Hydronium Technology

B SCIENCE®
BIOMEDICAL

WE CREATE THE FUTURE OF STERILIZATION !

$H_3O^+ + O_3 + H_2O_2$ & REACTIVE OXIDANT COMBINATION

GAS PHASE COLD PLASMA INTEGRATED HYBRID STERILIZER

hdrOzone®

4th Generation High Sterilization Technology for **Polymers.**

FIRST & UNIQUE
IN THE WORLD

Made in Türkiye

ISO 13485:2016

ISO 9001:2015

kiwa certified CE MARK

kiwa certified ISO 13485

CE 1984

TEKNOMAR® Since 1993 Group

WHAT IS HDROZONE® ?

hdrOzone® Sterilization Device is a cold plasma sterilization system with double sterilants operating at low temperature, using [Hydrogen Peroxide (H_2O_2) and Ozone (O_3)] heavy molecules and **hydronium sterilization method (H_3O+, H2O4).**

154 L

Low-temperature cold sterilization
37–45 °C

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.

The products sterilized in **hdrOzone®** unique system are ready-to-use upon completion of the sterilization process.

Dual-Sterilant System (H_2O_2 + O_2)

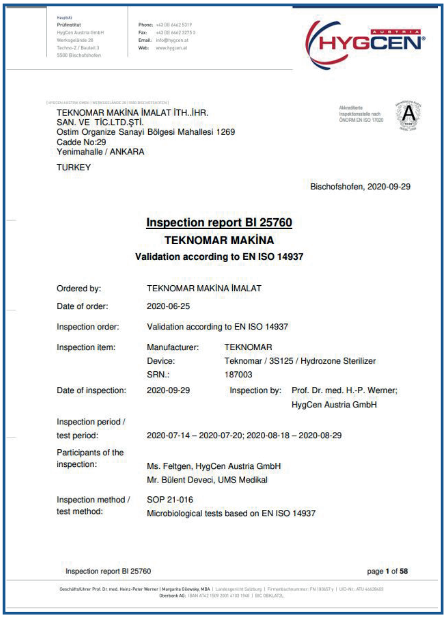
The end product formed consist of water vapour and oxygen which offers safe sterilization as well as safe use for personnel and the environment.

- **No need to classify** the materials to be sterilized and to choose the appropriate cycle and program as in old technology devices.

In HdrOzone device, O_3 is not used to neutralize H_2O_2 as in other ozone-based devices !

✱ Sterilizing of **all types of lumen-based instruments.**

Ensures safe and effective sterilization of long and complex endoscopes, including **multi-channel flexible endoscopes with up to 4 channels and 4.5 m length**, without any structural **deformation, corrosion and residue**.



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HYGCEN AUSTRIA

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SAN. VE TİC.LTD.ŞTİ.
Ostim Organize Sanayi Bölgesi Mahallesi 1269
Cadde No:29
Yenimahalle / ANKARA
TURKEY

Akkreditierte Inspektionsstelle nach ÖNORM EN ISO 17020

Bischofshofen, 2020-09-29

Inspection report BI 25760
TEKNOMAR MAKİNA
Validation according to EN ISO 14937

Ordered by:	TEKNOMAR MAKİNA İMALAT	
Date of order:	2020-06-25	
Inspection order:	Validation according to EN ISO 14937	
Inspection item:	Manufacturer:	TEKNOMAR
	Device:	Teknomar / 3S125 / Hydrozone Sterilizer
	SRN.:	187003
Date of inspection:	2020-09-29	Inspection by: Prof. Dr. med. H.-P. Werner; HygCen Austria GmbH
Inspection period / test period:	2020-07-14 – 2020-07-20; 2020-08-18 – 2020-08-29	
Participants of the inspection:	Ms. Feltgen, HygCen Austria GmbH Mr. Bülent Deveci, UMS Medikal	
Inspection method / test method:	SOP 21-016 Microbiological tests based on EN ISO 14937	

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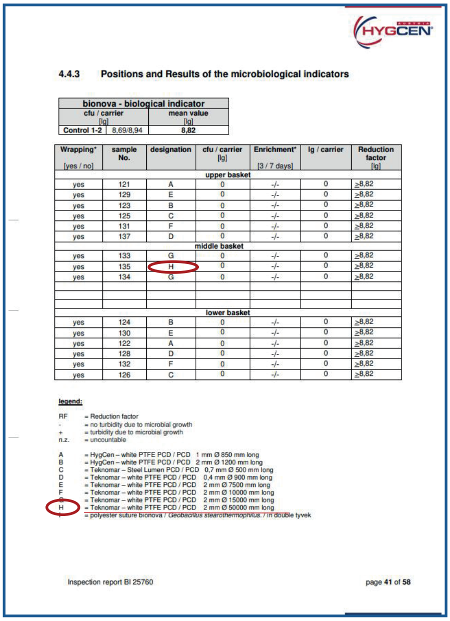

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4.4.3 Positions and Results of the microbiological indicators

bionova - biological indicator		
cfu / carrier [lg]		mean value [lg]
Control 1-2	8,69/8,94	8,82

Wrapping* [yes / no]	sample No.	designation	cfu / carrier [lg]	Enrichment* [3 / 7 days]	lg / carrier	Reduction factor [lg]
upper basket						
yes	121	A	0	-/-	0	≥8,82
yes	129	E	0	-/-	0	≥8,82
yes	123	B	0	-/-	0	≥8,82
yes	125	C	0	-/-	0	≥8,82
yes	131	F	0	-/-	0	≥8,82
yes	137	D	0	-/-	0	≥8,82
middle basket						
yes	133	G	0	-/-	0	≥8,82
yes	135	H	0	-/-	0	≥8,82
yes	134	G	0	-/-	0	≥8,82
lower basket						
yes	124	B	0	-/-	0	≥8,82
yes	130	E	0	-/-	0	≥8,82
yes	122	A	0	-/-	0	≥8,82
yes	128	D	0	-/-	0	≥8,82
yes	132	F	0	-/-	0	≥8,82
yes	126	C	0	-/-	0	≥8,82

legend:

RF = Reduction factor
- = no turbidity due to microbial growth
+ = turbidity due to microbial growth
n.z. = uncountable

A = HygCen – white PTFE PCD / PCD 1 mm Ø 850 mm long
B = HygCen – white PTFE PCD / PCD 2 mm Ø 1200 mm long
C = Teknomar – Steel Lumen PCD / PCD 0,7 mm Ø 500 mm long
D = Teknomar – white PTFE PCD / PCD 0,4 mm Ø 900 mm long
E = Teknomar – white PTFE PCD / PCD 2 mm Ø 7500 mm long
F = Teknomar – white PTFE PCD / PCD 2 mm Ø 10000 mm long
G = Teknomar – white PTFE PCD / PCD 2 mm Ø 15000 mm long
H = Teknomar – white PTFE PCD / PCD 2 mm Ø 50000 mm long
I = polyester suture bionova / *Geobacillus stearothermophilus*. / in double tyvek

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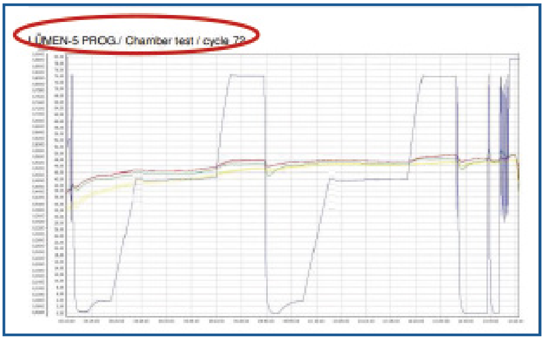
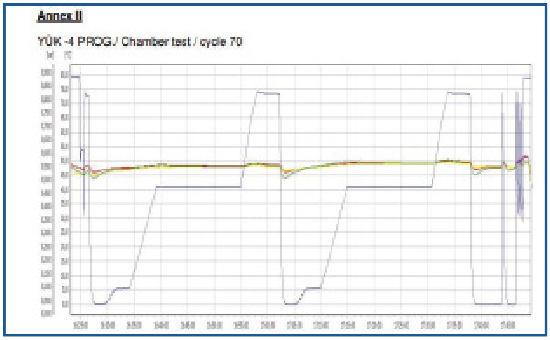
Proven effectiveness for lumens up to Ø 2 mm in diameter & **15,000 mm** in length.



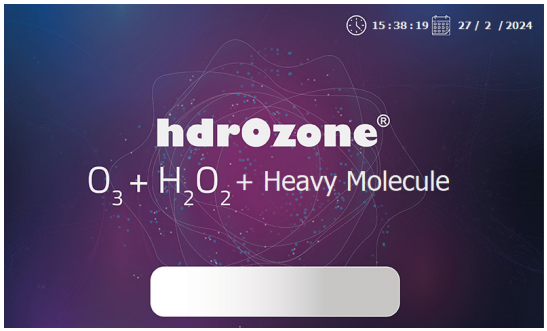


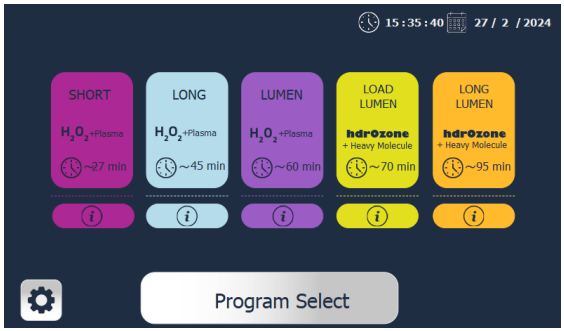
EN ISO 14937 validation and performance testing were completed under full-load conditions by the accredited laboratory **HygCen GmbH**, with certified performance of **"Ø 2 mm & 50 meters"**.

TEKNOMAR® Group Since 1993

Application to set the record on GWR'S been submitted.

hdrOzone® can also operate as a Hydrogen Peroxide Plasma Sterilization Device !





HYDROGEN PEROXIDE PROGRAMS
H_2O_2

SHORT	LONG	LUMEN
27 Min.	45 Min.	60 Min.

HDROZONE PROGRAMS
H_2O_2+ O_3 + Hydronium

LOAD	LONG LUMEN
70 Min.	95 Min.

- Automatically detects **moistured load**, dries and continues sterilization process uninterrupted.
- EN ISO 14937 validation and performance testing
  There is a special Validation programme on **half cycle**!
- No limitation on **“Diameter or Length”,** even with **full** or **mixed loads.**
- **Economical -** Provides a low-cost operation.
  Since the HdrOzone device allows all items to be sterilized together in a **fully loaded chamber** without the need for sorting, its cost per cycle is roughly one-third that of standard hydrogen peroxide sterilizers, while significantly reducing labor and processing time.

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.

NO RESIDUE !

NO CORROSION !

NO DEFORMATION !

ENDOSCOPES Mixed loading is done in all sizes, diameters and lengths. No need for product classification. No limit in diameters.	
RIGID ENDOSCOPES/LUMEN	FLEXIBLE ENDOSCOPES/LUMEN
Laryngoscope	Bronchoscope
Arthroscope	Ureteroscope
Laparoscopes	Hysteroscope Cystoscope
Trocar Cannula Trocar Case	Choledoscope etc.
Resectoscope etc.	
DEVICE & TOOL	
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® 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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Ethylene Oxide, Hydrogen Peroxide and Hydronium Heavy Molecule

Sterilization Comparison Table

Sterilization Method	Ethylene Oxide	Hydrogen Peroxide	HdrOzone® Hydronium Heavy Molecule
Teknomar	EO - C_2H_4O	H_2O_2	Hydronium (H_3O)
Efficacy	Effective	Limited Efficacy	High Efficacy on Lumen Products
Cycle Time	~ 4-12 hrs	~ 70 Minutes	~ 95 minutes
Cost of Cycle	~ 12,^{00}* €	~9,^{00}* €	~ 10,^{00}* €
Cartridge Storage	Challenging	Appropriate	Appropriate
Dangerous	High	Environmental Friendly	Ecologic
Preparation for Sterilization	Medium	Long	Short
Capacity	Limited Capacity	Limited Capacity	High Capacity
Material Compatibility	Mixed Material	Various Programs for Different Products	Mixed Material
Pollutant	Risky	Ecologic	Ecologic
External Connection	Needed	No Needed	Needed
Working Temperature	37-55 °C	37-55 °C	37-45 °C
Sterility Assurance Level (SAL)	10^{-6}	10^{-6}	10^{-6}
Maintenance	Expensive	Reasonable	Reasonable
Installation	Challenging	Easy	Easy
Working Principle	ETO Only	H_2O_2 Only, but Upgradable	1: H_2O_2 2: H_2O_2 & O_3 3: O_3
Diameter and Length	Limitless	1 mm Ø - 400 mm / 2 mm Ø 1200 mm	Ø 0,1 mm inner diameter ../.. Min. 4,5 meter Length
Residue on Product	Risky	No residue on Product	No Residue on Instruments and Long Lumen Products

The ranking shows that the most suitable sterilizer is Hydronium Heavy Molecule Plasma Sterilizer with 16/18 points. The second one is Hydrogen Peroxide Gas Plasma Sterilizer in terms of Cost and Capability-with 8/18. The third is Ethylene Oxide Gas Sterilizer with limited advantages and high considerable risks 7/18.

$H_2O_2 + O_3$ STERILIZATION DEVICE & PLASMA VH_2O_2 DEVICE & HEAVY MOLECULE HDROZONE STERILIZATION DEVICES TECHNICAL COMPARISON TABLE

This comparison table includes the technical comparison of three widely used low-temperature sterilization systems in the field: O_3 Sterilization Device & Plasma VH_2O_2 Device & Heavy Molecule HDROZONE Sterilization Device They are compared in terms of sterilant type, plasma usage, chemical reaction mechanism, vacuum pressure, temperature, and reactive species.

1. GENERAL SYSTEM COMPARISON

FEATURE / SYSTEM	$H_2O_2 + O_3$ STERILIZATION DEVICE	PLASMA VH_2O_2 DEVICE	HEAVY MOLECULE HdrOzone® STERILIZATION DEVICE
Sterilization Type	Chemical hybrid ($H_2O_2 + O_3$)	Plasma-assisted VH_2O_2 (RF plasma)	Hybrid plasma + heavy molecular reactive system
Sterilants	$H_2O_2 + O_3$	VH_2O_2	$H_2O_2 + O_3$ + humidity (H_2O) → H_3O^+ / H_2O_4 / ·OH
Activation Method	Chemical redox ($O_3 + H_2O_2$ → ·OH)	RF energy (13.56 MHz)	DBD (Dielectric Barrier Discharge) 6 kV, 50–100 Hz
Plasma Phase	None	Present	Present (cold plasma)
Pressure (Vacuum)	10–20 Torr	0.3–1 Torr	10^{-3} Torr
Temperature	45 ± 5 °C	45–55 °C	35–45 °C
Main Reactive Species	·OH, O_2, H_2O_2, O_3	e^-, O_2^+, ·OH, HO_2·	·OH, H_3O^+, H_2O_4, O_2^-, O_3^-
Sterilization Effect	Chemical oxidation	Ionized VH_2O_2 + radicals	Heterogeneous ion/radical combination

2. CHEMICAL AND PHYSICAL MECHANISM

PARAMETER	$H_2O_2 + O_3$ STERILIZATION DEVICE	PLASMA VH_2O_2 DEVICE	HEAVY MOLECULE HdrOzone® STERILIZATION DEVICE
Radical Formation	$H_2O_2 + O_3$ → ·OH + O_2 + H_2O	H_2O_2 → ·OH + HO_2·	$H_2O_2 + O_3 + H_2O + e^-$ → H_2O_4 + H_3O^+ + ·OH
Plasma Type	—	RF (capacitive)	DBD (barrier discharge)
Electron Energy	—	3–10 eV	1–5 eV
Radical Diffusion Depth	~1 mm	1–3 mm	3–10 mm
Sterilant Regime	Chemical	Electronically controlled	Combined reactive + electronic
Lumen sterilization	2 m	1.5 m	15 m

3. TECHNICAL RESULT AND EVALUATION

· **$H_2O_2 + O_3$ Sterilization Device:** A non-plasma chemical hybrid system. Its advantage is low complexity and high safety; however, its disadvantage is the limited penetration depth of reactive species.

· **Plasma VH_2O_2 Device:** A plasma-assisted VH_2O_2 system. Ionization of H_2O_2 by RF plasma provides strong surface sterilization, but the lumen penetration depth remains limited.

· **Heavy Molecule HDROZONE Sterilization Device**: A gas-phase hybrid plasma system. Under DBD plasma, the interaction of $O_3 + H_2O_2 + H_2O$ produces H_2O_4 and H_3O , delivering deep diffusion and a broad diversity of reactive species.

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Frequently Asked Questions (FAQ)

1. Can I use the Hdrozone device as a Hydrogen Peroxide sterilizer? - Yes.

2. How many cycles can I run with one sterilant cartridge?

-At least 6 double cycles. The cartridge is 120 ml and contains 59% H_2O_2.

3. How do we supply the cartridges?

-They can be supplied by the manufacturer or the authorized distributor.

4. Does it sterilize all low-temperature–resistant materials? - Yes.

5. Which materials cannot be sterilized in the Hdrozone device?

-Fabric, cellulosic materials (paper, cloth), silver-coated materials, liquids, powders, copper, natural rubber, and similar materials are not suitable for this sterilization method.

6. What happens in the event of a power outage?

-When power is back, the device asks “Finish?” / “Continue?” on the screen.

It resumes or ends the cycle according to the user’s selection.

7. What is required to generate ozone? - External oxygen.

8. What oxygen purity is required?

-Above 80% when using central oxygen supply, and above 98% when using a medical oxygen cylinder.

9. How often should the device undergo maintenance? - Maintenance should be performed every 3–6 months (350 cycles)

10. Is an exhaust connection required? -Yes. An exhaust line is necessary to vent residual ozone outside.

11. How much load can be placed inside the device for sterilization?

-In Hdrozone mode, the entire sterilization chamber can be fully loaded. (Max. 131 Lt)

12. Can mixed loads be sterilized? - Yes, they can.

13. What packaging material should be used for items to be sterilized? -Tyvek.

14. Which biological and chemical indicators are used?

-The same chemical and biological indicators used for VH_2O_2 systems.

15. What happens if moist/wet items are placed in the device? Does it trigger a moisture error?

-The device detects moisture, dries the items, and continues sterilization without interruption.

16. Is it necessary to separate lumened instruments by length or diameter?

-No. There is no lumen, diameter, or length limitation. All lumened items can be sterilized together in a full mixed load.

17. Can I view past sterilization records on the device? -Yes. A minimum of 100 cycle records are stored.

18. Does the Hdrozone device include a validation program?

-Yes. The device includes additional quarter-cycle and half-cycle validation programs.

19. What is the sterilization cost compared to VH_2O_2 devices?

-Since full and mixed loads can be sterilized in a single cycle, the cost is approximately one-third of VH_2O_2 devices.

20. Do sterilized items require additional aeration? - No.

21. Is a booster required for lumen sterilization? - No.

22. Is specially trained staff required to operate the device? - No.

23. Is there any hazardous waste? -No hazardous waste. The final by-products are only water vapor and oxygen.

24. Is a separate room or special installation area required for the device?

- No. It can be installed in any area suitable for a hydrogen peroxide sterilizer.

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