

# Low Temperature Hydrogen Peroxide & Plasma sterilizer MATACHANA 50HPO®

COMMERCIAL DESCRIPTION – REF. 76120



## PRESENTATION

MATACHANA **50HPO®** is the result of an exhaustive research process based on the needs and suggestions of our customers and users. The technological developments that this model includes are a reflection of their contribution in the development of this device.

This sterilizer uses vaporized hydrogen peroxide, complementary method to steam sterilization. Sterilization cycles are low temperature process (nominal working temperature of 50 °C), adequate to process medical devices included invasive surgical instruments, especially those which are sensible to high temperatures. An aqueous solution of hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>) with a concentration of 59 % is used as sterilizing solution presented in a specific container called BluKat®.

This unit does not require further aeration and does not release toxic waste. The preparation of the material to be sterilized is similar to the usual practices employed in other technologies, that is; washing, disinfecting, drying and packaging.

MATACHANA **50HPO®** is designed in accordance with technical specifications of the European Standard EN ISO 14937 with the provisions contained in the quality Standards ISO 9001 and EN ISO 13485.



## MAIN ADVANTAGES

- Low Temperature sterilization of thermolabile materials able to withstand temperatures up to 50 °C.
- Fast cycle time thanks to the high-performance vacuum pump.
- Ease of use and intuitive menu navigation thanks to MATACHANA EasyRUN user interface (See USER INTERFACE).
- Extra safety and total control thanks to the double PLC.
- Appealing appearance given by the minimal and clean design and the use of polycarbonate.
- Sterilization chamber manufactured in high quality aluminium for quick heat transfer and energy saving.
- Front panel in smart polycarbonate for protection, hygiene and easy cleaning.
- Side panels and support table made of AISI 304 quality stainless steel.
- Ergonomic loading with removable trays and automatic locking system.
- Automatic door locking system.
- Safe handling of the sterilizing solution thanks to the anti-drip design of the BluKat® container and the automatic perforation system.
- Easy traceability of the sterilizing solution thanks to the RFID tag that avoids the use of expired containers.
- Long lifespan of sterilizing solution containers, up to 18 months shelf life and up to 30 days, once introduced.
- “Plug and play” technology thanks to the easy installation and electrical requirements.

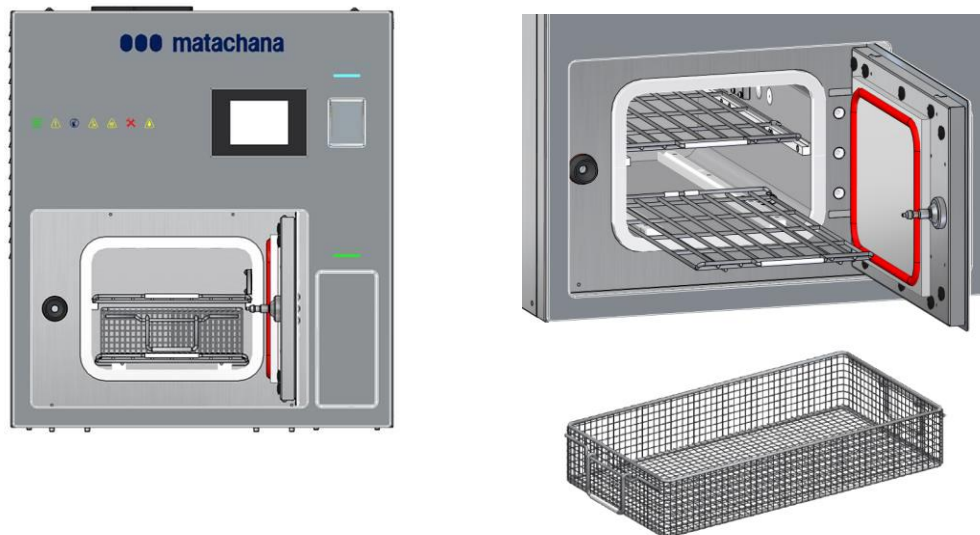
## AVAILABLE MODELS

Ref. no.	Model	Description
76120	50HPO®	Low Temperature Hydrogen Peroxide & Plasma sterilizer

## CAPACITY

**50HPO®** is equipped with a rectangular chamber with a total capacity of 52 litres.

It features 2 removable shelves to accommodate one loading basket (**Ref. 57058.2**): 580 mm x 290 mm x 100 mm.



The standard equipment of the sterilizer is:

- One lower loading shelf: **Ref. 55068.8**
- One upper loading shelf: **Ref. 55068.9**
- One loading basket: **Ref. 57058.2**

## STERILIZATION PROGRAMS

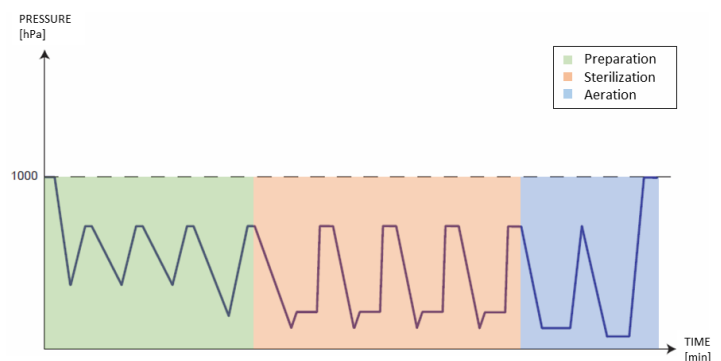
When a process starts, the sterilization program proceeds as per the following stages: preparation, sterilization and aeration. MATACHANA 50HPO® sterilizers include the preparation phase as part of the cycle and it is included in the total cycle time.

### Preparation

First, preheating is executed. In this stage, load is prepared to be sterilized. When preheating is finished, **preparation** phase starts. This is a stage of fractionate vacuum pulses, which successively alternates prevacuums with air injections in order to heat the material to be sterilized and remove any moisture remaining in the load which could hinder achieving adequate vacuum levels during the process. After the initial vacuum pulses, a deeper vacuum is undertaken in order to verify that the required vacuum levels can be reached, followed by another air admission.

### Sterilization

Once preparation is completed, four identical **sterilization** stages are performed. Each stage starts with a vacuum until reaching the required chamber pressure (vacuum phase), followed by the sterilizing solution injection (injection phase). Then chamber pressure is increased and sterilant is allowed to diffuse inside the chamber (holding phase 1). After this time, chamber pressure is increased until reaching the preset pressure value (pressure increase phase) and this pressure is maintained for some time (holding phase 2). As said, this sequence is repeated 4 times to allow proper sterilization of the load.



### Aeration

Then, a first vacuum is performed in order to eliminate any sterilant residuals inside the chamber and the load. After a pressure increase, a second deeper vacuum is performed to ensure proper sterilant removal (**aeration** phase).

Last, the air penetrates into the chamber (vacuum breaking phase) in order to level out the chamber pressure with the atmospheric pressure. The end of process is acoustically announced by a signal tone and optically by the touch screen.

MATACHANA 50HPO® performs three pre-set sterilization programs:

- **Rapid program** sterilizes non-lumened and/or hollow instruments as well as medical devices.  
Cycle time: 35 minutes approximately.
- **Advanced program** sterilizes single or dual channel surgical flexible endoscopes.  
Cycle time: between 45 minutes approximately.
- **Standard program** for the sterilization of lumened and non-lumened instruments, as well as single and dual channelled, rigid and semi-rigid endoscopes.  
Cycle time: 60 minutes approximately



Additionally, the sterilizer is equipped with a test program:

- **Vacuum test** is used to test the leak-tightness of the sterilization chamber.

## STERILIZING SOLUTION (BluKat®)

The sterilizing solution uses a concentration of 59 % hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>). It is available in disposable containers, with a sterilizing solution volume of 180 ml which enables to perform up to 30 cycles. Its patented design called BluKat® is specific for the use in MATACHANA HPO sterilizers series.

Content	N. ° de cycles x container
180 ml	30

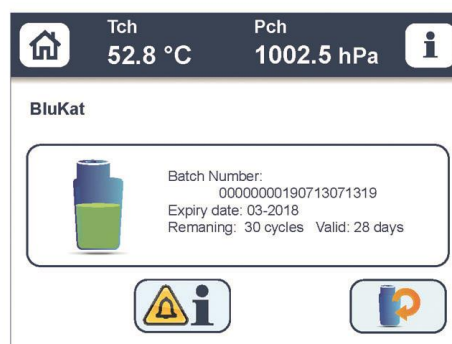
**Note:** BluKat® is supplied in 3 units box.

The main features of the BluKat® are:

- **Safe handling:**
  - ❖ BluKat® unique design avoids spills and drips, and ensures a mistake-free insertion of the container in the sterilizer.
  - ❖ The container has a protective membrane that prevents staff exposure to the chemical solution.
  - ❖ The BluKat® drawer can only be opened when the existing container is empty.
  - ❖ Furthermore, the high-density polyethylene used to produce the containers is an extra protection in case of accidental drops.
  - ❖ RFID tag ensures the sterilizing solution traceability, avoiding the use of expired containers.
- **Productivity:** one BluKat® container is able to perform up to 30 cycles. This reduces the replacement frequency compared with other devices on the market, which means time saving in the daily use.
- **Expiry:** the extended **shelf life** of 18 months offered by BluKat® allows a flexible consumable stock management. The refrigerated drawer located on the front of the sterilizer, which is a unique feature provided by MATACHANA HPO sterilizers Series, guarantees an **expiry date** of 30 days, once introduced into the sterilizer.
- **Easy access to BluKat® information:** once the BluKat® is inserted, the LED located in the top of the housing indicates the amount of cycles that may be performed:
  - ❖ Green: the content is between 30 and 9 cycles
  - ❖ Orange: the content is between 8 and 3 cycles
  - ❖ Red: the content is between 2 and 1 cycles
  - ❖ Blinking red: the content is 0 cycles



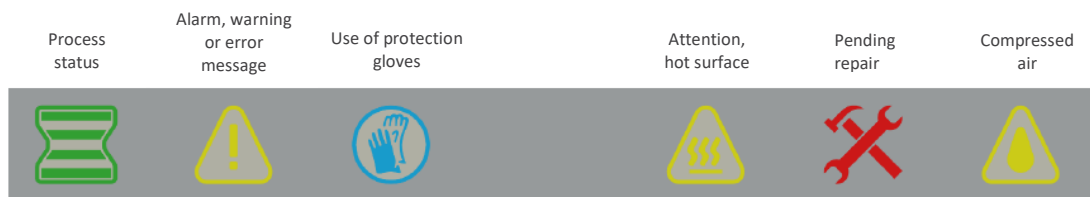
If more detailed information is requested by the user, the intuitive interface EasyRUN allows to quickly visualize the batch number and related the expiry date of the BluKat®, remaining number of cycles and remaining days prior to expiry.



## CONSTRUCTIVE FEATURES

The MATACHANA sterilizer **50HPO**® is equipped with the following constructive features:

- **CHAMBER AND DOORS:** built in aluminium according to EN 485-2 Standard.
- **DOOR:** manually operated and automatic locking, provided with the appropriate locking device active throughout the entire cycle.
- **VAPORIZER:** designed to supply directly the hydrogen peroxide (vapour) inside the chamber. Its patented design ensures optimal vaporization of the sterilizing solution.
- **CATALYTIC CONVERTER:** the residual hydrogen peroxide is decomposed inside this converter into water and oxygen and therefore does not release any toxic waste to the environment.
- **PLASMA GENERATOR:** gas plasma is generated with the function to reduce any residual hydrogen peroxide in the chamber during the vacuum phases.
- **VALIDATION:** the chamber features one specific inlet connection for the periodical validations and qualifications.
- **PNEUMATIC VALVES:** pneumatic valves are incorporated as standard in the main internal circuit of the sterilizer to ensure high reliability and operating safety. The sterilizer integrates an air compressor to operate the valves.
- **BACKLIT FRONTAL:** incorporates a number of highly visible indicators icons, giving constant information on the sterilizer's status and indicates the existing hazards as described below.



- **INDEPENDENT CONTROL AND REGISTER:** the unit incorporates two industrial PLC, as well as independent temperature and pressure sensors ensuring an autonomous operation of the process main variables between control and register.
- **LOCKING SYSTEM:** motorized solution that enables the user to guide the door without requiring any additional effort or action. Once the cycle starts, the door locks automatically.
- **MAINTENANCE:** easy access to the main components (maintenance operations).
- **SUPPORT TABLE:** The sterilizer is delivered mounted on a support cabinet with wheels that facilitates its movement, mainly to perform maintenance tasks. This support table has different compartments to store consumables, packaging material, etc.

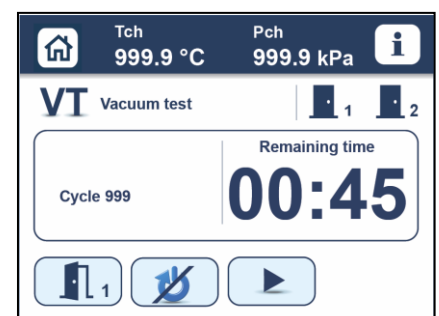
## USER INTERFACE

The sterilizer is equipped with two PLCs, one for cycle control and other functions when the cycle is stopped, integrated in the touch screen located on the front panel, and a second PLC, located in the electric board, for the recording of the cycle carried out.

The sterilizer is equipped with a high-quality TFT color touch screen, which provides color brightness and an increased viewing angle. It incorporates the EasyRUN user interface that allows the user's menus to be identical to those used in MATACHANA steam sterilizers. This common feature makes the **50HPO**® a simple and quick system when it comes to user training.

By means of the color touch screen, the user interacts with the micro-computer of the sterilizer in order to carry out the following functions:

- Access to menus for selecting programs, information, maintenance and statistics.



- Operation of the door, status indication.
- Viewing of program parameters.
- Monitoring of the current cycle data: temperature, pressure, phase, time, cycle time and phase name.
- Indication and management of alarms, operator errors and reset cycle.
- Viewing of process curves (pressure and temperature) in real time.
- Management of user names and passwords.

The interpretation of the successful completion of the cycle is made simple through a green background display for correct cycles and by means of a red background display for incorrect cycles.

The modern and ergonomic menu allows to give support to the user in many ways, such as the selection and start-up of the cycles, process status display with corresponding values of temperature and pressure as well as error, alarm and warning messages that can be acknowledged if necessary, simply by clicking on the “acknowledge” button.



## DOCUMENTATION & CONNECTIVITY

- **Printer**  
MATACHANA **50HPO**® sterilizers are equipped with an alphanumeric digital printer installed on the loading side, for the detailed recording of the sterilization process. Besides, pressure, temperature and time, the printer provides other important data such as cycle number, batch, date, total cycle time, etc. The printer paper roll enables to print up to 220 cycles.
- **Internal memory**  
The large internal memory of the screen allows to store the data of the last 1000 process cycles (including 80 cycles with complete analogue curves).
- **USB port**  
The sterilizer features a USB port located in the back side of the sterilizer, next to the feeder cable connection. All cycle reports may be saved in the USB pen drive. The reports saved in HTML format can be opened in any browser and printed in any printer.
- **Ethernet port**  
Thanks to the Ethernet port the user can also print cycle reports in A4 format, using an external printer.
- **Remote diagnosis**  
The sterilizer includes the remote connection which allows to the Technical Service to monitor the sterilizer condition and prepare a diagnosis in case of failure.
- **Connection to traceability software**  
**50HPO**® is ready for connection to external systems (EasyLOOK, third-party traceability systems, etc.) as well as to the Internet through its Ethernet port.

## MAINTENANCE

Main maintenance access of the equipment is carried out from the side panels. Thanks to the four-wheels support table the unit can be easily moved to carry out any revision or repair.

## STANDARD CONFIGURATION

**50HPO**® sterilizer has the following complements as standard configuration:

- Support table.
- Lower and upper shelves.
- 1 loading basket. External dimensions (width x height x depth): 580 mm x 290 mm x 100 mm.
- Air compressor (integrated).
- Side panels.
- USB connector.

## OPTIONS

50HPO® sterilizer has several options.

- Frequency change, **Ref. 86600.6.**
- EasyLOOK supervision software, **Ref. 78450 + 78451.4.**

## PROCESS MONITORING AND LOAD RELEASE CONSUMABLES

- Adhesive tape specific for Hydrogen Peroxide & Plasma sterilization processes, **Ref. 85456.6.**  
Adhesive tape (25 mm x 50 m) for Hydrogen Peroxide & Plasma sterilization processes, high-strength and easy to cut for a simple handling during preparation and packaging of sterilization packages. Latex free. Hospital use. Developed and manufactured according to EN ISO 11140-1.
- Chemical Strips for Hydrogen Peroxide & Plasma (Type 4), **Ref. 85203.**  
Chemical Strips for Hydrogen Peroxide & Plasma sterilization process monitoring. This product is placed inside the packaging, next to medical devices. Initial color is VIOLET and final color is PINK. Developed and manufactured according to EN ISO 11140-1. 400 units/box. Shelf life: 3 years.
- PCD-Helix + Chemical Strips for Hydrogen Peroxide & Plasma (Type 2), **Ref. 85202.**  
Chemical Indicators to determine penetrability effectiveness of for Hydrogen Peroxide & Plasma sterilization process. Adequate monitoring for cannulated medical devices. Developed and manufactured according to EN ISO 11140-1 and EN 867-5. PCD-Helix shelf life: 250 cycles. Chemical Indicators shelf life: 3 years.
- Self-contained Biological Indicators for Hydrogen Peroxide & Plasma, **Ref. 85207.**  
Self-contained Biological Indicators for Hydrogen Peroxide & Plasma sterilization process monitoring. These Indicators are designed to obtain results after 48 hours according to SAL level (Sterility Assurance Level) defined in EN 556-1. Developed and manufactured according to EN ISO 11138-1. Vials average lifespan: 2 years.
- Starter kit for Hydrogen Peroxide & Plasma sterilization process monitoring, **Ref. 85053.**  
This starter kit provides samples of the different Indicators available for monitoring the sterilization process by Hydrogen Peroxide & Plasma.  
Indicators for the sterilization process routine monitoring:  
1 box of PCD-Helix + 25 Chemical Indicators for Hydrogen Peroxide & Plasma (Ref. 85202)  
5 units of Self-contained Biological Indicators (Ref. 85207)  
25 units of Chemical Indicators Type 4 for Hydrogen Peroxide & Plasma (Ref. 85203)  
1 Crusher for Self-contained Biological Indicators (Ref. 85209)  
Elements required for sterilization process microbiological evaluation:  
5 Fiberglass Spore Discs for Hydrogen Peroxide & Plasma (Ref. 85608)  
4 Ampoules with culture medium for Hydrogen Peroxide & Plasma (Ref. 85028)
- Quarterly kit for Hydrogen Peroxide & Plasma sterilization process monitoring (1 turn, 6 cycles/day approx.), **Ref. 85007.**  
Kit recommended for monitoring the Hydrogen Peroxide & Plasma sterilization process during 3 months during one working shift and an average of 6 cycles/day. This kit includes:  
1 box of PCD-Helix + 250 Chemical Indicators for Hydrogen Peroxide & Plasma (Ref. 85202)  
2 boxes of Chemical Indicators Type 4 for Hydrogen Peroxide & Plasma (Ref. 85203)  
8 boxes of Self-contained Biological Indicators for Hydrogen Peroxide & Plasma (Ref. 85207)
- Incubator for Biological Indicators, **Ref. 85208.**  
Incubator for the verification of the growth of spores of *G. stearothermophilus* at 57 °C.



- Tyvek rolls.  
MATACHANA Tyvek rolls for sterilization processes by Hydrogen Peroxide & Plasma, quality 1073B. With an external process Indicator for H<sub>2</sub>O<sub>2</sub> that changes from RED to YELLOW.  
Available in different dimensions:
  - ❖ Box of 4 Tyvek rolls, 75 mm x 70 m, **Ref. 85661.0.**
  - ❖ Box of 4 Tyvek rolls, 100 mm x 70 m, **Ref. 85661.1.**
  - ❖ Box of 4 Tyvek rolls, 150 mm x 70 m, **Ref. 85661.3.**
  - ❖ Box of 2 Tyvek rolls, 200 mm x 70 m, **Ref. 85661.5.**
  - ❖ Box of 2 Tyvek rolls, 250 mm x 70 m, **Ref. 85661.7.**
  - ❖ Box of 2 Tyvek rolls, 300 mm x 70 m, **Ref. 85661.9.**
  - ❖ Box of 1 Tyvek roll, 400 mm x 70 m, **Ref. 85662.**
  - ❖ Box of 1 Tyvek roll, 500 mm x 70 m, **Ref. 85662.1.**
- MATACHANA SMS wrapping sheets.  
SMS wrapping sheets, 100% synthetic, 40 g/m<sup>2</sup> with complete flexibility during its handling. It allows packaging in a single action with 2 sheets.  
Available in different dimensions:
  - ❖ Pack of 300 SMS wrapping sheets, 50 cm x 50 cm, **Ref. 85521.4.**
  - ❖ Pack of 350 SMS wrapping sheets, 60 cm x 60 cm, **Ref. 85521.5.**
  - ❖ Pack of 300 SMS wrapping sheets, 75 cm x 75cm, **Ref. 85521.6.**
  - ❖ Pack of 300 SMS wrapping sheets, 90 cm x 90 cm, **Ref. 85521.7.**
  - ❖ Pack of 200 SMS wrapping sheets, 100 cm x 100 cm, **Ref. 85521.8.**

## DIRECTIVES AND STANDARDS COMPLIANCE

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The low temperature sterilizers of Series HPO, which intended use is for the sterilization of medical devices, including those for invasive use in healthcare facilities, are within the scope of the European Medical Device Directives (MDD) 93/42/EEC, and in accordance with Annex IX are classified as Medical Device class IIb.

Series HPO sterilizers, along with the sterilizing solution and the sterilization process have been designed and developed following the requirements established in the European Standard EN ISO 14937 on general requirements for characterization of a sterilizing solution and the development, validation and routine control of a sterilization process for medical devices.

The company has established a quality management system according to the International Standards ISO 9001 and EN ISO 13485, certified by entities Lloyd's and TÜV Rheinland respectively.

On this basis, the conformity of the low temperature sterilizers of Series HPO has been evaluated according to the procedure in agreement with Annex II (except point 4) of Directive 93/42/EEC certified by the Notified Body No. 0197 TÜV Rheinland, and the fulfilment of the essential requirements of Annex I of the same Directive has been proven.

Besides, the MATACHANA sterilizers also fulfil the essential requirements of the following European Directives:

- European Machinery Directive 2006/42/EC.
- EMC Directive 2014/30/EU.
- Low Voltage Directive 2014/35/EU.
- 2011/65/EU (RoHS) on the restriction of the use of certain hazardous substances in electrical and electronic equipment.



**TECHNICAL SPECIFICATIONS**

Technical Specifications	50HPO®
Total dimensions (mm) (*)	
Width	780
Height	1733
Depth	796
Chamber dimensions (mm)	
Width	330
Height	250
Depth	640
Chamber volume (l)	52
Power (kW)	2,2
Weight (kg) (*)	300
Power supply	230 V~ + PE / 50 Hz <i>Note: other frequencies and voltages on request</i>

(\*): Weight and dimensions are referenced including the support table.