1. Introduction

Matachana model 130 LF 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 our customers’ participation in the development of this sterilizer. This sterilizer works with a Low Temperature Steam and Formaldehyde with a 2% of concentration of this substance. This procedure achieves terminal sterilization of the products. The items to be sterilized are packed using traditional wrapping systems, and cycle monitoring is performed using standard chemical and biological indicators (Bacillus stearothermophilus).

Matachana’s model 130 LF fulfils all requirements of the Euro norm for LTSF - sterilizer, EN 14180.

2. Available Models

<table>
<thead>
<tr>
<th>Matachana 130 LF</th>
<th>1 door LTSF Sterilizer. Product code: 78026</th>
</tr>
</thead>
<tbody>
<tr>
<td>Matachana 130 LF - 2</td>
<td>2 doors LTSF Sterilizer. Product code: 78029</td>
</tr>
</tbody>
</table>

3. Application Areas

Matachana’s model 130 LF has been developed for the sterilization of heat – sensitive products that cannot withstand the temperatures required for steam sterilization (121°C), can be treated at temperatures of 60°C or 78°C and are resistant to vacuum and humidity.

4. Capacity

The chamber, of a total volume of 130 liters, holds a useful volume of 320 x 320 x 900 mm. This chamber allows the usage of large capacity baskets.

5. Sterilization Solution
The sterilization solution uses only a concentration of 2% formaldehyde and it is provided in resistant plastic bags of 2.7 liters.

**FORMALDEHYDE**

Formaldehyde is an organic component, with a broad performance range opposite microorganisms and viruses. Solutions of formaldehyde are widely used within the hospitals in autopsy, surgical and pathology departments and also in dermatology and surgical clinics, X-ray departments and other health care units. Formaldehyde occurs naturally in most living things and is a vital part of our ecology; it is naturally decomposed by the human body and is not accumulated.

The human smell threshold at 0.05 ppm is significantly lower than the full-day working limits, therefore itself prevents to higher levels of exposition.

The **130 LF** sterilizer uses a mix of steam and only 2% formaldehyde. **130 LF** obtains the formaldehyde solution from bags installed on sterilizer front side, in a consumption components compartment. From this location, its content is emptying in the corresponding container in an automatic way, without extra manipulation by the user. With a special quick coupling piece, it is easier to connect and disconnect the sterilizing solution. By this way, the bag can be exchanged detached from the sterilizer.

There are two containers placed inside the sterilizer, for the sterilizing solution and for the distilled water. The distilled water container is directly fed from a demineralized water outlet or from the integrated demineralizer. This stainless steel container is constantly heated above 60°C to avoid possible contaminations.

Through a dosage pump system, the necessary dose of sterilization solution and distilled water is collected for the process phases where they are necessary. From there, these components are directly sent to the integrated evaporator in the machine.

The low concentration of formaldehyde of only 2%, together with its way of use and application, makes the system safe for user, patients and environment.

**6. Programs**

The program execution is totally automated and controlled by a microcomputer. For the operator’s convenience, the equipment features 2 work programs as standard:
- 60°C program, with an approximate global duration of 3.30 hours.
- 78°C program, with an approximate global duration of 2.15 hours. **IMPORTANT:**

This program has a higher temperature than the usual one for heat-sensitive material. Some plastics cannot withstand the 78°C temperature, therefore it should be checked the compatibility with the products before using it. Please, consult with the manufacturer.

- And a test program, the Vacuum Test.

**7. Cycle description**

The sterilization process with Matachana’s Model **130 LF** is developed under negative pressure for 60°C and 78°C program, according to the fractioned vacuum procedure. Cycle developing:
- After starting the sterilizer and during the warm-up phase, a cleaning of the generator will be carried out, during 2 minutes approximate.
- Initial vacuum phase: With the water vacuum pump, the vacuum is performed inside the sterilizer chamber.
- Alternated vacuum phases with steam pulses with formaldehyde: It is developed to facilitate the air extraction inside the materials and the steam formaldehyde penetration in the sterilization materials.
- Holding time: During this phase, the steam and formaldehyde pressure is kept in a constant level during a predetermined time, depending of the selected program:
  - 60°C program: 30 minutes of sterilizing time.
  - 78°C: 10 minutes of sterilizing time.
- Devaporating phase with a determined number of pulses with water steam.
- Final phases of drying and chamber aeration.
When the cycle has been finished, it is possible to remove the sterilized materials and to be used in an immediately way with the patients, without a supplementary aeration.

8. Sterilizer description

- Construction materials:

  The chamber and the door are built in aluminum alloy; the exterior panels are built in AISI 304L stainless steel.

- Door:

  Access is through an horizontal door, of manual operation, provided with a safety lock that does not allow the opening of the door at any time during the entire cycle.

- Vacuum system:

  The effectiveness in vacuum is accomplished through a two phases compact liquid ring water pump. The advantages of this system are: rapid elimination of condensates, getting a thorough vacuum and a considerable reduction in decibels level. The pump is equipped with a controlled water feeding system through a valve and a device protecting the motor.

- Validation:

  The chamber features two fittings for thermo elements of 1/2” gas to obtain future qualifications of the physical parameters - validation.

- Reverse Osmosis Water Pre-treatment:

  On some locations, the user of the sterilizer 180 LF is confronted with extremely high mineralization of the raw water. For this reason, Matachana incorporates a Reverse-Osmosis-Device. This device is upstream to the DS-water cartridge. The advantage is a significantly higher life period of the DS-water cartridge thus making it more cost effective.

- Steam Generator incorporated

- Electrical circuit:
The electrical circuit is completely mounted in a modular fashion.

9. Control unit

The sterilizer 130 LF is controlled by a programmable industrial MICROCOMPUTER SAIA, PCD2 model, where all of the operations of the sterilizer are centralised. It has the appropriate elements for viewing and printing the parameters of the development of the process.

The MICROCOMPUTER allows performing the following operations:

- Information and selection of the sterilization or test programs that the device can perform.
- Display of the device status: phases, cycle number and process time.
- Parameter information - temperature, pressure, FA concentration, etc. – of each program.

The device is designed to detect malfunctions or operation alarms of the sterilizers and to display warning messages.

Control elements

The display of parameters that configure the programs takes place through the front panel keyboard. This panel has the following elements:

- Colour touch screen: EXOR model eTOP11, that offers information about the sterilizer, describes the phase of the program in progress, and warns if a failure in the program has occurred, activating a failure program that will depressurize the chamber.
- Linear graphic recorder (standard): It registers the temperature and pressure evolution throughout the working or test program progress.

On the customer’s request, it is possible to incorporate a digital alphanumerical printer, to obtain written information of the selected program and cycle parameters.

10. Process management with a PC

The interface card incorporation in the sterilizer allows performing an effective cycle management with their relevant data, through the software application “CSSDoc”. This program offers printed and computer register of the different carried out cycles. Equally, through a modem, Technical Assistance Service can make an "on line" diagnosis of the sterilizers in case of failure.

11. Accessories

The sterilizer Matachana model 130 LF - 1/2 doors, features a series of components that can be added to the equipment to obtain greater functionality.

Standard accessories:

- Linear graphic recorder: records the chamber pressure and temperature evolution throughout the sterilization or test process.
- 2 loading baskets: made of stainless steel, these baskets ease the sterilizer loading and unloading. Dimensions are: 140 x 300 x 880 mm.
- 1 sterilizing solution box: includes 3 bags of 2.7 liters of 2% formaldehyde solution.
- Water demineraliser and reverse osmosis pre-treatment.

Optional accessories:
- Alphanumerical printer: to obtain a written record on the development of the process. At the end of the cycle it is printed a full report.
- Label printer
- Loading/unloading baskets (260 x 300 x 880 mm.)
- Loading/unloading trolley
- Interface card
- CSSDoc software

12. Directive and standard compliance

Directives:
The sterilizer Matachana 150 LF - 1/2 doors complies with the European directive on electromagnetic compatibility 89/336/EEC and the directive on safety machines 89/392/EEC, bearing the adequate Medical Device CE marking.
Sterilizers also are considered Class Ila Medical Device. For this reason, they must meet the standards set out in the European Directive of Medical Devices 93/42/EEC, which has been obligatory since 1998.

By last, only to mention that Matachana 150 LF fulfils all requirements of the Euro norm for LTSF sterilizers, EN 14180

13. Technical data

<table>
<thead>
<tr>
<th>Total dimensions</th>
<th>Measures</th>
<th>Observations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Height</td>
<td>1850 mm</td>
<td></td>
</tr>
<tr>
<td>Width</td>
<td>750 mm</td>
<td></td>
</tr>
<tr>
<td>Depth (1 and 2 doors)</td>
<td>1100 mm</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chamber dimensions</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Height</td>
<td>320 mm</td>
<td></td>
</tr>
<tr>
<td>Width</td>
<td>320 mm</td>
<td></td>
</tr>
<tr>
<td>Depth</td>
<td>900 mm</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Volumen (liters)</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>130</td>
<td></td>
</tr>
<tr>
<td>Useful load</td>
<td>92</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number of programs</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2 work programs (60º and 78ºC) and Vacuum test.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Power (KW)</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>7</td>
<td></td>
</tr>
</tbody>
</table>

Temperature water supply < 15°C; if the temperature of the water is higher then 24°C the duration of the cycle is longer. Use demineralized water.

14. Documentation:

With the sterilizer, the following documentation and drawings are provided:
- Manual of instructions (includes list of original parts)
- Fluid diagram (water, steam and air)
- Installation drawing