +/- 1%
-  Plug and Play

INTEGRATED SOLUTION WITH ISOLATOR BARRIER TECHNOLOGY

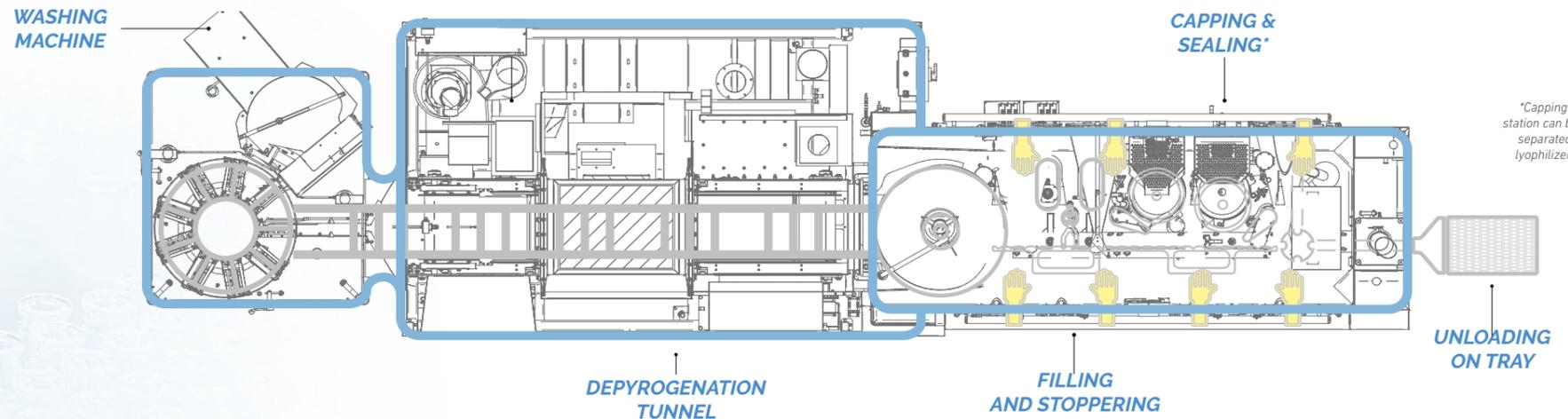
- Possibility to operate in Positive or Negative pressure regime (monitoring & alarms)
- Airborne Particulate cleanliness classification: ISO 5 for internal environment
- Laminar Air flow system (Zero Frame) for 0.45m/s
- HEPA or ULPA filtered air supply
- Recirculation up to 70% of the air flow
- Continuous Monitoring: Diff. Pressure, Temp, RH%
- Preliminary CFD Engineering Study.



CONFIGURATION FOR PRE-STERILIZED VIALS



CONFIGURATION FOR NOT STERILIZED VIALS



illuminate™
MANUFACTURING INTELLIGENCE

Release the full potential of Baby Phill with illuminate™ Manufacturing Intelligence. Use real-time machine performance data to pinpoint where to focus efforts to reduce downtime, maximize line throughput, improve product quality, and make sustainable production improvements.

*Capping and sealing station can be supplied as separated station, for lyophilizer integration

BAG REMOVAL & NO TOUCH TRANSFER

- ORABS for Debagging & No-Touch-Transfer, or
- Vial Washer & Depyrogenation Tunnel
- Fast Decontamination Chamber
- Easy waste bag management
- Tray Inversion System
- Manual or Automatic feeding.



VIAL FEEDING & ROTATING TABLE

- Manual feeding from NTT, or direct link with Washing machine & Tunnel
- Minimum and max load sensors
- Central opening for better air flow, less turbulence
- Servo driven, adjustable speed
- Easy change over of format parts
- Vial trap and reject station for upside-down vials
- Walking beam entrance with vial optical counter.



FILLING & STOPPERING

- Linear Transport System, walking beam
- Peristaltic or Volumetric Piston Pumps, or both
- No Vial – No Fill function
- 100% IPC with Load Cells (tare & gross)
- Nitrogen Injection, during and/or after filling
- Pick & Place Stoppering System, with stopper presence detection
- Independently Servo Driven Filling function
- 1 + 1 Filling pump, for double shot filling (large volume > 20ml)
- Independent filling volume per each pump, adjustable from HMI
- Easy change over, from piston to peristaltic (both systems)
- Diving needle holder, bottom-up filling available
- Priming function included, with less product loss (fill to weight).



CAPPING AND SEALING STATION

- Suitable for Flip-off, Tear-Off or Press-on Caps
- Idle Ring sealing System, less particles generation
- Partition wall between filling-stoppering & capping station, with mouse hole
- Cap presence detection No Vial – No Stopper – No Cap function
- Suitable for all format size, 2R-100R
- Pressure control during capping available as option.



REJECT STATION & EXIT ON TRAYS

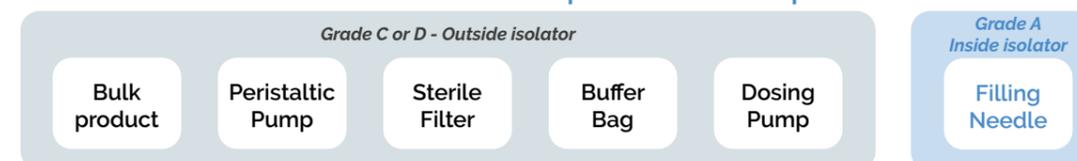
- After Cap sealing an indexing star wheel separate the good vials from the sample vials and the eventually rejected vials (no stopper; no cap; out of tolerance)
- The vials are directed to a dedicated RTP port, connected with waste bag or a sampling container
- The good product is accumulated at the machine outfeed on a removable tray.



A REAL SMART APPROACH

Thanks to its modular design, the filling line is available with different possible configurations in order to fulfil the requirements of different production needs.

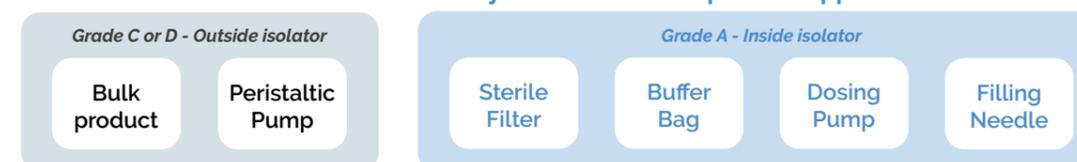
Preferred solution for suspension or viscous products



Preferred solution for small batches



Preferred solution for cytotoxic and multi process applications



The rotary intermittent washer is a fully automatic, intermittent motion, rotary washing machine, suitable to wash and clean brand-new containers, such as vials.

The rotary washing machine is developed to handle vials in order to permit the internal and external decontamination of the containers.

OPERATING CYCLE

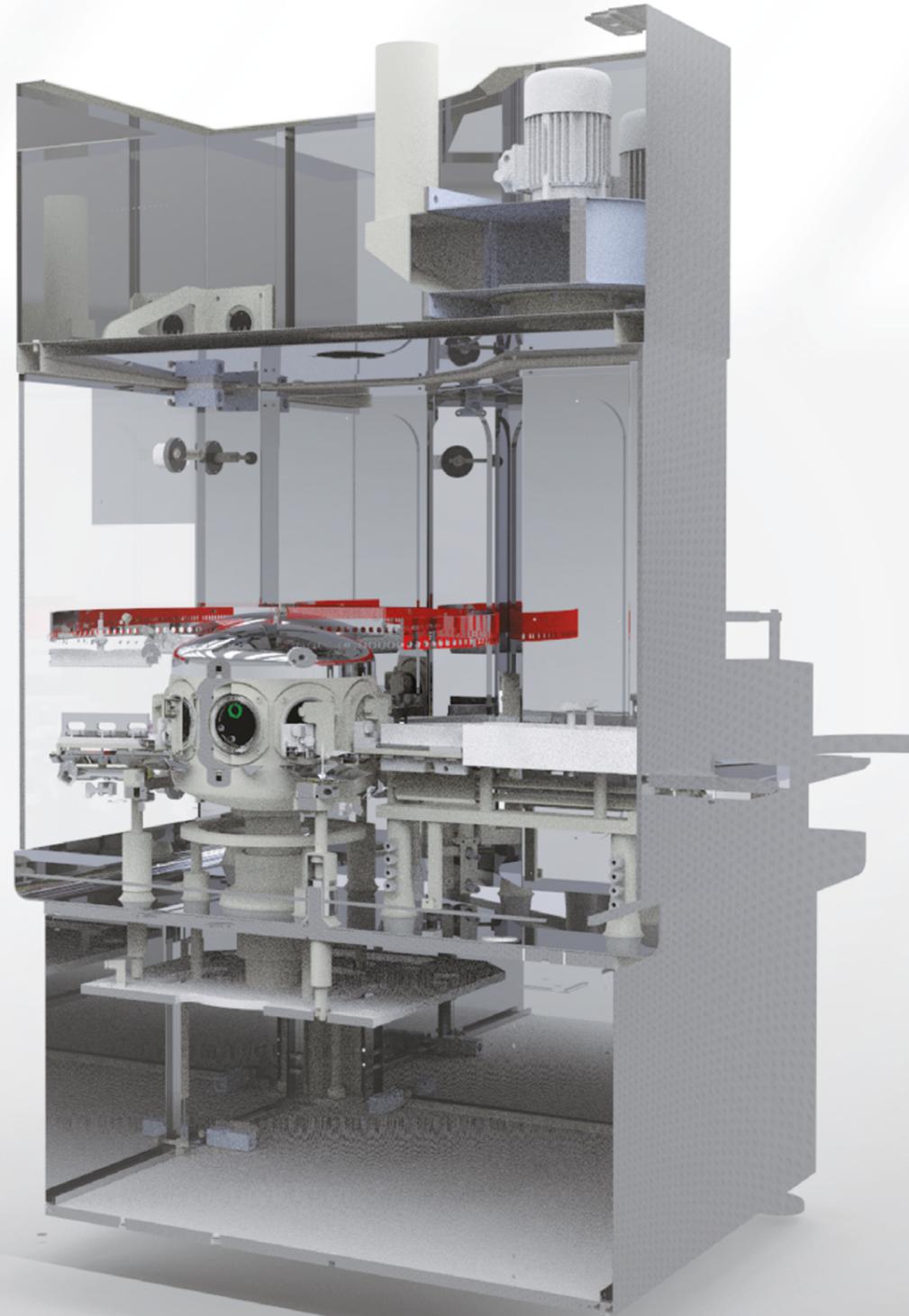
The loading section is composed by a dead plate, directly connected with a rotary table, here the operator can push the vials from the plastic tray to the loading station.

The washing system has plunging needles with the possibility of varying the phases and times of the fluid dispensing.

WASHING CYCLE

The rotary intermittent washing machine is proposed with a standard washing cycle is completely modifiable in the media order/type and programmable as washing times depending on items to treat and/or availability of washing media.

1. Pincers loading
2. Blowing with filtered compressed air - INT
3. Washing (PW or WFI) - INT/EXT
4. Blowing with filtered compressed air - INT
5. Washing (PW or WFI) - INT
6. Blowing with filtered compressed air - INT/EXT
7. Washing (WFI) - INT
8. Blowing with filtered compressed air - INT
9. Dripping and unloading.



Direct water station

Direct water is used in the final rinsing/washing steps, both internal and external.
The pressure switch with alarm is used to control that the direct water pressure before needles is always enough.
Given the limited consumption, water is disposable. It's possible to adjust the washing time of each station.

Compressed air station

Dry and oil free compressed air (customer supplied) is used to dry the vials between washing steps and before the discharge.
The air is filtered by 0.22 micron hydrophobic cartridge (by customer). The manometer before filter (10") allow to estimate the filter efficiency. The pressure switch with alarm is used to control that the compressed air pressure before needles is always enough.

Automatic draining

The scope of this operation is to avoid stagnating water for a long time in the idle washer. This operation is automatically carried out at the end of production.
The system is composed by valves located in the lowest points of the pipes, tanks and pumps.
The drain valves, equipped with pneumatic actuators, are automatically operated by PLC. It's possible to execute the automatic cycle DIP, to dry the pipes with sterile air.

Depyrogenation tunnel guarantees the continuous sterilization and depyrogenation of glass containers such as vials, type R or type H, by means of filtered high temperature air (max 350°C) in laminar flow conditions.

The air laps vertically the containers, with uniform increase of the heat, achieving a shorter time sterilization process.

The Tunnel consists of three zones:

INFEEED ZONE

A vertical laminar flow protects the tunnel entrance from the external contamination, and avoids the coming out of the hot air.

The air is prefiltered, HEPA filtered and then flows over the vials in laminar condition, at a speed adjusted around to 0,4 - 0,5 m/s, with air speed measurement.

DEPYROGENATION ZONE

The chamber is made by stainless steel shell, externally protected by approved insulation materials (ceramic).

The tunnel is provided of a variable number of HEPA filters for high temperature (max 350°C).

In the depyrogenation chamber the air is fully ricirculated.

For each filter, a fan placed in the bottom of the tunnel, sucks the air out from under the conveyor belt (in the coolest point of the recirculation loop) and blows the air towards the heaters, placed along the supply duct, directly on the equalization system, through the filters and, finally, on the vials.

In this way there is a pressure increase in the air flow just for the temperature increase, with less efforts in the fan functioning and a longer device lifetime.

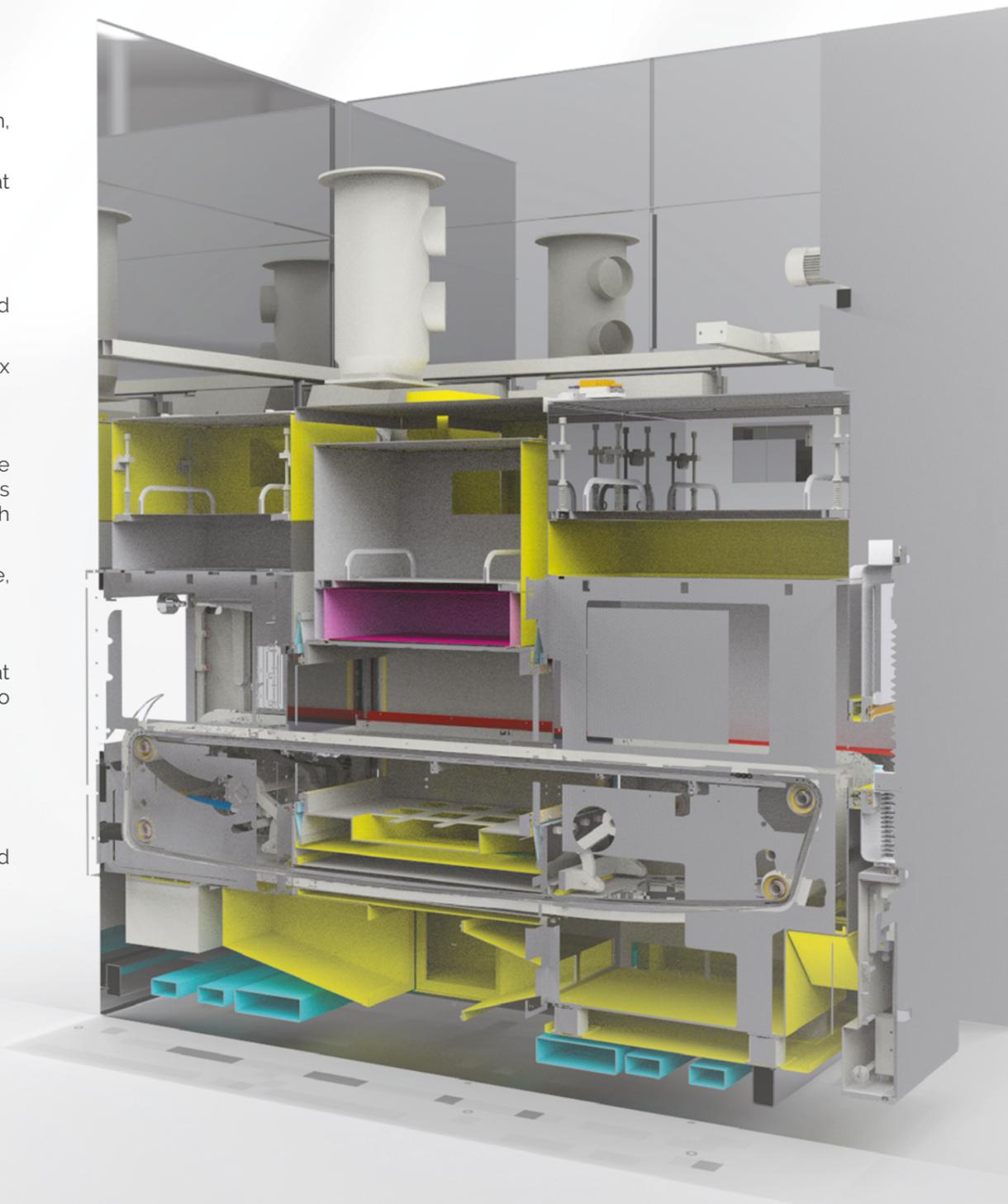
The air speed is adjusted and controlled with optimal unidirectional flow conditions.

The max temperature set-point is 350°C. In order to save energy and to not overheat the glass, each type of vial is processed with the suitable time/temperature setting to achieve the desired depyrogenation degree.

COOLING ZONE

In the cooling module the air is sucked from the room.

The air is first pre filtered, HEPA filtered and the air speed is adjusted and controlled with optimal unidirectional flow conditions.



Heaters

The heaters are installed on the side of the sterilizing chamber.

The air speed through the heater is designed in order to have the temperature of the heaters surface as low as possible allowing them a longer life.

Filters

The HEPA filters have an efficiency of ~99,997% (H14) on 0,3 µm particles. The HEPA filters of the depyrogenation chambers have an efficiency of ~99,99% on 0,3 µm particles (H13).

Closing system

At the entrance and the exit of the tunnel, two motorised doors will lower down to close the machine ends, when the closure is complete, the gaskets are pressurised to guarantee the perfect tightness and to perform the cooling chamber sterilisation cycle (optional).

Conveyor belt

The conveyor belt is made of AISI 304 stainless steel (option AISI 316) connected with vertical wings at the sides to avoid friction between vials and the walls of the tunnel.

What makes BABY PHILL special?

- Extremely reduced footprint, so it can be easily fit in your existing lab
- Plug-and-play design, suitable for fast installation and start production
- All-in-one system, so all key features are included as standard
- Different dosing systems available, peristaltic or piston pumps
- Best integration within isolation technology, as Comecer designs and manufactures both
- Fast change over between batches, to make the most of your investment and time
- Possibility to integrate and connect with Freeze Dryer System
- Outstanding value proposition, in terms of flexibility, overall quality, price and readiness on the market.

Technical data

Material

Shell structure	AISI 316 L
Stainless steel finish	external: Scotch-Brite internal: Mirror-Brite

Air classification

Filling chamber	grade A (after decontamination)
Tray Inversion chamber	grade A (after decontamination)

Working internal pressure

Filling chamber	50-100 Pa
Tray Inversion chamber	25-50 Pa

Filters

Filling chamber	H14 inlet and outlet
Tray Inversion chamber	H14 inlet and outlet

Make up air flow rate	945 m ³ /h
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Overall dimensions complete configuration (w x d x h)	7160 x 1220 x 3095 mm
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Weight	~ 6500 kg
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HMI Software	GAMP5 Compliant CFR 21 part11 Compliant
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Utilities requirements

Compressed air	6 bar, 25 nL/min
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Power supply

Filling Machine	400V (3Ph+N+PE) 50Hz TN-S 480V (3Ph+N+PE) 50/60Hz 20A
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VPHP generator	230V (1Ph+N+PE) 50Hz TN-S 208V/120V (2Ph+N+PE(GND)) 60Hz
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Installed power	8900 W
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Comecer is an Italian company based in Castel Bolognese (Ravenna) and established in the mid-1970s.

Comecer develops and manufactures high-tech systems in the field of aseptic processing and containment for the pharma industries, specialising in isolation technology solutions for regenerative medicine and tissue engineering.

Today Comecer is part of ATS Life Sciences Group, a group of companies having expertise to deliver turnkey solutions from API production to packaging.



a COMECER company

DF, being part of Comecer, is an Italian company based in Siena since 1987 specialized in supplying solutions for aseptic filling in the pharmaceutical industry.

Today DF is a Comecer company and one of its main production sites for pharma equipment.



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