



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

TEKNOMAR®
Since 1993
Group

WHAT IS HDROZONE® ?

hdrozone® Sterilizer is a cold plasma sterilization system operating at low temperature utilizing dual sterilants (H_2O_2 and O_3) and an advanced **hydronium-based sterilization mechanism (H_3O^+ , H_2O_4^+)**.



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.**

HYGCEN

TEKNOMAR MAKİNA İMALAT İTH.İHR. SAN. VE TİC.LTD.ŞTİ.
Optik Organize Sanayi Bölgesi Mahallesi 1269
Cadde No:29
Yenimahalle / ANKARA
TURKEY

Biochhofaden, 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 / 95125 / HydroLine 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. Filizgen, HygCen Austria GmbH
Mr. Bilent Devici, UMS Medical
Inspection method /
test method: SOP 21-016
Microbiological tests based on EN ISO 14937

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4.4.3 Positions and Results of the microbiological indicators

biobay - biological indicator	
ctu / carrier	result value
Control 1-2	8.500.000

Wrapping	sample No.	designation	ctu / carrier (p)	Enrichment (p)	log carrier	Reduction factor
yes / no				30 - 7 (min)		
upper basket						
yes	121	A	0	<-	0	>0.82
yes	129	B	0	<-	0	>0.82
yes	125	B	0	<-	0	>0.82
yes	126	C	0	<-	0	>0.82
yes	131	F	0	<-	0	>0.82
yes	127	D	0	<-	0	>0.82
middle basket						
yes	133	D	0	<-	0	>0.82
yes	135	B	0	<-	0	>0.82
yes	134	B	0	<-	0	>0.82
lower basket						
yes	124	B	0	<-	0	>0.82
yes	130	B	0	<-	0	>0.82
yes	122	A	0	<-	0	>0.82
yes	128	D	0	<-	0	>0.82
yes	122	F	0	<-	0	>0.82
yes	120	C	0	<-	0	>0.82

Legend:

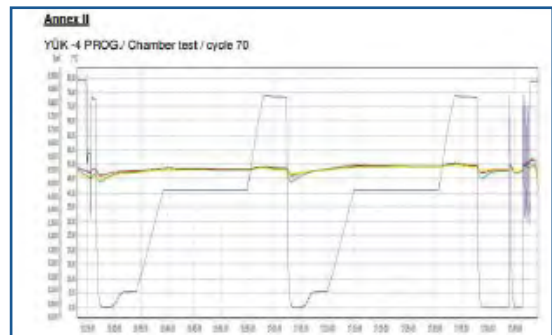
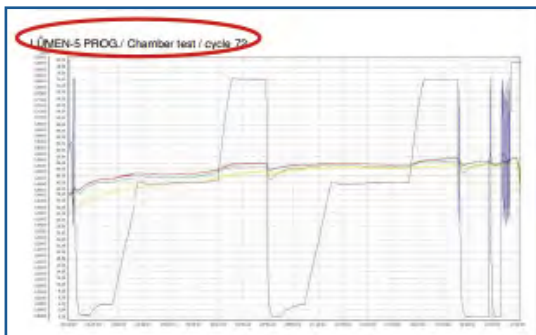
- 00 = Reduction factor
- = no activity due to microbial growth
- + = activity due to microbial growth
- 6.2 = non-sterile

A = HygCen - white PTFE PCD / PCD 1 mm Ø 800 mm long
 B = HygCen - white PTFE PCD / PCD 2 mm Ø 1200 mm long
 C = Teknomar - Steel Lumen PCD / PCD 0.7 mm Ø 900 mm long
 D = Teknomar - white PTFE PCD / PCD 2.6 mm Ø 900 mm long
 E = Teknomar - white PTFE PCD / PCD 2 mm Ø 1700 mm long
 F = Teknomar - white PTFE PCD / PCD 2 mm Ø 1500 mm long
 G = Teknomar - white PTFE PCD / PCD 2 mm Ø 1500 mm long
 H = Teknomar - white PTFE PCD / PCD 2 mm Ø 1500 mm long
 I = Teknomar - white PTFE PCD / PCD 2 mm Ø 1500 mm long
 J = Teknomar - white PTFE PCD / PCD 2 mm Ø 1500 mm long

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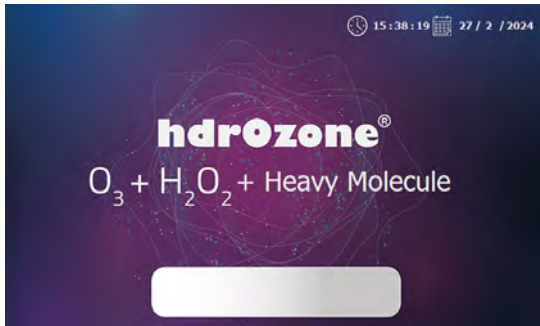
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Proven effectiveness for lumens up to Ø 2 mm in diameter & **15,000 mm** in length.



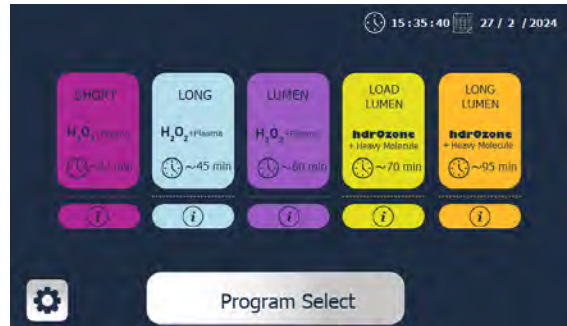
EN ISO 14937 validation and performance testing were completed under full-load conditions by the accredited laboratory **HygCen GmbH**, with certified performance of **“Ø 2 mm & 50 meters”**.

* **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 $H_2O_2 + O_3 + \text{Hydronium}$

LOAD	LONG LUMEN
70 Min.	95 Min.

- * Automatically detects **moistured load**, dries and continues sterilization process uninterrupted.
- * No **residue** in the product with **HRF Cold Plasma** Technology in chamber !
- * EN ISO 14937 validation and performance testing
There is a special Validation programme on **half cycle**!
- * No limitation on **“Diameter or Length & Weight”**, even with **full** or **mixed**
- * **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 Arthroscope Laparoscopes Trocarr Cannula Trocar Case Resectoscope etc.	Bronchoscope Ureteroscope Hysteroscope Cystoscope Cholescope 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.

Ethylene Oxide, Hydrogen Peroxide and Hydronium Heavy Molecule Sterilization Comparison Table

Sterilization Method	Ethylene Oxide	Hydrogen Peroxide	HdrOzone® Hydronium Heavy Molecule
Teknomar	EO - C ₂ H ₄ O	H ₂ O ₂	H ₂ O ₂ & O ₃ & Hydronium
Efficacy	Effective	Limited Efficacy	High Efficacy on Lumen Products
Cycle Time	~ 4-12 hrs	~ 65 Minutes	~ 70 Minutes (Load)
Cost of Cycle	~ 20.00* €	~ 16.00* €	~ 17.00* €
Cartridge Storage	Challenging	Suitable	Suitable
Dangerous	High	Environmental Sensitive	Ecological
Preparation for Sterilization	Medium	Long	Short
Capacity	High Capacity	Limited Capacity	High Capacity
Material Compatibility	Mixed Materials	Different Programs for Different Products	Mixed Materials
Pollutant	Risky	Ecological	Ecological
External Connection	Required	Not Required	Required
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-Easy
Installation	Challenging	Easy	Easy
Working Principle	ETO Only	H ₂ O ₂ Gas Vapor or Plasma Only	1: H ₂ O ₂ 2: H ₂ O ₂ & O ₃ 3: Hydronium
Diameter and Length	Unlimited	1 mm Ø - 850 mm / 2 mm Ø 1200 mm	Ø 0.1 mm - 50 cm / 2 mm Ø internal diameter min. 4.5 - 15 meters length
Residue on Product	Risky	No residue on Product	No residue on equipment and multi-channel long-lumen devices
Device Cost (based on 100 units)	~25 units	~55 units	~75 units

The ranking shows that the most suitable sterilizer is the HdrOzone Sterilization Device with 16/18 points. Second, with 8/18 in terms of Cost and Capacity, is the Hydrogen Peroxide Gas Plasma Sterilizer. Third, with limited advantages and high risks, is the Ethylene Oxide Gas Sterilizer with 7/18.

H₂O₂ + O₃ STERILIZATION DEVICE & PLASMA VH₂O₂ 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: O₃ Sterilization Device & Plasma VH₂O₂ 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 ₂ O ₂ + O ₃ STERILIZATION DEVICE	PLASMA VH ₂ O ₂ DEVICE	HEAVY MOLECULE HdroZone® STERILIZATION DEVICE
Sterilization Type	Chemical hybrid (H ₂ O ₂ + O ₃)	Plasma-assisted VH ₂ O ₂ (RF plasma)	Hybrid plasma + heavy molecular reactive system
Sterilants	H ₂ O ₂ + O ₃	VH ₂ O ₂	H ₂ O ₂ + O ₃ + humidity (H ₂ O) → H ₃ O ⁺ / H ₂ O ₄ / ·OH
Activation Method	Chemical redox (O ₃ + H ₂ O 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 ₂ O ₂ , O ₃	e ⁻ , O ₂ ⁺ , ·OH, HO ₂ ⁺	·OH, H ₃ O ⁺ , H ₂ O ₄ , O ₂ ⁻ , O ₃ ⁻
Sterilization Effect	Chemical oxidation	Ionized VH ₂ O ₂ + radicals	Heterogeneous ion/radical combination

2. CHEMICAL AND PHYSICAL MECHANISM

PARAMETER	H ₂ O ₂ + O ₃ STERILIZATION DEVICE	PLASMA VH ₂ O ₂ DEVICE	HEAVY MOLECULE HdroZone® STERILIZATION DEVICE
Radical Formation	H ₂ O ₂ + O ₃ → ·OH + O ₂ + H ₂ O	H ₂ O ₂ → ·OH + HO ₂ ·	H ₂ O ₂ + O ₃ + H ₂ O + e ⁻ → H ₂ O ₄ + H ₃ O ⁺ + ·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

- **H₂O₂ + O₃ 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 VH₂O₂ Device:** A plasma-assisted VH₂O₂ system. Ionization of H₂O₂ 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 O₃ + H₂O₂ + H₂O produces H₂O₄ and H₃O⁺, delivering deep diffusion and a broad diversity of reactive species.

* 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% H₂O₂.
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 VH₂O₂ 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 VH₂O₂ devices?
-Since full and mixed loads can be sterilized in a single cycle, the cost is approximately one-third of VH₂O₂ 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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