# LOW - TEMPERATURE **PLASMA** STERILIZATION DEVICES







## **BSCIENCE**<sup>®</sup> HYDROGEN PEROXIDE PLASMA STERILIZATION DEVICE

New generation ecological sterilization device that sterilizes all kinds of reusable, heat and humidity sensitive medical materials such as all kinds of metal, plastic, polymer, inorganic, medical-grade, electromechanical instruments and surgical instruments, etc. It offers fast, safe, environmentally friendly, and low-cost solutions for sterile services departments.

The device is effective on all microorganisms, bacterial forms, viruses, fungal forms, and prions on the product to be sterilized together with Hydrogen Peroxide ( $H_2O_2$ ) sterilization agent, under vacuum and in the low-temperature range of 37-55°C.

### **BSCIENCE**<sup>®</sup> HYDROGEN PEROXIDE PLASMA STERILIZATION DEVICE

Hydrogen Peroxide plasma sterilizer is used for sterilization of heat and humidity sensitive instruments/materials in places where surgical procedures are performed and the material is required to be reused, such as hospitals, polyclinics, veterinary clinics.

Products that can be applied EO and Gamma Sterilization can be easily sterilized with  $H_2O_2$  plasma sterilizers. Used for sterilization of medical materials those need to be sterilized at low temperatures.





MODEL	BS75	BS125	
ТҮРЕ	BSCIENCE	BSCIENCE	
SCREEN	Touch Screen 7"	Touch Screen 7"	
EXTERIOR DIMENSIONS (W-D-H) mm	730x955x1860	730x955x1860	
INTERIOR DIMENSIONS (W-D-H) mm	440x370x700	440x500x700	
CHAMBER VOLUME (Lt)	113	154	
CHAMBER EFFECTIVE VOLUME (Lt)	92	134	
MAXIMUM POWER (Watt)	3200	3200	
WORKING VOLTAGE	220/230 VAC, 50-60 Hz	220/230 VAC, 50-60 Hz	
PROTECTION CLASS	IP20	IP20	
EXTERIOR CHASSIS MATERIAL	STAINLESS STEEL 304	STAINLESS STEEL 304	
CHAMBER MATERIAL	STAINLESS STEEL 316	STAINLESS STEEL 316	



NO RESIDUE IN THE PRODUCT WITH HRF COLD PLASMA TECHNOLOGY IN CHAMBER **BSCIENCE** 

#### **WORKING PRINCIPLE**

(After the chamber temperature reaches the set value)

- Preparation (vacuum test, conditioning, drying etc.)
- Sterilization  $(H_2O_2)$  injection, sterilization, diffusion, plasma, etc.)
- Ventilation (Air Washing)

All phases start and end automatically without the need for user intervention. For safety reasons, as long as there is Hydrogen Peroxide  $(H_2O_2)$  in the chamber, the doors of the sterilizer cannot be opened without air washing.

# ] PROGRAMS

HRF 3000 Hydrogen Peroxide Sterilization Devices use a fixed-programmed sterilization cycle, which eliminates user error in sterilization safety.

Offers simple and fast use with language selection and pre-determined program options for sterilization on the large touch screen. The device complies with ISO 14937 sterilization validation standards. There are 3 working programs in the HRF 3000 Hydrogen Peroxide Sterilization Device as seen on the right.

#### SHORT STERILIZATION PROGRAM

Used in materials with low product amount and no lumen, in cases where sterilization is urgent. Short Sterilization Program performs the sterilization process faster than other programs. It provides a quick and economical solution when the number of products to be sterilized is low.

LONG STERILIZATION PROGRAM (45 Minutes H<sub>2</sub>O<sub>2</sub>) Used in the sterilization of non-lumen products and classical

materials where the chamber volume of the products to be sterilized is more than half.

#### **LUMEN** STERILIZATION PROGRAM

(60 Minutes H<sub>2</sub>O<sub>2</sub>) Used for sterilization of products such as Laryngoscope with Lumen, Arthroscope, Laparoscope, Trocar Cannula, Trocar Sheath, Resectoscope, Bronchoscope, Ureteroscope, Hysteroscope, Cystoscope, Choledoscope etc. **No need for additional apparatus like a booster to connect the lumen.**  Hydrogen Peroxide Plasma Sterilizer, specified below; performs the sterilization of, in addition to endoscopes, devices and instruments, conventional-type disposable materials, medical products and other materials with similar characteristics. No apparatus is needed like a booster for sterilization of non-complex lumen material in  $H_2O_2$  plasma sterilization device.

ENDOS	SCOPES				
RIGID ENDOSCOPES/LUMEN	FLEXIBLE ENDOSCOPES/LUMEN				
Laryngoscope	Bronchoscope				
Arthroscope	Ureteroscope				
Laparoscopes	Hysteroscope				
Trocar Cannula Trocar Case	Cystoscope				
Resectoscope etc.	Choledoscope etc.				
DEVICE	DEVICE & TOOLS				
Implants	Fiber Optic Cables				
Defibrillator Pedals	Laser Hand Products				
Electrocautery Products	Fiber Accessories				
Oesophagus Dilators	Ophthalmic Lenses				
Kri-Probes	Radiation Therapy Instruments				
Doppler	Surgical Power Equipment				
Head Pressure Transducer Cables	Drilling Tools				
Endoscopic Products etc.	Ultrasound Probes				
	Video Camera and Connection Apparatus etc.				

Compatible Packaging Materials are Tyvek<sup>®</sup> Sterilization Roll, Wrap Papers, Various Surgical Container Systems. Fabric, cellulosic materials (paper, cloth) silvery materials, liquid sterilization, powder, copper, natural rubber etc. are not suitable for this sterilization method.

The device is a mobile type and has 4 wheels, 2 of which are locked, for easy transportation and installation. No need for any installation or infrastructure other than electricity. No need for an additional waste disposal system.

Vacuum Pump and Maintenance Periods: In 6 months (350 cycles) and 1 year (700 cycles), the vacuum pump oil is changed and the device is also maintained.

**INSTALLATION & MAINTENANCE** 

### **SECURITY FEATURES**



- Audible and visual warning system showing error and error codes that may occur during sterilization phases,
- In power failure; The process continues according to the sterilization stage, or it terminates the program and informs the user in writing and visually that the sterilization has not been completed.
- In case of failure to reach the sterilization requirements, it cancels the cycle for safety reasons and warns the user.
- Overload and excessive humidity warning,

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Supporting monitorization with chemical and biological indicators,

(no brand dependency in the chemical and biological indicator)

• Emergency stop button.



- PLC and Microprocessor control that continuously controls values such as heat, pressure, etc. and plans to work according to these values by showing the sterilization stages,
- The system is controlled by Microprocessor and PLC and makes the necessary arrangements automatically.



# • Automatically detects damp load, dries and continues sterilization process uninterrupted.

- Delivers a Sterility Assurance Level (SAL) of 10<sup>-6</sup>.
- Suitable for heat and humidity-sensitive materials.
- It does not harm plastic and electronic materials because it sterilizes at low temperatures, and it is safe for sterilization of instruments such as camera heads, fiber optic cables, rigid and flexible endoscopes.
- Easy, comfortable, and safe use.
- Short sterilization cycle time. Shortens the sterilization process time in sterilization centers (CSSD).
- Sterilization cost is low.
- Extends the life of medical devices and instruments.

### NOT CAUSE CORROSION AND RESIDUE ON STERILIZED PRODUCTS!

With in Group, our Hydrogen Peroxide Plasma Sterilization device; To validate the Hydrogen Peroxide Sterilization and its plasma effect, EN ISO 14937 validation tests performed at full load by the Accredited Organization HYGCEN Gmbh

HygCen - Wh	ite PTFE PCD	
Material	PTFE	
Length	1200 mm	
Ø Diameter	2 mm	



With in the scope of EN ISO 14937:2009:

- Fourier Transform Infrared Spectrophotometer (FTIR) and Scanning Electron Microscope (SEM) tests
  were carried out at İzmir Katip Çelebi University Central Research Laboratory Application and Research
  Center and have been proven that the device does not cause any residue or corrosion on the sterilized
  materials.
- The ELISA test was performed in KUBTUAM, and the effectiveness of the device on Prions has been proven.



### **hdrOzone**<sup>®</sup> HEAVY MOLECULE STERILIZATION DEVICE H<sub>2</sub>O<sub>2</sub> + O<sub>3</sub> + HYDRONIUM

hdrOzone Sterilization Device is used safely to sterilize all kinds of heat and moisture sensitive medical instruments, plastic, lumen materials, electromechanical instruments, surgical instruments, complex and long lumen materials such as single and multi-channel flexible endoscopes. Used safely for the sterilization of long, complex endoscopes and also multi-channel flexible lumen endoscopes with 4 channels and 4.5m length. Has a sterilization effect up to diameter Ø2mm and length 15 meters.

hdrOzone Sterilization Device is a cold plasma sterilization system with double sterilants operating at low temperature (37 °C – 45 °C), using [Hydrogen Peroxide  $(H_2O_2)$  and Ozone  $(O_3)$ ] heavy molecules and hydronium.

Used under vacuum gas sterilization technical feature in hdrOzone sterilization. No lumen, diameter, size disadvantages and limitations seen in the Hydrogen Peroxide sterilization device. It is much more effective than  $H_2O_2$  plasma sterilization in the sterilization of complex lumen materials.

### **hdrOzone**<sup>®</sup> HEAVY MOLECULE STERILIZATION DEVICE $H_2O_2 + O_3 + HYDRONIUM$

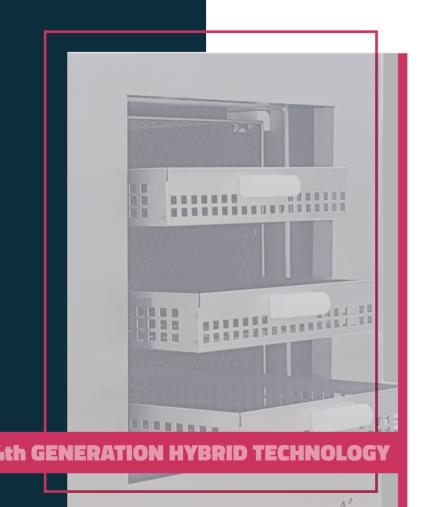
In addition to the chemical reaction sterilization process in the device, the formation of hydroxyl radicals and plasma efficiency is very high. Not cause corrosion or residue on sterilized products.

The materials coming out of the hdrOzone Plasma Sterilization Device are presented as ready-to-use without the need for extra ventilation with technological design and applications. No harmful waste, the end products formed consist of water vapour and oxygen. Therefore, offers safe sterilization as well as safe use for personnel and the environment.

The device uses 60% Hydrogen Peroxide  $(H_2O_2)$  solution and min. 90% Medical Oxygen for safe and no-limit sterilization. In this way, thanks to the intelligent program design, Ozone and Hydrogen Peroxide are used together for the most effective sterilization at the lowest dose.



hdrOzone sterilization technique with the effect of heavy molecules, radicals, hydroxyls and ions, with the application of  $H_2O_2$  and  $O_3$ , HYDRONIUM (HO<sub>3</sub>, HO<sub>4</sub>,  $H_2O_3$ ,  $H_2O_4$ , HO<sub>5</sub>, OOH,  $H_3O$  etc.)



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#### Sterilization Device operating principles;

(After the chamber temperature reaches the desired temperature)

- 1. Vacuum phase
- 2. Injection phase
- 3. Diffusion phase
- 4. Ozonation phase
- 5. Hydronium phase
- 6. Adsorption of hydronium and heavy molecules
- 7. Dilution phase
- 8. Plasma phase
- 9. Ventilation phase



#### HYDRONIUM HEAVY MOLECULE STERILIZATION TECHNIQUE

MODEL	B3S125		
TYPE	BSCIENCE		
SCREEN	Touch Screen 7"		
EXTERIOR DIMENSIONS (W-D-H) mm	730x955x1980		
INTERIOR DIMENSIONS (W-D-H) mm	440x500x700		
CHAMBER VOLUME (Lt)	154		
CHAMBER EFFECTIVE VOLUME (Lt)	134		
MAXIMUM POWER (Watt)	3200		
WORKING VOLTAGE	220/230 VAC, 50-60 Hz		
PROTECTION CLASS	IP20		
EXTERIOR CHASSIS MATERIALS	STAINLESS STEEL 304		
CHAMBER MATERIAL STAINLESS STEEL 316			



NO RESIDUE IN THE PRODUCT WITH HRF COLD PLASMA TECHNOLOGY IN CHAMBER hdrozone®

HRF 3000 hdrOzone sterilization device uses a fixedprogrammed sterilization cycle, which eliminates user error in sterilization safety.

No need to classify the materials to be sterilized and to choose the appropriate cycle and program as in old technology devices. Mixed loading can be done. The ability of the device to operate mixed loads maximizes device efficiency, safe sterilization returns while minimizing the amount of material classification to be sterilized, reducing labour cost.

## Automatically detects damp load, dries and continues sterilization process uninterrupted.

HygCen - White PTFE PCD		
Material	PTFE	K
Length	850 mm	
Ø inner	1 mm	

Teknomar - Steel Lumen PCD       Material     Steel		el Lumen PCD	
	Material	Steel	
	Length	500 mm	
	Ø inner	0,7 mm	

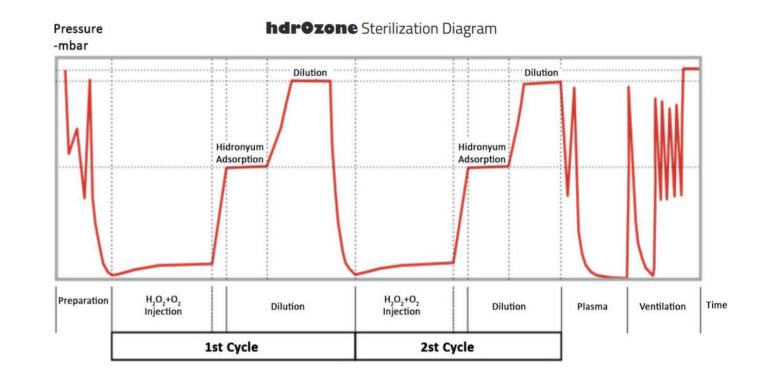
Teknomar - White PTFE PCD		
Material	PTFE	sada.
Length	50000 mm	
Ø inner	2 mm	

Teknomar - V	Vhite PTFE PCD	
Material	PTFE	
Length	900 mm	
Ø inner	0,4 mm	

To validate Ozone & Hydrogen Peroxide Sterilization and Plasma Effect of our hdrOzone device, EN ISO 14937 validation tests were made by Accredited Organization HYGCEN Gmbh, at full load.

Hydrogen Peroxide  $H_2O_2 + O_3$ Ozone Plasma Sterilization Device perform the sterilization of medical products and other materials with similar properties, except for conventional type disposable materials.

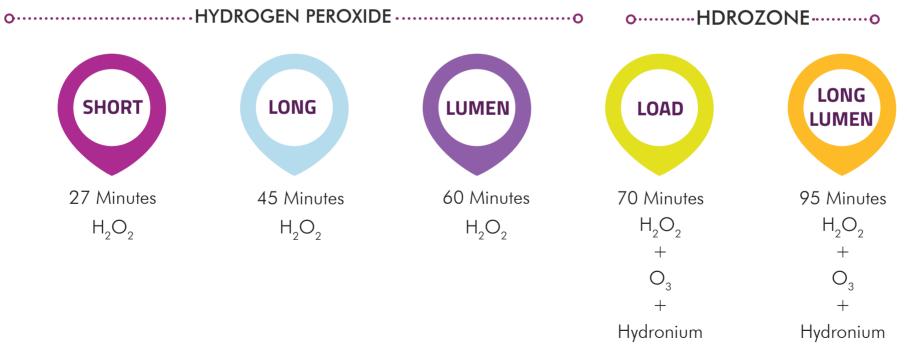
No apparatus is needed for the sterilization of complex lumen materials (like a booster).



hdrOzone Sterilization Device, besides its superior specifications, can also be used as a stand-alone Hydrogen Peroxide Sterilization Plasma Device.

## PROGRAMS

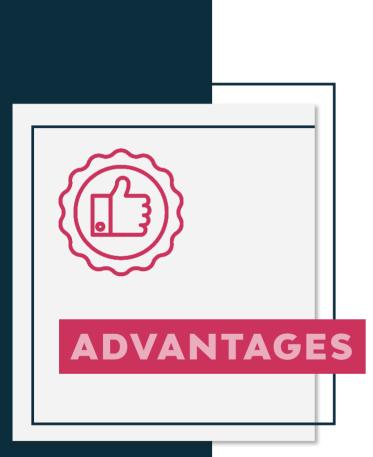
Offers simple and fast use with pre-determined program options for language selection and sterilization on the large touch screen. The device is in compliance with ISO 14937. HdrOzone Sterilization Device, besides its superior specifications, can also be used as a stand-alone Hydrogen Peroxide Sterilization Plasma Device. There are 5 programs in total, including 3- H<sub>2</sub>O<sub>2</sub> Programs and 2 - hdrOzone programs. Has a simple user interface.





## **ADVANTAGES**

- No need for separation and one by one sterilization when placing materials in the sterilization chamber such as long lumen, short lumen, load and other materials !
- No length limit in lumen material!
- All kinds of material sterilization with full load,
- Mixed load capability,
- Non-wet moist materials can be sterilized. No need for a product drying operation as with other hydrogen peroxide devices.
- Suitable for sterilization of flexible surgical instruments with very long and thin lumen at full load.
- Fast sterilization process at full load,



- The use of heavy molecules instead of the only hydroxyl in the new hdrOzone technique and technology,
- Using  $H_2O_2 + O_3$  and gaseous hydronium instead of condensed  $H_2O_2$ ,
- All kinds of sterilization safety,
- In the sterilization of long and thin (ø 1mm \* 100 cm) lumen materials,

sterilizes multiple 15 meters (ø 2mm diameter) at full load without the need for

manufacturer's declaration.

- Short sterilization cycle duration,
- No auxiliary apparatus such as a booster is required.
- Completes the sterilization process at low temperature and humidity.

- It is a sterilization method that does not leave toxic residues.
- Suitable for temperature and humidity sensitive materials.
- No ventilation time is required.
- Has easy, comfortable and safe use.
- Reduces material selection error to zero.
  - Reduces the need for qualified personnel.
- Sterilization cost per material and low labour.
- A normal  $H_2O_2$  device cartridge is used. Because sterilization is FULL load cartridge consumption is 1/3 compared to normal  $H_2O_2$  devices.
- Not harmful to the environment since it is  $H_2O_2$  and  $O_2$  as the final product. It is a safe method for the environment and human health.



#### **ENDOSCOPES**

Mixed loading is done in all sizes, diameters and lengths. No need for product classification. No limit in diameters.

#### **RIGID ENDOSCOPES/LUMEN**

Laryngoscope Arthroscope Laparoscopes Trocar Cannula Trocar Case Resectoscope etc.

#### FLEXIBLE ENDOSCOPES/LUMEN

Bronchoscope Ureteroscope Hysteroscope Cystoscope Choledoscope etc.

#### **DEVICE & TOOL**

Implants Defibrillator Pedals Electrocautery Products Oesophagus Dilators Kri-Probes Doppler Head Pressure Transducer Cables Endoscopic Products etc. Fiber Optic Cables Laser Hand Products Fiber Accessories Ophthalmic Lenses Radiation Therapy Instruments Surgical Power Equipment Drilling Tools Ultrasound Probes Video Camera and Connection Apparatus etc.

Compatible Packaging Materials are Tyvek® Sterilization Roll, Wrap Papers, Various Surgical Container Systems. Fabric, cellulosic materials (paper, cloth) silvery materials, liquid sterilization, powder, copper, natural rubber etc. are not suitable for this sterilization method.

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### LUMEN CHART SUITABLE FOR STANDARDS

With the lumen program of the Hydrogen Peroxide Plasma Sterilization Device, safe sterilization of lumen materials can be performed in the lengths and diameters given in the table.

According to the standards;

- Suitable for sterilization
- Sterilization should be checked and verified

Program	Length						
	2000 mm						
LUMEN	1500 mm						
	1000 mm						
	800 mm						
	600 mm						
LONG	500 mm						
	400 mm						
	300 mm						
SHORT	200 mm						
	Diameter	1 mm	2 mm	3 mm	4 mm	5 mm	6 mm



- MDD 93/42/EEC, CE Certificate
- EN ISO 13485:2016
- EN ISO 9001:2015
- TUR Technological Product Experience Certificate
- Domestic Goods Certificate
- Certificate of Free Sale
- TEYDEP Project Success Certificate
- LVD Test Report / EN 60601-1

- EMC Test Report / EN 60601-1-2
- EN ISO 14937 Validation Test
- Prion Test
- Lumen Material Sterilization Test
- Residue Test
- Corrosion Test
- ELISA Test
- Device Type Test





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