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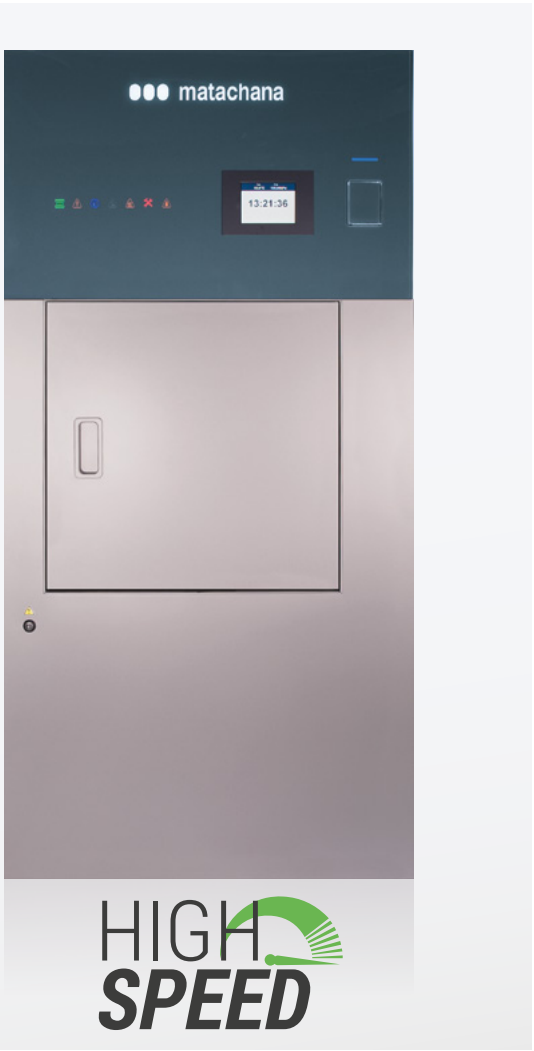
Infection Control



Low Temperature Steam
and **2 %** Formaldehyde Sterilizers
Matachana 130LF®

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MATACHANA,
specialists in low temperature

At MATACHANA GROUP, low temperature sterilization technology has a long history, parallel to the development of steam sterilization processes. Ethylene oxide and peracetic acid solutions were the forerunners in 1975. Then, Low Temperature Steam and Formaldehyde (LTSF) sterilization was the continuation of this process.

In 2016 MATACHANA launched its first hydrogen peroxide sterilizer, 130HPO® model and in 2019, the HPO Series is extended with the compact 50HPO® model. In the same year we revolutionized LTSF technology with a new High Speed version.

In this way MATACHANA completes its range of low temperature sterilizers and consolidates its know-how and experience in this field, being the only manufacturer that has designed and manufactured all the existing systems in the market.

Comparing technologies:

	H_2O_2	LTSF
High penetrability		
Speed		
Capacity n°. cannulated instruments		
Saving per cycle		
Installation simplicity		
Gentle with instruments		

130LF®:
Speed, safety, penetrability

SPEED

Increasing RUMED productivity is an ever-present need. Optimizing the speed of the sterilization cycle was a major requirement during the development of the 130LF® sterilizer.

SAFETY

The safety of patients, users and hospital staff while protecting the environment has always been an essential requirement during the development of MATACHANA sterilization systems and the 130LF® is a clear example.

PENETRABILITY

The 130LF® penetrability is highly superior to the Hydrogen Peroxide and Plasma sterilizers, making the perfect solution for the sterilization of geometrically complex flexible endoscopes.

Maximum efficiency with minimum % of formaldehyde

The estimated 80 % speed increase combined with a sterilizing solution of **only 2 % formaldehyde** and high penetrability, positions the new 130LF® at the forefront of LTSF technology and makes it the perfect solution for multichannel/complex endoscopy sterilization.

Maximum speed:
Programs and applications of 130LF® sterilizer

The 130LF® low temperature sterilizer features two differentiated cycles to meet all needs in low temperature and beyond!

RECORD **CYCLE TIME!**

from - to

STERILIZATION PROGRAMS	60 °C	[1]89 - 110 min	[2]Multi-channel rigid and flexible endoscopes, complex instruments (cannulated), optics and cameras.	12 kg
	78 °C	[1]58 - 90 min	[2]Rigid endoscopes, complex instruments (cannulated), optics and cameras.	12 kg
TEST PROGRAMS	VT		Vacuum test to ensure the tightness of the sterilizer chamber.	

[1]All time in minutes, depending on the load, power supply and water supply temperature

[2]Able to withstand steam sterilization with formaldehyde up to 60 °C or 78 °C

Maximum penetrability

Compared to low temperature hydrogen peroxide sterilization technology, LTSF offers far superior penetrability.

PENTAX duodenoscope ED34-i10T2

	Technology	Geometric limitations			Capacity limitation
		Minimum int. Ø (mm)	*Maximum length (m)*	*Maximum n°. of channels*	*Maximum number of devices*
PLASTIC	**LTSF**	[3]0.5	[3]3	Without limitations	Non-limited quantity. Only weight limitation (kg)
	H_2O_2	1	1	2	2
METAL	**LTSF**	0.5	0.5	Without limitations	Non-limited quantity. Only weight limitation (kg)
	H_2O_2	1	0.125	1	7

[3] Tests performed with a blind end, thus increasing the challenge

Position Statement of the European Society of Gastrointestinal Endoscopy (ESGE) and European Society of Gastroenterology Nurses and Associates (ESGENA) - Update 2018

"6.10. Sterilization of endoscopes

Because of their material and design restrictions, most flexible endoscopes are not temperature-resistant. Therefore, steam sterilization processes at elevated temperatures cannot be applied for sterilization of flexible endoscopes. The following alternative low temperature processes are available:

- *Ethylene oxide gas sterilization;*
- *Hydrogen peroxide gas sterilization with and without plasma;*
- *Low temperature steam and formaldehyde sterilization…"*

"…At present the hydrogen peroxide gas sterilization used on some GI endoscopes has technical limitations. Gastroscopes, colonoscopies, and duodenoscopes have from three to seven long separate channels and therefore exceed the lumen capacity of existing sterilizers…"

Refer: https://www.esge.com/2018-a-0759-1629.html

Maximum safety

LTSF a safe technology for patients, users and gentle on the environment.

LTSF technology has been developed in conjunction with international independent research and scientific support, giving priority to all aspects related to safety.

PATIENT SAFETY FIRST

Residues on medical devices 28 % below the limits stipulated in the European Standard EN 14180.

While the average value limit is 200µg, the value measured in medical devices sterilized in 130LF® is 145µg.

GUARANTEED USER SAFETY

The 0.04 ppm (0.051 mg / m^3) measured when operating the 130LF® sterilizer are:

- 7 times lower than the lowest European 8 hours exposure limit of 0.3 ppm (0.37 mg / m^3), in compliance with the DIRECTIVE (EU) 2019 / 983.
- 2 times lower than the lowest value in the application range of LTSF sterilizers in the world, prescribed in Japan at 0.1 ppm (OEL).
- More than 18 times lower than the permissible exposure limit (PEL) declared by OSHA of 0.75 ppm (TWA).

FORMALDEHYDE

Formaldehyde is a substance found in nature and metabolized daily by our body (≈ 50 mg/day).

Formaldehyde content:

Coffee	50 mg/liter
Apples	17.3 mg/kg
Pears	60 mg/kg
Pork	20 mg/kg
Cheese and milk	up to 3.3 mg/kg
Codfish	20 mg/kg
Crustaceans (ocean)	from 3 to 98 mg/kg
Onion	13.3 mg/kg

HIGHEST RESPECT FOR THE ENVIRONMENT

Residues in drains far from local boundaries.

The 0.2 g of formaldehyde per litre of water measured directly in the drainage of the 130LF® sterilizer is well below average limit levels, thus ensuring respect for the environment.

Given figures for the results are governed from representative **type tests** on this model 130LF®. Results at user's site may differ due to not identical test conditions and procedures.

LTSF Sterilizing solution

e-bag®

- The plastic bag containing the LTSF sterilizing solution is called **e-bag®** and it has been specially developed to be used only in MATACHANA sterilizers model 130LF®.

- The LTSF sterilizing solutions is only 2 % concentration of formaldehyde aqueous solution.
- The **e-bag®** is made of high impact resistant polyethylene (LDPE)
- With **RFID** tag to ensure the traceability of the LTSF sterilizing solution and greater control of expiration.

- **36 months** shelf life! For greater flexibility in stock management.
- Provided in boxes of 3 **e-bag®** with volume of 2.7 liters each.

- Easy fitting and automatic puncture.
- Pilot light in **e-bag®** compartment facilitates its replacement.
- On-screen LTSF sterilizing solution traceability information: batch and shelf life.

Secure load release

FORM

As safety is first and foremost, the Chemical and Biological Indicators have been carefully studied to be used as an additional measure in assessing the effectiveness of the process. They comply with the International Standards ISO 11140-1 and ISO 11138-1, -5.

60 °C

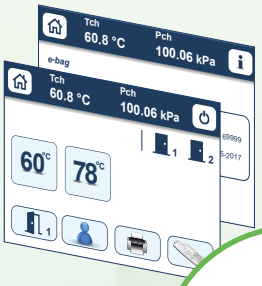
78 °C

Type 4 Indicator for packs and pouches

Type 2 Helix penetrability Indicator

Biological Indicator

A wide spectrum of advantages
to suit all your needs



DESIGN

- Modern and minimalist design facilitates the cleaning process.

EASY USE

- Intuitive EasyRUN user interface.
- Status of the unit visible from a distance thanks to the backlit front panel.
- Users' easy and quick learning.

SAFETY

- Safe handling of the sterilizing solution.
- **2 % formaldehyde** only.
- Integrated osmosis system for an optimal rinsing.

CONNECTIVITY AND DOCUMENTATION

- Built-in thermal printer.
- Large capacity internal memory with a track record of the last 1000 cycles.
- USB port that allows backup of cycle logs.
- Ethernet port for connection to monitoring and traceability software.

ERGONOMICS

- Automatic bag perforation system
- Extensible and removable shelves for ease and flexibility during the loading process.

STERILIZING SOLUTION EXPIRY DATE

- The **e-bag**® sterilizing solution has a shelf life of **36 months**! For greater flexibility in inventory management.

GENTLE WITH INSTRUMENTS

- LTSF technology is more delicate with instruments compared to other low temperature sterilization systems.

HIGH SPEED

PENETRABILITY

- The penetrating power of the 130LF® sterilizer makes it possible to sterilize complex, multi-channel cannulated instruments up to 3 m in length and 0.5 mm in internal diameter.

SPEED

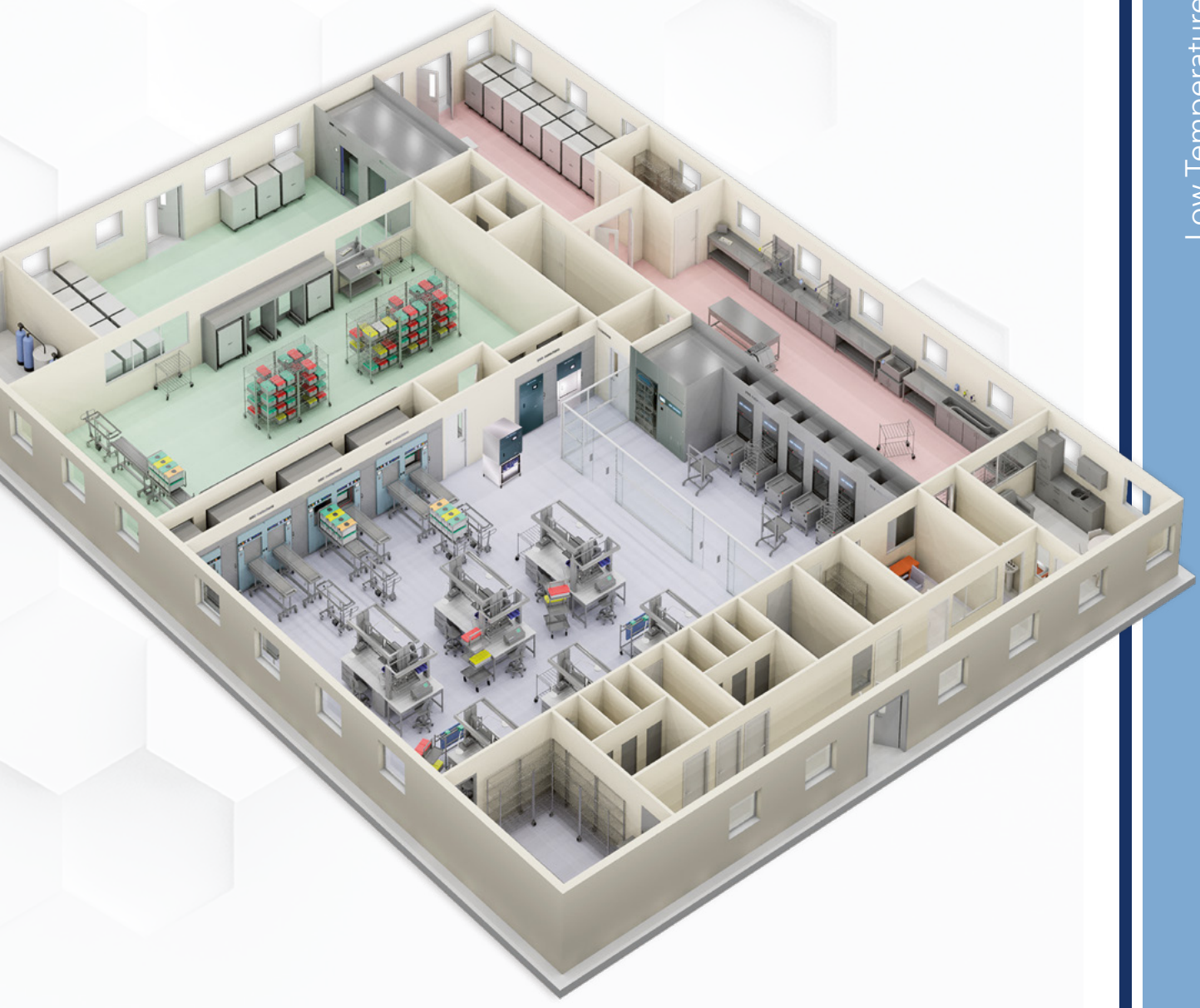
- **12 kg** treated in **90 min**!
  This cycle time turns the 130LF® sterilizer into the fastest on the market.

Technical specifications 130LF®

Technical specifications	130LF®-1 1 door	130LF®-2 2 doors
Overall dimensions (mm)		
Width	900	900
Height	1864	1864
Depth	1101	1118
Chamber dimensions (mm)		
Width	335	335
Height	363	363
Depth	929	972
Chamber volume (liters)	143	148
Weight (kg)	550	600
Power (kW)	8	
Power supply	*400 / V 3~ / N + PE / 50 Hz	

** Other options on request*

MATACHANA integral solutions for sterile processing departments



Project briefing ▶ Design ▶ Installation ▶ Training ▶ Technical support

Innovation is the way forward

Since the company's foundation more than 50 years ago, our mission has been to provide the best service, bringing our knowledge and field experience to our customers to facilitate their daily work, allowing them to be efficient in the production whereas keeping rigorously the quality.

MATACHANA has a worldwide presence, with offices based in Spain, France, Germany, Italy, United States, Argentina and Malaysia, or through its distributors in over 110 countries.

In MATACHANA we are aware that Training and Service contribute decisively to achieve customer satisfaction. For this reason, we have always invested in the development of these two areas of activity, which enables a direct contact with customers and help us to develop together a continuous improvement process.

Technical Engineering Support

An assistance provided by engineers, highly skilled expert technicians and support staff, all committed to ensure the proper equipment operation and condition.

MIEC, training center

As we feel seriously committed and liable for achieving the optimum operation from the MATACHANA equipment, we invest in the training of future users, proposing a service of educational courses to all our customers on a regular basis and in the 5 continents.

Environmentally friendly

The devices are designed and manufactured using the latest technologies on the market to achieve the best results in terms of energy savings and reduction in water consumption. Our Production Center located in Castelldefels (Barcelona) complies with the ISO 14001 Environmental Management System and ISO 50001 Energy Management.

Quality

The MATACHANA devices are developed, manufactured and tested within a strict quality control according to the international Standards ISO 9001 and EN ISO 13485 for the quality management of medical devices.

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