

TECHNICAL SPECIFICATION

PlazMax – Low Temperature Plasma Sterilizer



TECHNICAL DATA

MODELS		P50 1D	P50 2D	P80 1D	P80 2D	P110 1D	P110 2D	P160 2D	
Doors		1	2	1	2	1	2	2	
Useful Volume (Liter)		44 Lt	44 Lt	81 Lt	81 Lt	107 Lt	107 Lt	158 Lt	
Total volume (Liter)		47 Lt	47 Lt	83 Lt	83 Lt	109 Lt	109 Lt	162 Lt	
Tray Dimensions (mm)	W	400	400	400	400	400	400	400	
	L	600	600	600	600	600	600	600	
Chamber Dimensions (mm)	W	420	420	420	420	420	420	420	
	H	180	180	320	320	420	420	420	
	D	620	620	620	620	620	620	920	
	W	700	700	700	700	700	700	700	
	H	1580	1580	1700	1700	1800	1800	1800	
Sterilizer External Dimensions (mm)	D	640	640	640	640	640	640	940	
	Weight (Kg)		170 Kg	170 Kg	200 Kg	200 Kg	210 Kg	210 Kg	270 Kg
	Power Supply	Voltage (V)	230 V	230 V	230 V	230 V	380 V	380 V	380 V
Frequency (Hz)		50 Hz	50 Hz	50 Hz	50 Hz	50 Hz	50 Hz	50 Hz	
Power (kW)		2,9 kW	2,9 kW	3 kW	3 kW	5 kW	5 kW	7 kW	

UTILITY DATA / REQUIREMENTS

Ventilation

10 air replacements per hour.

Ambient Temperature

Plant room temperature should be in the range from 5 to 40 °C and 85% RH (relative humidity).

Floor

The unit mass shall be considered no less than 10000 N/m² according to the DIN 58949-7:2004 standard.

Sterilizing Agent

Number of cycles per machine from one bottle of sterilizing agent.

Model	Sterilizing Agent Reference	No. of Cycles
P50	AS040400	12
P80	AS080400	7
P110	AS100400	5
P160	AS150400	4

Note: Users must follow storage instructions for the sterilizing agent.

d. **Contact with skin**

The sterilizing agent can cause skin irritation and itching. In case of contact with skin, immediately rinse with plenty of water and seek medical advice.

e. **Accidental ingestion**

Sterilizing agent ingestion can cause serious damages and even death. You must prevent the contact of your mouth with the sterilizing agent. If the sterilizing agent is ingested drink water to dilute it; do not induce vomit and seek medical advice.

f. **Storage**

We recommend that the bottles will be stored in a cool and dry place and kept away from the sun light, at room temperature between 15°C and 25°C.

2.3.2 **PlazMax Sterilizing agent**

Sterilizing agent safety

The sterilizing agent safety is assured due to the following PlazMax safety measures:

- Using “Tuttnauer” sterilizing agent only
- Avoiding contact with the sterilizing agent
- Automatic sterilizing agent refilling

Only the use of “Tuttnauer” sterilizing agent is allowed as the system only recognize the “Tuttnauer” recommended bottle of PlazMax Sterilizing Agent.

Any contact of the operator with the sterilizing agent is avoided since the sterilizer recharged drawer can only be opened after the operator receives a signal (from the sterilizer system) that indicates that additional new agent supply is required.

The supply of sterilizing agent is possible only after placing of a new bottle.

The refilling begins automatically after the operator’s gives instruction on the touch screen.

The refilling process of the sterilizer is completely automatic, avoiding any accidental contact with the operator.



Warning!

Under no circumstance the user shall manually perforate the sterilant agent bottle

The refilling process of the sterilizer is completely automatic, avoiding any accidental contact with the operator.

The sterilizing agent is not toxic but it is corrosive as it is hydrogen peroxide (H₂O₂).

The sterilizing agent should be stored away from the sun light, at room temperature, preferably in a dry and cool place.

Each recharge box includes instructions and recommendations on the proper and safe handling of the sterilizing agent. Follow the instructions.

After the automatic emptying of the bottle the drawer opens, allowing the closure of the bottle with the lid supplied within the bottle, and then its removal from the drawer. The bottle can be disposed

in the domestic waste, or can be sent to the residual circuit recommended by the hospital's infection control.

The new designed PlazMax sterilizer systems, provide unique automatic features that enhance the operation & safety by minimizing sterilant agent contact with the operator, the systems include:

- Dosing system and perforating unit system
- Sterilant agent tank
- Sterilizing Agent Dosing
- Electrical components Safety
- Ventilation Safety

2.3.3 Dosing system and perforating unit system safety

The Dosing system and perforating unit system enhance the operation safety of the PlazMax sterilizer:

The dosing system operation is ensured by an assembly of components that include the drawer for the bottle placing, the perforating unit and the bottle identification unit.

A peristaltic pump takes the sterilant agent into the sterilizer tank. (For detailed description refer to paragraph 3.1.1)

2.3.4 Sterilizing Agent Dosing system safety

The sterilizing agent dosing system and perforating unit, enhance the operation safety by minimizing sterilant agent contact with the operator.

The Sterilizing Agent Dosing features are detailed in chapter 3 paragraph 3.1.5.

2.3.5 Electrical components Safety

PlazMax design provides a high level of electrical safety to the operator and the technician. (For detailed description refer to chapter 3)

2.3.6 Ventilation Safety

For the ventilation detailed description, refer to chapter 3.

2.4 Handling and Storage of the PlazMax Sterilizing Agent



Warning!

Important: The correct handling and storage of the PlazMax Sterilizing Agent is extremely important for insuring the safety of personnel and equipment.

In order to prevent Sterilizing agent leakage:

Make sure that the sterilizing agent used is the recommended for the PlazMax sterilizer. The use of wrong bottles of sterilizing agent may cause leakage. In case of leakage, use protection gloves and clean with abounding water.

Only the use of recommended sterilizing agent is allowed as the system will only recognize the recommended bottle of PlazMax Sterilizing Agent.

PlazMax Sterilizing Agent product can be stored at room temperature (15° to 30°). This applies only if the product is stored in the upright position.

Note:

If the bottles are not stored in the correct position there is a risk of an eventual leakage of liquid inside the boxes especially if the temperature is high. This could start a fire of the materials stored close to the Sterilizing Agent as it is a chemical product and an oxidizing agent.

2.4.1 Properties, Handling and Storage of the Sterilizing Agent

The Sterilizing Agent is H_2O_2 also commonly called Hydrogen peroxide in a concentration of 50% water and 50% H_2O_2 .

The H_2O_2 is not defined as TOXIC but is defined as corrosive and in contact with the skin can cause skin burn; therefore it is recommended not to get in contact with the packaging / bottle only when wearing latex gloves and protective glasses.

The freezing temperature of this liquid is 50 degrees Celsius and it boils at 115° C.

The PlazMax sterilizing agent is clear, colourless and it looks like water and has a proper odour filter. It is not flammable; it is soluble with water independently of the sterilizing agent concentration.

The H_2O_2 substance shall be stored in a dark and clean place which is not exposed to sun light and the surrounding temperature is not higher than 25 ° C. No papers, leaves or wood shall be present in the substance proximity.

When placing a new charge of sterilizing agent bottle, the system will recognize it automatically, due to the RFID installed in each bottle.

The RFID on the bottle contains information about the expire date, lot number and packaging date.

When passing on the refilling system, the RFID will change its program preventing the use of the same bottle again.

The Hydrogen peroxide substance must be placed with the arrows facing upward.

Sort and verify that the **RFID** tag at the bottom of the bottle is not damaged.

Do not throw bottles that contain liquid, only defective packaging.

2.4.2 Sterilizing Agent Storage Safety Instructions

To insure safety perform the following instructions:

1. Check the products immediately as soon as you receive them. Open the boxes by peeling back the label that contains the batch data, and confirm that boxes and bottles are completely dry.
2. If there is a leakage and depending on the damage, act according to the instructions of use inside the box. Then close the box again putting the label in its place and store it.
3. Open the box (If you are going to use the product) by pulling the handle out. (See the Figure below).

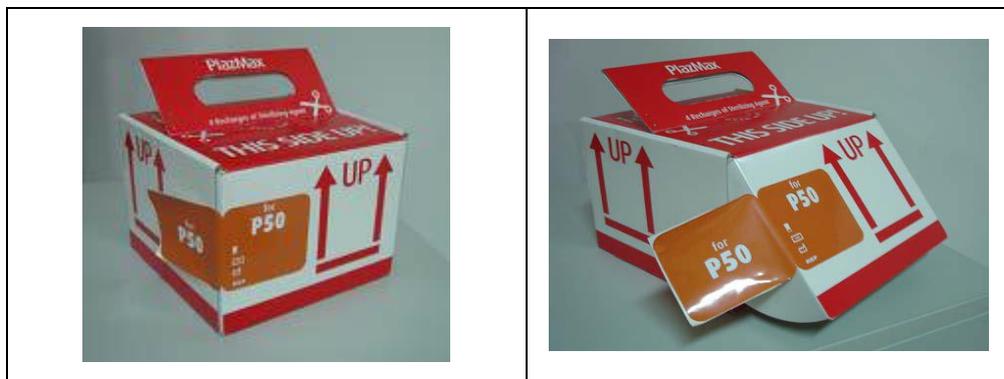


Figure 2 - PlazMax Sterilizer Agent Box

4. Transport and store the boxes/bottles in the upright position as indicated by the arrows of the packaging.
5. Store H₂O₂ at room temperature (15 to 30°C) or in a cooler place if you are located where the room temperature is higher; make sure that the product is not stored together with inflammable materials.
6. Check the stored product regularly. Refer to the Material Safety Data Sheet attached, especially to point 7. Handling and Storage.

2.4.3 How to Handle the Sterilizing Agent Boxes



Warning!

Important: It is extremely important to handle and keep the PlazMax Sterilizing Agent Boxes in the correct position always with the arrows as shown on the boxes facing upward (See paragraph 2.3.2), in order to prevent leakage and thus to ensure the safety of personnel and equipment.

In order to prevent Sterilizing agent leakage:

Make sure that the sterilizing agent used is the recommended for the PlazMax sterilizer. The use of wrong bottles of sterilizing agent may cause leakage. In case of leakage, use protection gloves and clean with abounding water.

EC CERTIFICATE

Number: 2123763CE02

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)

(Devices in Class IIa, IIb or III)

Manufacturer:

Tuttnauer Ltd.

Har - Tuv B Industrial Zone

P.O. Box 170

Beit Shemesh 9910101

Israel

For the product category(ies)

Ozone sterilizer and Hydrogen peroxide low temperature sterilizers for use with medical devices

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 2123763CN, initially dated 12 February 2009
Addendum, initially dated 29 April 2015

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 1 February 2023
Issued for the first time: 29 November 2012
Revised: 2 March 2016
Reissued: 1 February 2018

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

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DEKRA Certification B.V. is Notified Body with ID no 0344

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ADDENDUM

Belonging to certificate: 2123763CE02

1/1

CE MARKING OF CONFORMITY MEDICAL DEVICES

Ozone sterilizer and Hydrogen peroxide low temperature sterilizers for use with medical devices

Issued to:

Tuttnauer Ltd.
Har - Tuv B Industrial Zone
P.O. Box 170
Beit Shemesh 9910101
Israel

This certificate covers the following product(s):

- PlazMax sterilizer P50, P80, P110, P160 (Class IIb)
- OZMAX sterilizer (Class IIb)

Accessories:

- Hydrogen Peroxide sterilizing Agent as accessory for use with PlazMax (Hydrogen peroxide low temperature) sterilizer (Class IIb)

Initial date: 29 April 2015

Revision date: 1 June 2015

DEKRA Certification B.V.

A blue ink signature of drs. G.J. Zoetbrood, consisting of a stylized first name and a last name.

drs. G.J. Zoetbrood
Managing Director

A blue ink signature of ing. A.A.M. Laan, consisting of a stylized first name and a last name.

ing. A.A.M. Laan
Certification Manager

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