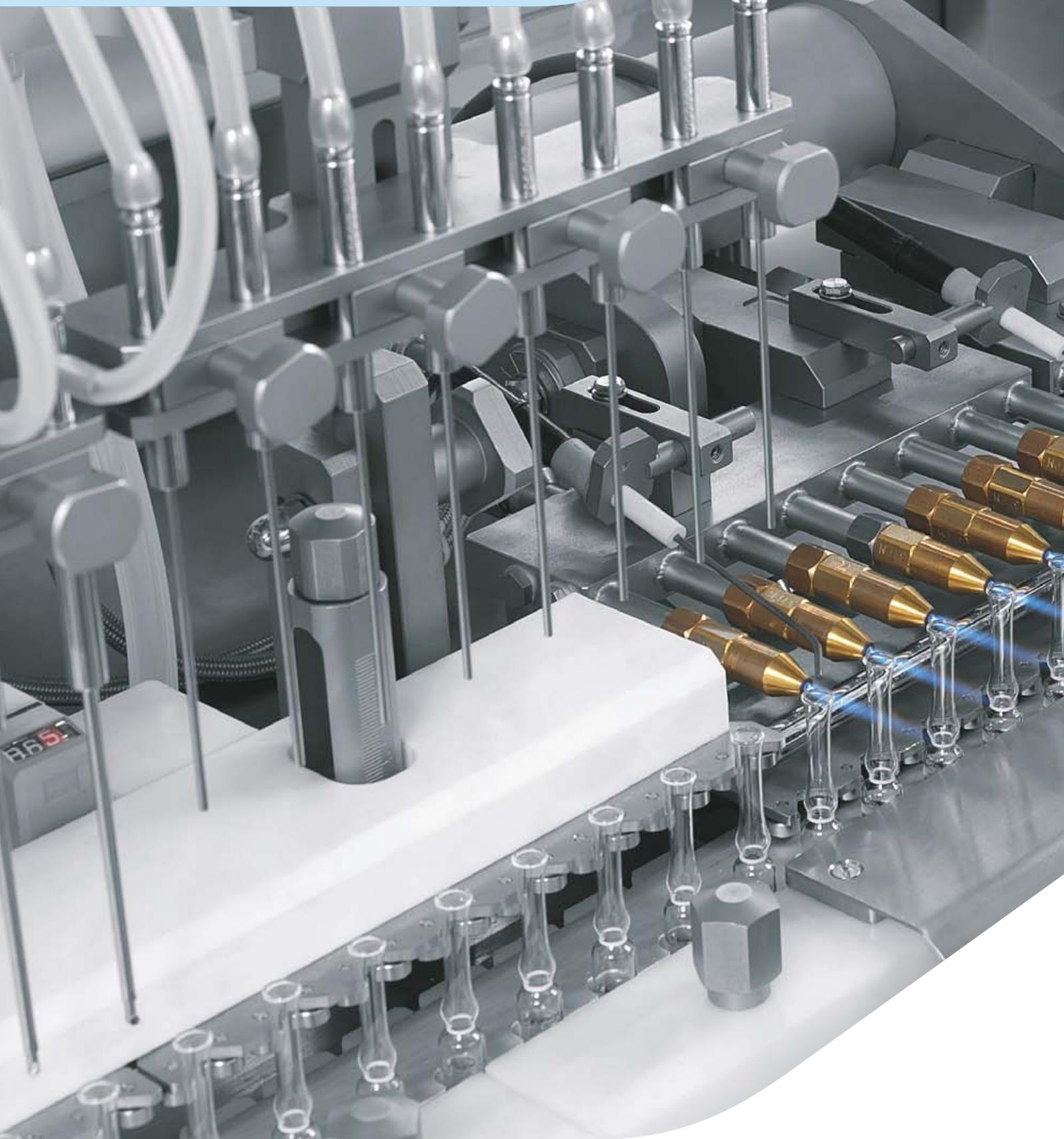


# AMPOULE FILLING

AMPOULE FILLING & SEALING MACHINE



# AMPOULE IN-FEED

## ■ MACHINE DESIGN COMPLIANT WITH GMP AND FDA REGULATIONS

STERIFILL ampoule filling and sealing machine is a linear filler suitable to process 4, 6 or 8 ampoules at each machine cycle, according to the output required.

The machine has been designed following the criteria typically needed in aseptic environments, such as, reduced dimensions, the geometry facilitating the unidirectional airflow, high ergonomic level, slim design. The IMA LIFE expertise in the aseptic filling technology is the background of this new ampoule filler which can satisfy even the most stringent requirements of the pharmaceutical industry.

The very accurate constructive concepts allow the machine to condition ampoules at high speed: up to 400 ampoules/min and the possibility to handle both open and closed ampoules.

## ■ AMPOULE IN-FEED

The ampoules are fed to the machine by a conveyor belt filled from the upstream de-pyrogenating tunnel (or supplied manually by the operator if it is a "stand alone" machine).

A large transfer star-wheel introduces the ampoules to the in-feed scroll driven by brushless motor, which provides for ampoule spacing. From here, another intermediate star-wheel transfers the ampoules on the comb transport system.

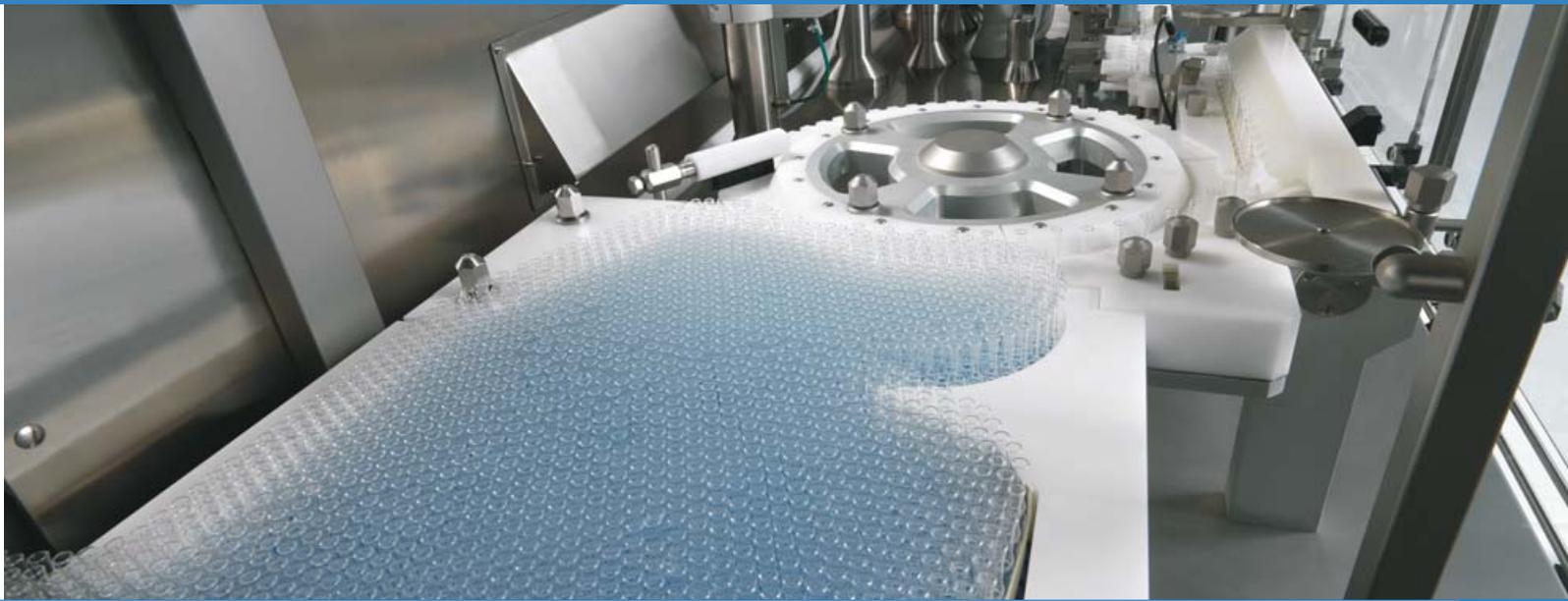
## ■ EASY TO OPERATE

The machine is operated from a central HMI where all production data are recalled.

## ■ IN-LINE OR STAND-ALONE

If part of a complete processing line, whether a direct connection with the de-pyrogenating tunnel is foreseen, the ampoules are automatically loaded onto the stainless steel in-feed tray and from here, through a star-wheel conveyed to an in-feed scroll for further spacing and transport to the in-line transport system.





# FILLING & SEALING

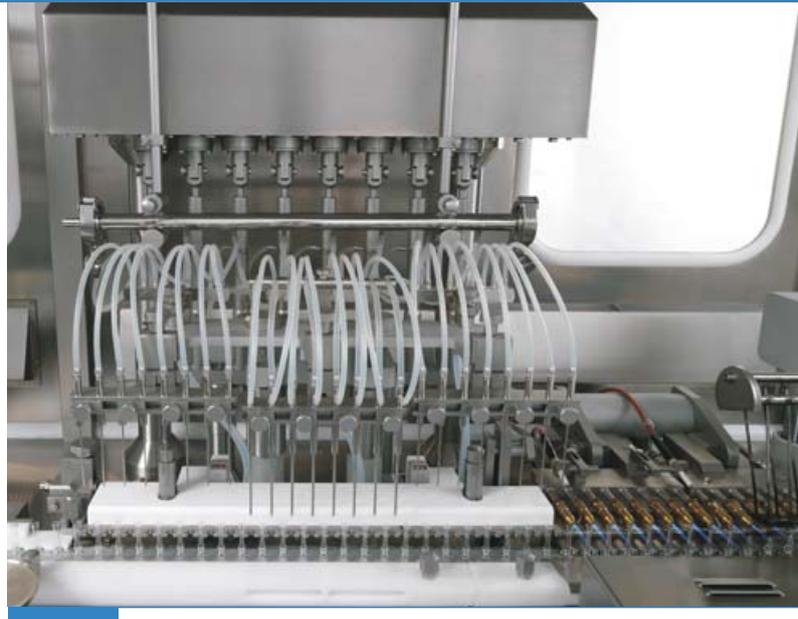
## ■ DOSING STATION

The dosing station is equipped with 4, 6 or 8 rotary piston pumps either in st.st. or in ceramic. The nozzle carrier height is automatically adjustable by brushless motor. Other types of filling systems, typical of the aseptic operations such as Time/Pressure or Peristaltic Pumps, are also available. The filling volume to be dispensed is automatically defined by the machine, according to the recipe stored in the HMI.

The machine is equipped with brushless motors which make it very flexible and versatile.

- Nozzle carrier height adjustment
- Filling needle movement
- Filling pumps individual adjustment
- In-feed scroll motion
- Main machine drive
- Sealing gripper height adjustment

Machine equipped with "NO AMPOULE – NO FILL" system.



## ■ A MACHINE SUITABLE FOR RABS

The very compact machine (1000 mm) allows the machine to be operated from one side only, thereby making it suitable for wall installation. The slim design and the streamlined processing area create the ideal conditions to work either under LAF - Laminar Air Flow or contained by a R.A.B.S.

## ■ ACCURATE DESIGN & ERGONOMIC CONCEPT

Built according to cGMP guidelines the machine is very easy to operate and features an excellent cleaning accessibility. All product contact parts are made out of AISI 316 L st.st. Quick change over is essential when working with different ampoule sizes. On STERIFILL the operator can carry out the changeover very quickly and without the need of tools.

## ■ HIGH VERSATILITY

The STERIFILL Series of ampoule fillers consists of 3 basic machine versions with 4, 6 or 8 filling nozzles to meet even the most demanding production capacity. Output ranges from 150 to 400 ampoules/minute - with ampoule size from 1 to 25 ml.

STERIFILL can be equipped with CIP/SIP systems, particularly advanced and effective, provided with programmable automatic cycle, with no need for components removal.

The system ensures no product contact parts need to be removed from the machine. All parts are filled with the suitable cleaning media, rinsed and steam - sterilized in - situ.

WHEN NECESSARY THE MACHINE CAN BE EQUIPPED WITH AN ADDITIONAL OPENING STATION FOR DOMED CLOSED AMPOULES. WITH THIS OPTIONAL FEATURE THE AMPOULES WILL BE OPENED BEFORE. THE OPENING STATION IS OPERATED BY GAS BURNERS.



#### ■ AMPOULE TRANSPORT SYSTEM

The further transport of the ampoules throughout the working process is gentle by means of a comb which hold the ampoules from the body in order not to damage them. The in-line transport systems moves 4, 6 or 8 ampoules at a time, positioning them under the filling and sealing stations. The transport system driven by is also brushless motor.

**On demand, nitrogen gas purging to prevent contamination of delicate products is available before, during and after filling and during the sealing operations.**

#### ■ SEALING STATION

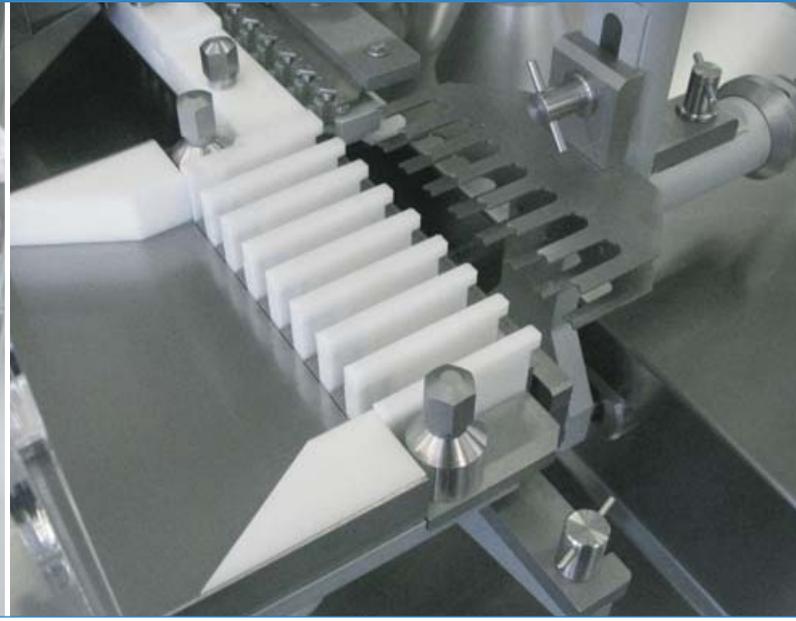
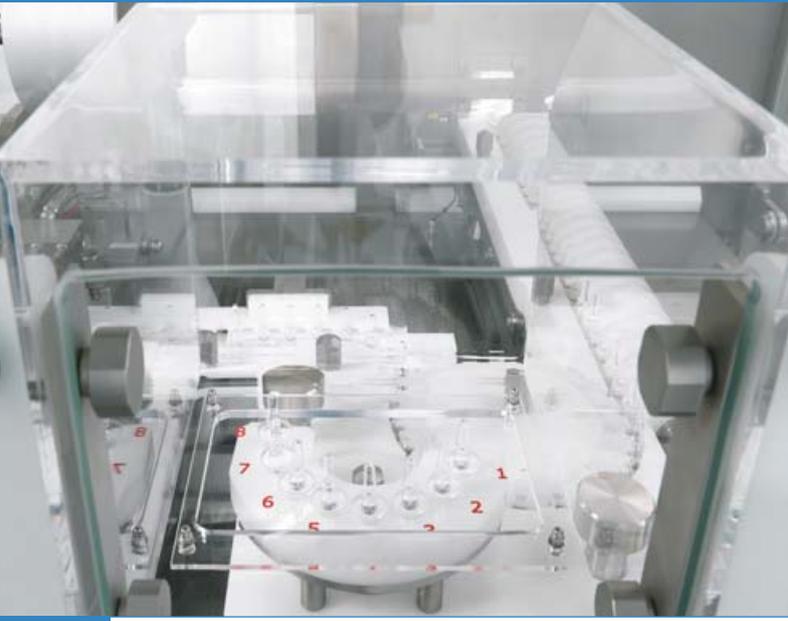
Once the ampoules have been filled, they will be transferred under the pre-heating station before being finally sealed. The two stations have two different burning temperatures. **The burning time is adjustable according to the ampoules glass thickness and the flames can be electronically started-up (optional).**

The ampoules are sealed by welding the glass and the ampoules glass trims are then removed by means of very gentle grippers. The grippers driving mechanism is fully closed and no cables are exposed on the burning station. The ampoules rotate during the entire sealing process.

The mix of fuel gas and oxygen produces a constant burner flame. The gas flow can be adjusted separately for the two sealing stations.

**The machine is also supplied with the gas shut off system in case the flames go out.**

# OUT-FEED AND SAMPLING



## AMPOULE SAMPLING STATION

An additional station for in-line non destructive sampling can be installed on request. The operator will manually take the ampoules for further inspection (check weighing glass cracks).

## COMPLETE PROCESSING AND PACKAGING LINE

STERIFILL ampoule filling & sealing machine constitutes the core of fully integrated processing lines. IMA LIFE design and develop complete aseptic processing lines, starting from ampoule washing and de-pyrogenating, through filling & sealing, up to the final labelling and secondary packaging of the product.

The ampoule fillers of the STERIFILL Series are equipped with safety micro-switch devices on the glass hood, to block the door opening after the flames have been started up.

GAS AND OXYGEN SAFETY VALVES AND EXHAUST FUMES ASPIRATION ARE A STANDARD FEATURE IN THE STERIFILL SERIES OF AMPOULE FILLERS, AS WELL AS REINFORCED PTFE HOSES AND SPECIAL FASTENINGS FOR GAS/OXYGEN CIRCUIT.

A COMBI VERSION IS ALSO AVAILABLE TO MATCH AMPOULE AND VIAL FILLING.

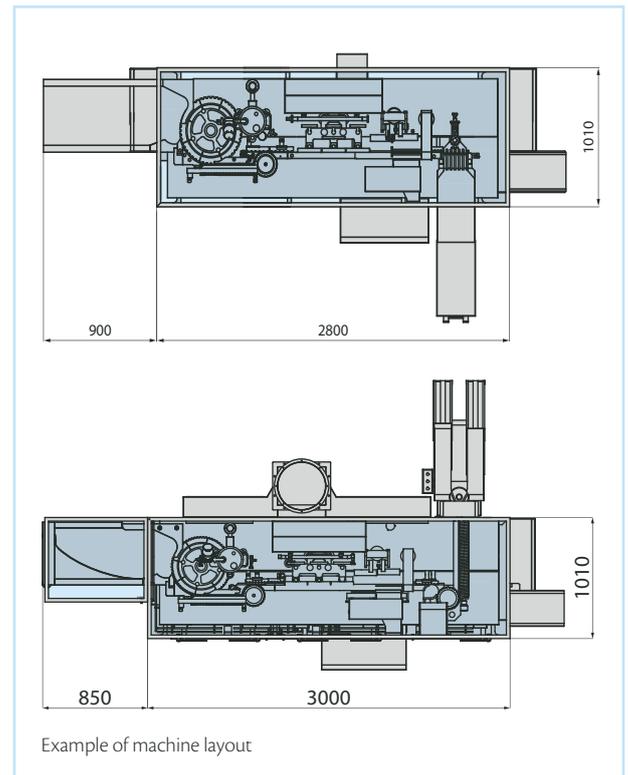


# TECHNICAL DATA

AT THE END OF THE PROCESS, THE AMPOULES ARE AUTOMATICALLY DISCHARGED ONTO AN OUT-FEED TRAY, WHICH CAN BE POSITIONED IN-LINE OR AT 90°, DEPENDING ON THE DESIRED CONFIGURATION.



STERIFILL B8-A



MACHINE VERSION WITH WALL INSTALLATION AND PASS THROUGH SCROLL

Output	Output to 12000 with 4 filling pumps
	Output to 18000 with 6 filling pumps
	Output to 24000 with 8 filling pumps
Ampoule size	1 – 25 ml
Weight	1200 kg
Voltage	400 V - 50 Hz
Installed Power	12 kw

[www.ima-pharma.com](http://www.ima-pharma.com)

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