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# HEMOCLEAN<sup>®</sup> Reference Manual



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## I. INTRODUCTION

In 1902 peracetic acid which was developed by Ferry and Novy had no practical use because it had difficulties in circulating and keeping for its instability caused by high reactivity. In the latter half of 1970 in German more stable and circulation possible technique was developed and peracetic acid became practical use in industry fields as cleaner & disinfectant. Especially, fast and outstanding disinfection efficacy and cleaning efficacy comes together at low-temperature, in low-concentration, also the user safety and the environmental friendly (cause no 2<sup>nd</sup> environmental pollution) were came into the spotlight, peracetic acid was widely use as cleaner & disinfectant for dairy products, beverages, alcohol & liquor, food industries, manufacture equipments of cosmetic factories, medical equipments. In mid-1980 from U.S., medical peracetic type disinfection & cleaner were started to use for dialyzer reprocessing which were used for end stage renal disease patient hemodialysis. Nowadays, it is widely used as cleaner & disinfectant of hemodialysis equipments.

Cleaner & disinfectant for hemodialysis equipments are different by each equipment manufacturer's recommendation, most widely using methods are [acid + sodium hypochlorite] or [citric acid + sodium hypochlorite], separately doing cleaning & disinfecting method had the disadvantage of inconvenience for users and decrease of efficacy, also sodium hypochlorite cause corrosiveness to metals so the quantity of sodium hypochlorite consumed was rapidly shrunk. Especially, it was controlled in internal and external country for causing environmental pollution from the second – order reaction and lost of purification capability in the water-purifier tank after using sodium hypochlorite, and in Tokyo Metropolitan Government, sodium hypochlorite was regulated one of the 48 focus control subjects in waste water of public facilities including medical facilities and was intensively controlled and restricted.<sup>1)</sup> Use peracetic type cleaner & disinfectant for hemodialysis equipments can do cleaning & disinfecting at the same time and settled the inconvenient of separately doing cleaning & disinfecting, further more it has no environment pollution because it can be highly nature decomposed, the use is being increased rapidly.

**HEMOCLEAN®**, the special hemodialysis disinfectant & cleaner that firstly made by self developed patent technique and uniquely registered as special medicine, was firstly admitted FDA(US Food & Drug Administration) among all of the counties except U.S. and admitted CE(Conformité Européene, European Conformity). Especially, **HEMOCLEAN®** showed the outstanding protein cake and biofilm removal and restricted efficacy in Japan's hemodialysis systems where use high flux dialyzer and CDS system, the experiences were presented in JSDT (Japanese society for Dialysis Therapy) and demonstrated as clinical test results. Now, **HEMOCLEAN®** is the best seller among the peracetic acid cleaner & disinfectant market in Japan.

**HEMOCLEAN®**, as a kind of acid disinfectant with its main ingredients of peracetic acid and hydrogen peroxide, has fast disinfection rate, excellent disinfection power and cleaning power, easy concentration control in various condition, superior stability for long lasting efficacy, environmental friendliness for completely biodegradable, long lasting and effective scale removal power and restraint to equipment and pipes etc. During using **HEMOCLEAN®** to hemodialysis machine, the water purifiers and purified water supply system for cleaning & disinfection, it has superior economical efficiency for the reduction of electricity, water and time since it's no need to use extra chemicals, also it is convenient and safe for the users.

We made this manual on the bases of tests results from product development to after launching for 10 years, for the purpose of the correct comprehension and using convenience for users and hemodialysis equipments and system managers.

## II. PRODUCT INFORMATION OF HEMOCLEAN®

### 1. GENERAL INFORMATION OF HEMOELAN®

#### (1) Composition

■ Active ingredient:	Peracetic acid	1.73%
■ Sub ingredient:	Hydrogen peroxide	Less than 5.95%
■ Solvent:	Purified water	A proper quantity

Each ingredient in a solution maintains chemical equilibrium in a regular ratio, and synergy effect is caused by the each ingredient effect came together.

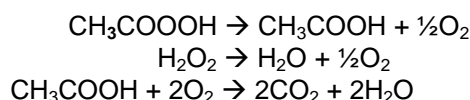
Peracetic acid and hydrogen peroxide contains peroxide (-O-O-) while contact with organics they do radical reactions which caused disincentive effects. Peracetic acid has short term disincentive efficacy and hydrogen peroxide has long-lasting disincentive efficacy as well as removal of organics. Acetic acid has decalcification and can clean the inorganic materials (calcium salt) in the tube.

#### (2) Physical properties

- Colorless liquid in a white plastic container
- Typical acetic odor
- Non-flammability
- Simply rinse after using for easily mixed with water in any proportion
- pH: 1.0
- Specific gravity: 1.097 g/cm<sup>3</sup>
- Freezing point: -21 ~ -22 °C

#### (3) Environmental friendly

**HEMOCLEAN®** react with microorganism's protein components and dialysis metabolites, finally peracetic acid decomposed into acetic acid and oxygen, hydrogen peroxide decomposed into water and oxygen. Acetic acid used for removing the calcium salt and oxidized by hydrogen peroxide and peracetic acid, lastly decomposed into water and carbon dioxide after being drained.



Follow is the result of BOD change from the Akida Red Cross hospital under the use of peracetic acid disinfectant by Mr. Kumagai, JSDT 2003. Drain liquid from dialysis was composed with used dialysate solution, cleaner and disinfectant, purified water and metabolite from patients.<sup>2)</sup>

Especially for dialysate solution, it may shows different figure of BOD according to glucose concentration. Dialysate solution which contains 0.10% ~ 0.15% glucose shows BOD figure from 1,100 ppm to 1,300 ppm which is considered to be high.

A Japan's local health environment institute did a BOD figure routine checkup about the water purified tank of medical facilities and according to the BOD they control the degree of environmental pollution. The graph is 3 year's BOD figure. The dialysate solution with high BOD was drained but the drained solution in water purified tank keeps low BOD. **HEMOCLEAN®** which belong to peracetic acid produce a mount of oxygen during drainage then the produced oxygen decompose the organics in the water purified tank during the stay of drained dialysate solution, disinfectant and after-dialysis pollutant so it can keep low BOD figure.

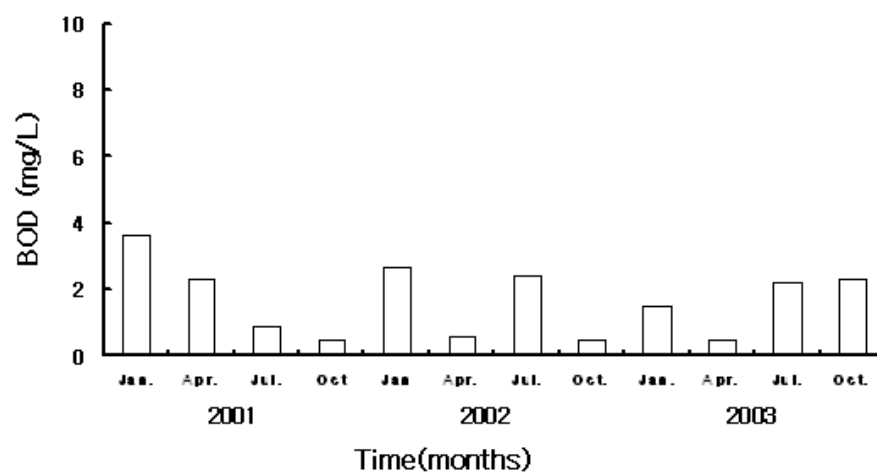


Figure 1. BOD change of Dialysate waste during 3 years

## 2. EFFICACY OF HEMOCLEAN®

FDA declared sterilizing power of spore, the disinfectant which can kill more than  $10^6$  tuberculous bacillus considered to be high level disinfectant<sup>3)</sup>, and at present FDA just admit aldehyde type and peracetic type disinfectants as high level disinfectants. Below table is the in vitro-test result from our company's microbiological study team, Pukyung national university institute, Korea Testing and Research Institute for Chemical Industry, overseas institutes as HygGen Centrum fur Hygiene und Medizinische Produktsicherheit GmbH of Austria and Chinese Center for Disease Control and prevention. The result come out to be spore as well as tuberculous bacillus, fungus, bacteria can be completely killed by HEMOCLEAN®.

### (1) Pathogenic microorganism *in-vitro* test of HEMOCLEAN®

Table 1. *In-vitro* test result from domestic institutes

Institute	Strains	Inoculum size (CFU/ml)	Dilute rate	Interference materials	Result
Huons Medicare Co., Ltd Attached Institute	<b>Bactericidal</b>				
	<i>E. coli</i> ATCC 2592	$1.2 \times 10^6$	x 100	-	5 minutes
	<i>S. typhimurrium</i> ATCC 14028	$1.3 \times 10^6$	x100	-	5 minutes
	<i>S. aureus</i> ATCC 6538	$1.3 \times 10^7$	x100	-	5 minutes
	<i>K. pneumoniae</i> ATCC 10051	$1.3 \times 10^6$	x100	-	5 minutes
	<i>P. mirabilis</i> ATCC 21100	$1.3 \times 10^6$	x100	-	5 minutes
	<i>P. aeruginosa</i> ATCC 9027	$1.4 \times 10^7$	x100	-	5 minutes
	<b>Tuberculocidal</b>				
	<i>M. tuberculosis</i>	$1.0 \times 10^8$	x34	-	5 minutes
Pukyung National Univ.	<b>Fungicidal</b>				
	<i>C. albicans</i> ATCC 10251	$1.4 \times 10^7$	x50	-	5 minutes
	<i>T. mentagrophytes</i> ATCC9533	$5.0 \times 10^6$	x50	-	10 minutes
	<b>Bactericidal</b>				
	<i>E. coli</i> KCTC 1039	$1.3 \times 10^7$	x34	-	5 minutes
	<i>E. coli</i> KCTC 1039	$1.3 \times 10^7$	x34	1% Blood	5 minutes
	<i>S. choleraesuis</i> KCTC 2425	$1.0 \times 10^7$	x34	-	5 minutes
	<i>S. aureus</i> KCTC 1928	$1.0 \times 10^7$	x34	-	5 minutes
	<i>S. aureus</i> KCTC 1928	$1.0 \times 10^7$	x34	Hard water	5 minutes
	MRSA	$1.9 \times 10^7$	x34	-	5 minutes
	<i>K. pneumoniae</i> KCTC 2245	$3.8 \times 10^7$	x34	-	5 minutes
	<i>P. aeruginosa</i> KCTC 2641	$3.6 \times 10^7$	x34	-	5 minutes
	<i>P. aeruginosa</i> KCTC 2641	$3.6 \times 10^7$	x34	1% yeast extract	5 minutes
	<i>P. mirabilis</i> KCTC 2510	$2.8 \times 10^7$	x34	-	5 minutes
	<i>B. subtilis</i> KCTC 1022	$1.2 \times 10^7$	x34	-	5 minutes
	<b>Fungicidal</b>				
	<i>C. albicans</i> KCTC 7121	$1.0 \times 10^7$	x34	-	5 minutes
	<i>T. mentagrophytes</i> KCTC 6316	$1.0 \times 10^6$	x34	-	5 minutes
KTR	<b>Sporicidal</b>				
	<i>B. subtilis</i> KTCT 1022	$2.0 \times 10^4$	x34	-	10 minutes
	<i>E. coli</i> ATCC25922	$2.0 \times 10^7$	x34	-	5 minutes
	<i>S. aureus</i> ATCC6538	$1.8 \times 10^7$	x34	-	5 minutes

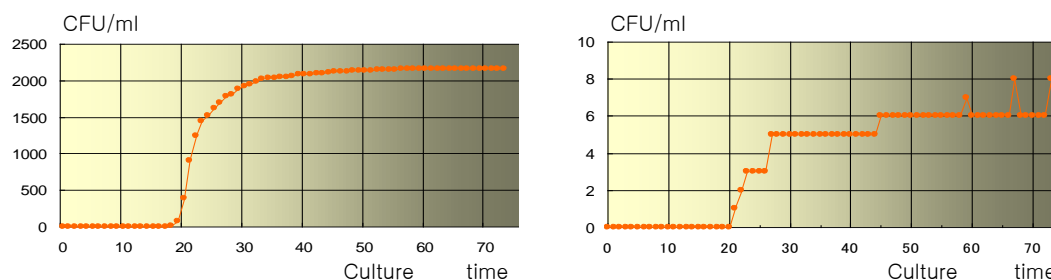
Table 2. *In-vitro* test from overseas institutes

Institute	Strains	Inoculum size (CFU/ml)	Dilute rate	Interference materials	Result
HygGen Centrum für Hygiene und Medizinische Produktsicherheit GmbH, Austria	<b>Bactericidal</b>				
	<i>S.aureus</i> ATCC 6538	$2.0 \times 10^9$	×100	Dirty conditions*	1 minute
	<i>E.hirae</i> ATCC 10541	$2.2 \times 10^9$	×100	Dirty conditions	1 minute
	<i>P.aeruginosa</i> ATCC 15442	$2.0 \times 10^9$	×100	Dirty conditions	1 minute
	<b>Tuberculocidal</b>				
	<i>M.terrae</i> ATCC 15775	$1.9 \times 10^9$	×25	Dirty conditions	10 minutes
	<i>M.terrae</i> ATCC 15775	$1.9 \times 10^9$	×33	Dirty conditions	15 minutes
	<b>Fungicidal</b>				
	<i>C.albicans</i> ATCC 10231	$3.1 \times 10^8$	×50	Dirty conditions	2 minutes
	<b>Simulated test</b>				
	<b>Bactericidal</b>				
	<i>S.aureus</i> ATCC 6538	$4.5 \times 10^9$	×100	Dirty conditions	5 minutes
	<i>E.hirae</i> ATCC 10541	$1.5 \times 10^9$	×100	Dirty conditions	5 minutes
	<i>P.aeruginosa</i> ATCC 15442	$1.3 \times 10^9$	×100	Dirty conditions	5 minutes
	<b>Tuberculocidal</b>				
	<i>M.terrae</i> ATCC 15775	$2.4 \times 10^9$	×33	Dirty conditions	5 minutes
	<b>Fungicidal</b>				
	<i>C.albicans</i> ATCC 10231	$2.1 \times 10^8$	×100	Dirty conditions	5 minutes
CCDC (Chinese center for disease control and prevention)	<b>Bactericidal</b>				
	<i>S. aureus</i> ATCC 6538	$2.3 \times 10^7$	×80	-	5 minutes, $> 10^5$
	<i>P. aeruginosa</i> ATCC15442	$3.1 \times 10^7$	×80	-	5 minutes, $> 10^5$
	<b>Fungicidal</b>				
	<i>B. albicans</i> ATCC10231	$2.1 \times 10^6$	×80	-	5 minutes, $> 10^4$
	<b>Sporicidal</b>				
	<i>B. subtilis</i> ATCC 9372 (Stainless steel piece)	$1.0 \times 10^6$	×33	-	1hr., $> 10^6$
	<i>B. subtilis</i> ATCC 9372 (hemostatic forceps)	$1.2 \times 10^5$	×33	-	1hr., $> 10^5$
	<i>B. subtilis</i> ATCC 9372	$2.4 \times 10^6$	×3	-	10 minutes $> 10^3$
ATS Labs	<i>B. subtilis</i> ATCC 9372 (Stainless steel piece)	$2.4 \times 10^6$	×33	-	15 minutes 0/30, $> 10^3$
	<i>B. subtilis</i> ATCC 9372 (Claw part of hemostatic forceps)	$2.4 \times 10^6$	×3		20 minute 0/30
	<i>B. subtilis</i> ATCC 9372 (claw part of hemostatic forceps)	$2.4 \times 10^6$	×33		15 minutes, 0/60, $> 10^3$
	<b>Virucidal</b>				
	Poliovirus type 1, ATCC VR-1562		×25	1% fetal bovine serum	20 minutes $> 5.0 \log_{10}$

\* Dirty conditions: 0.3% albumin +0.3% sheep erythrocytes

## (2) Sterilizing effect to endotoxin and bacteria<sup>4)</sup>

Endotoxin(pyrexia substance) and bacteria in purified water could cause fatal effects to chronic renal failure patients who expose to a quantity of purified water, so AAMI and medical service advanced countries provide a guideline to be followed. Endotoxin is a substance which exists in cell wall of bacteria. It can not be observed when bacteria are alive but when bacteria increase or killed, endotoxin was released from cell wall. One more, the relationship between bacteria and endotoxin is still being studied but till now there is no particular correlation between them so it need to control them by each.



After use 50 times diluted A company's product and HEMOCLEAN®  
Figure2. The decrease of bacteria in the pipe after use A company's product and HEMOCLEAN®

Akiyama hospital in Japan use 50 times diluted A company's product and HEMOCLEAN® for disinfect the pipes then check the bacteria number in purified water by auto checker.

The result is come out to HEMOCLEAN® sterilize power is 200 times better than A company's product. The endotoxin figure became lower when change A product to HEMOCLEAN® for the machine.

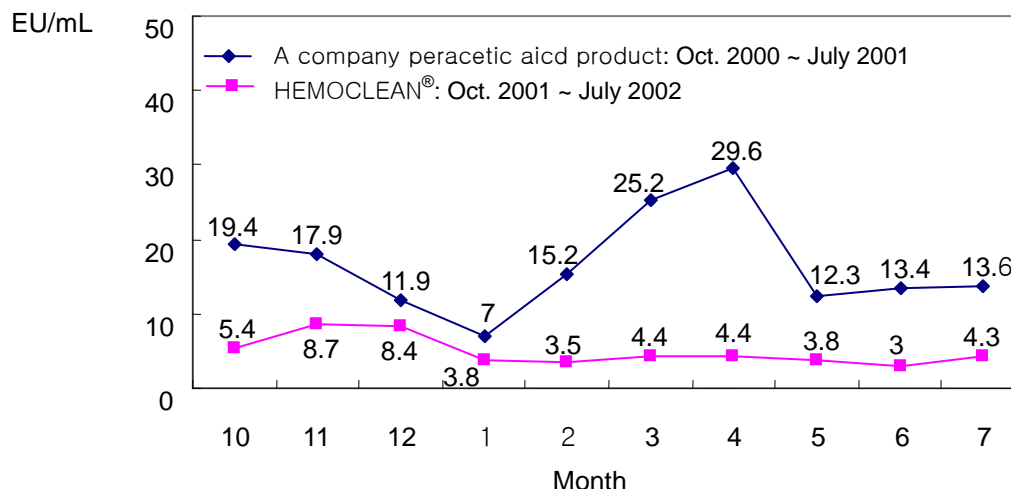


Figure 3. Endotoxin decrease in pipe using A product and HEMOCLEAN® as disinfectant

From the two test results, HEMOCLEAN® has more perfect bactericidal and endotoxin removal power.



### (3) Cleaning effect of HEMOCLEAN®

#### 1) Removal of biofilm

Most microorganisms are not free-floating instead habitat while adhering on the object or surrounding the extra cellular polymer substance (EPS) called biofilm. Such biofilm will resist against common cleaning and disinfectants and that can be the infection origin of water purifying system's pipes. Following pictures shows **HEMOCLEAN®**'s removal power against biofilm in vitro.

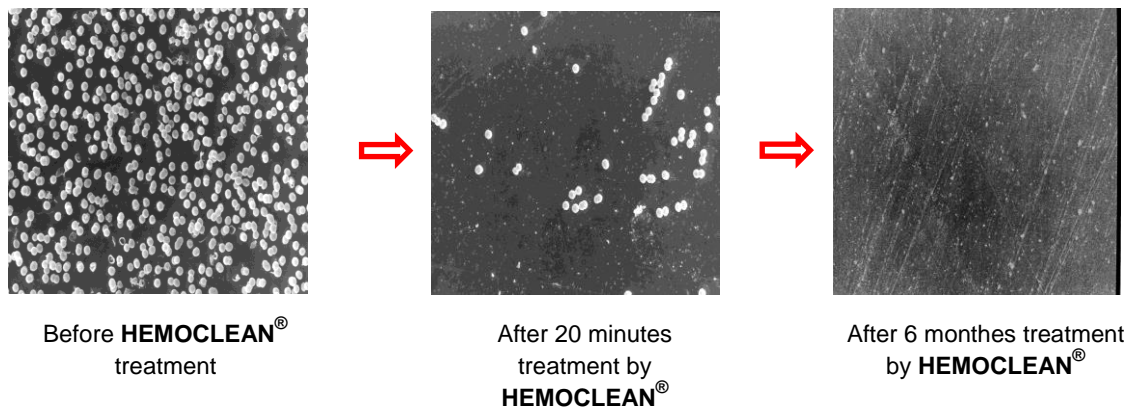


Figure 4. **HEMOCLEAN®**'s removal power against biofilm

#### 2) Application to biofilm

We compared the change of biofilm with the condition of hypochlorous acid type disinfectant, A company's peracetic acid type disinfectant and **HEMOCLEAN®**. And used biofilm is composed of gram negative bacillus and fungi. As time pass by, we can observe **HEMOCLEAN®** 50 times diluted solution could dissolve biofilm.<sup>5)</sup>

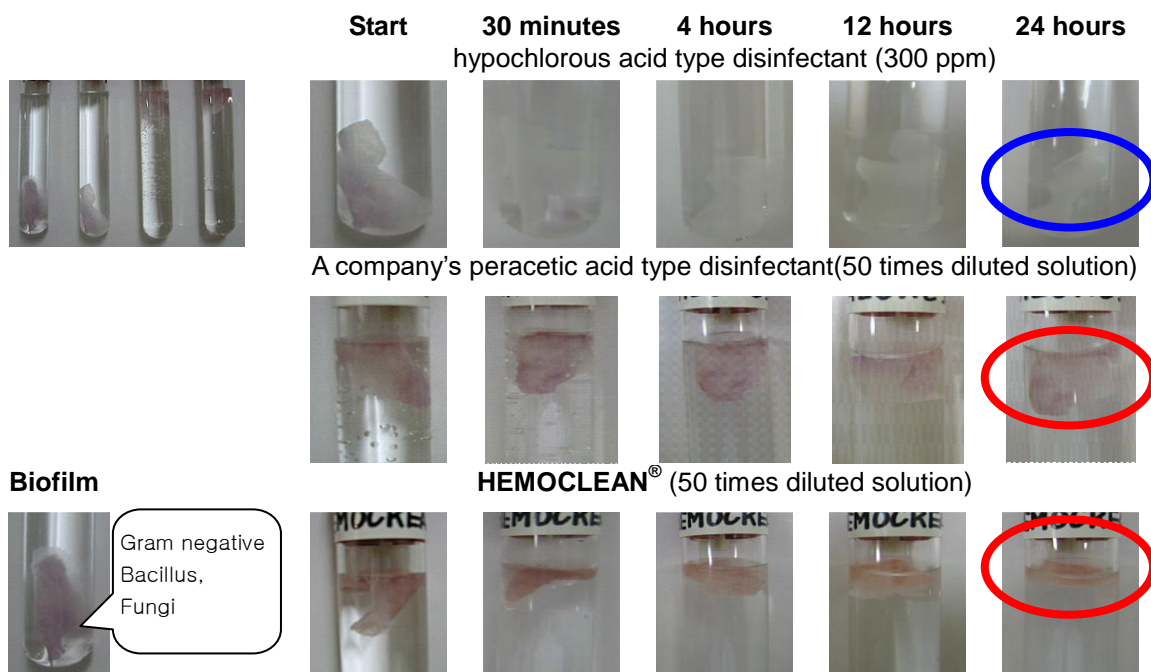


Figure 5. Biofilm decompose power of **HEMOCLEAN®**

### 3) Removal of organics

To test **HEMOCLEAN**®'s removal power against organic materials (protein cake), we used 24 hr patients' blood urine (GOT 68, GET 74, diabetes 328 mg) and 20% of serum albumin. Test method was voltammetry by using carbon electrode with 4% **HEMOCLEAN**® solution.

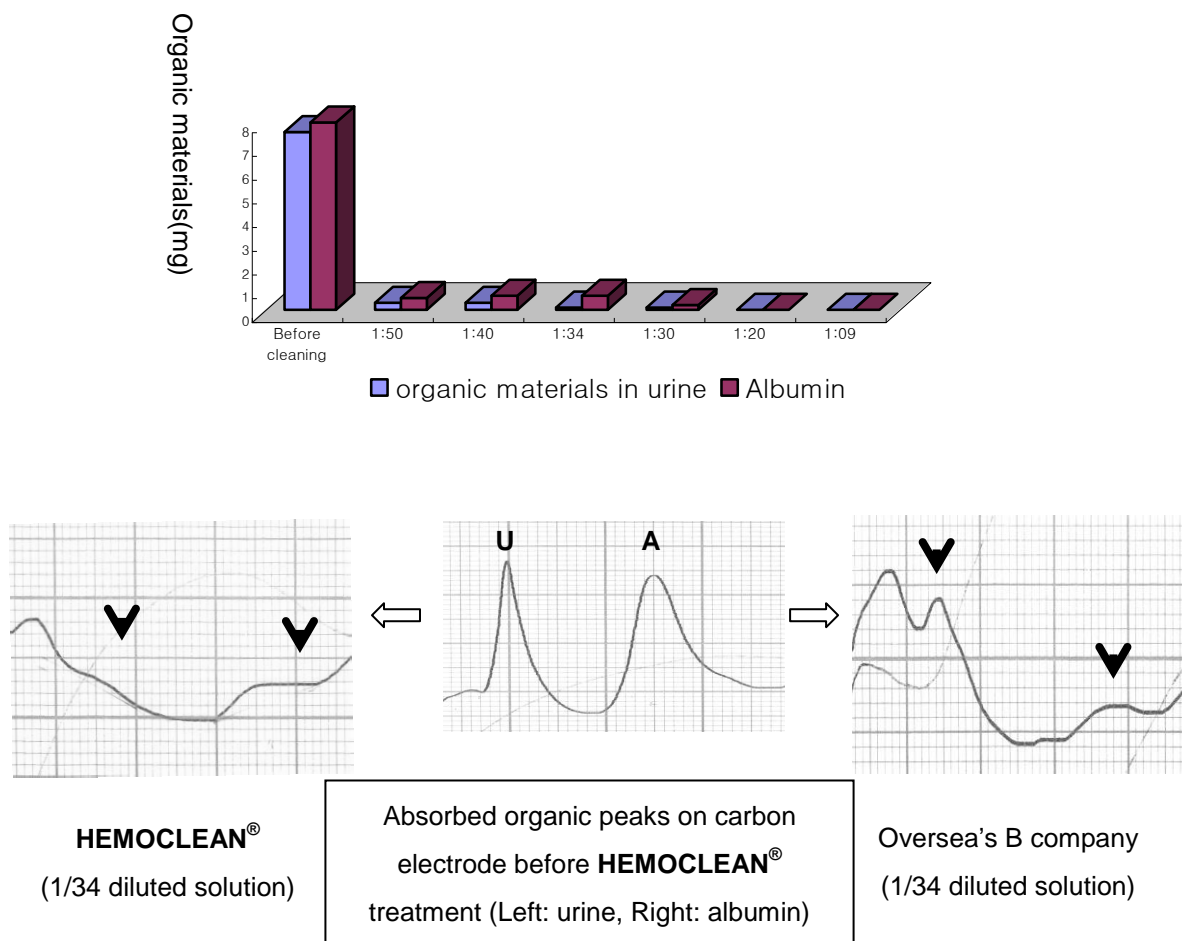


Figure 6. Organic removal power of **HEMOCLEAN**®

Above figure is the comparison result of organic matters (protein) removal power after change to use **HEMOCLEAN**® and use B company's disinfectant. We can observe that large quantities of urine and albumin were not removed during the use of B company's disinfectant, in the other side during the use of **HEMOCLEAN**®, most of the organics like urine and albumin were completely removed.

### 4) Removal power of protein cake

In Japan's dialysis environment (using central delivery system and high flux dialyzer with the pore size bigger than 80Å), protein cake became most considerable problem. After dialysis, protein from patients was drained with solution and it adsorbed to the drain line and formed protein cake. This protein cake might cause pipe blocking problems and various infect dangerousness, so the using experiences of many cleaner & disinfectants for removing protein cakes were presented in some societies.



Sodium Hypochlorite + A company's peracetic disinfectant



After use **HEMOCLEAN**® for 6 months

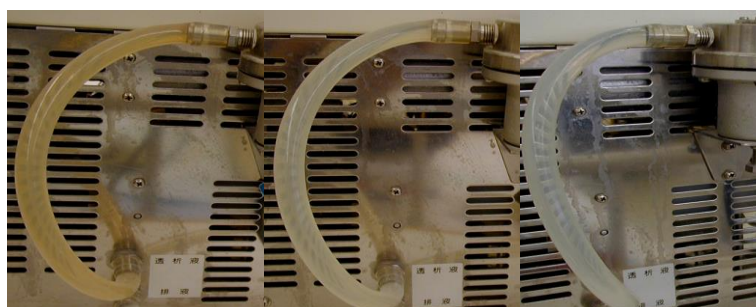


Figure 8. Protein cake removal power of **HEMOCLEAN**®

From the above pictures, protein cake was formed during jointly use sodium hypochloric acid and A company's peracetic acid cleaner& disinfectant. After change to use **HEMOCLEAN**® for 6 months, protein cake was perfectly removed. This using experience was presented at JSDT in 2004, and certificated **HEMOCLEAN**®'s excellent cleaning power.<sup>5)</sup>

#### 5) Cleaning about polluted coupling tube

**HEMOCLEAN**®'s using result (Nikkiso machine for 24 weeks) was presented at JSDT by Mr. Otobe in 2003. The tubes were polluted by biofilm during jointly using acetic acid and hypochloric acid type disinfectant, but after change to use **HEMOCLEAN**® for 24 weeks the pollutant inside of the tubes were completely removed.<sup>6)</sup>



Before use **HEMOCLEAN**®      Use for 6 weeks      Use for 24 weeks

Figure 9. **HEMOCLEAN**®'s cleaning power for tubes

## 6) Verification of pollutant inside of the silicon tubes

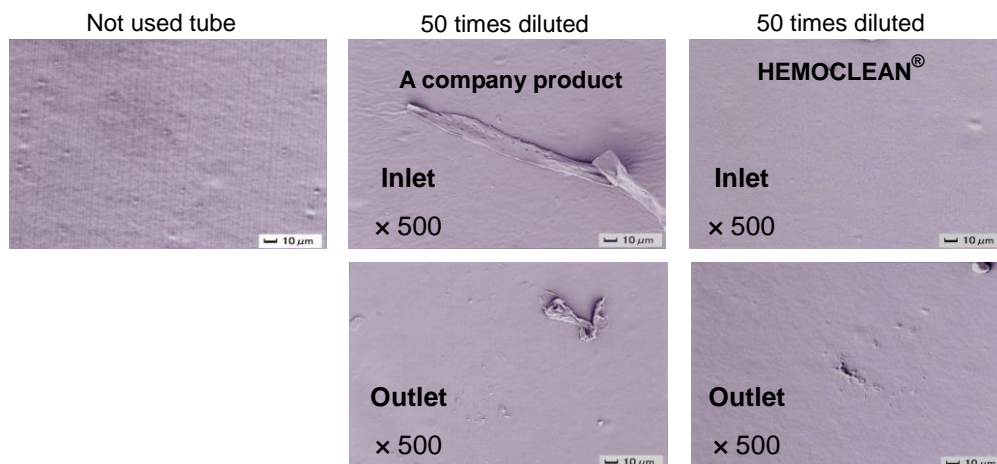


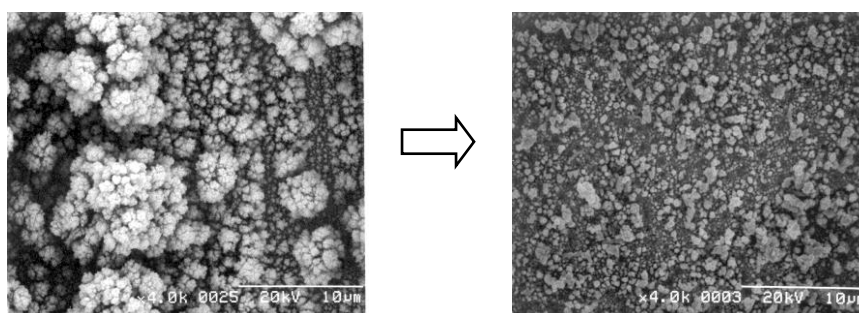
Figure10. Cleaning power of **HEMOCLEAN®** to inside of multi pumps silicon in/out tubes

Above pictures were inside of the silicon tubes which were joint to multipumps in the dialysis equipment. They compared inside of the tubes with different using condition of A company's peracetic acid + sodium-hypochlorite and 50 times diluted **HEMOCLEAN®**. The result is **HEMOCLEAN®** used tube are much more clean than A company's peracetic acid + sodium-hypochlorite used tube. It was tested at Sumiyoshigawa hospital and the results were presented by Mr. Akiyama at 10<sup>th</sup> HDF Japan.<sup>7)</sup>

## 7) Removal of scale

We collected some inorganic matter from long-term used hemodialysis machine's tube and analyses it with diffraction method, the main ingredient of inorganic matter was mainly calcium carbonate. Decalcification of **HEMOCLEAN®** is 3.88 g/ 100 ml and the test condition was in room temperature, for 24 hours. This means **HEMOCLEAN®** has much more better decalcification than similar peracetic products.

<b>HEMOCLEAN®</b>	A company's product	B company's product
3.88 g/100 ml	1.00 g/100 ml	2.04 g/100 ml



Before treatment (x4000)

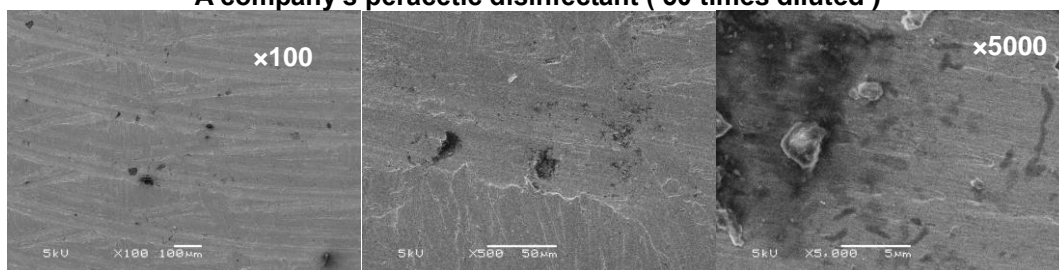
After 2 hours treatment (x4000)

Figure11. Decalcification of **HEMOCLEAN®**

Above pictures are before and after **HEMOCLEAN®** (33 times diluted solution) treated surface of carbon sensor and shows **HEMOCLEAN®**'s efficacy against organic matters. After 2 hours treatment, pollutants were completely removed.



**A company's peracetic disinfectant ( 50 times diluted )**



**HEMOCLEAN® ( 50 times diluted )**



Figure12. **HEMOCLEAN®**'s washing power for the stainless exterior

Mr. Akiyama used **HEMOCLEAN®** and A company's peracetic acid type disinfectant in Sumiyoshigawa hospital and compared the stainless exterior by Scan Electric Microscopy (SEM) pictures. The result was presented the 10<sup>th</sup> Japan HDF society. From the pictures we can observe the surface was cleaner after treated with **HEMOCLEAN®**.<sup>7)</sup>

Next is use comparison for electronic valve and other parts between chlorine disinfectant and **HEMOCLEAN®**. The corrosion was occurred during the use of chloride disinfectant for 2 years, but after change to use **HEMOCLEAN®** for 3 years and 6 months the rust was removed and no more corrosion was accured.<sup>6)</sup>



Used chlorine  
disinfectant for 2 years



Used  
**HEMOCLEAN®**  
for 3.5 years



Used chlorine  
disinfectant for 4.5  
years



Used  
**HEMOCLEAN®**  
for 3.5 years

Figure 13. Washing efficacy of **HEMOCLEAN®**

### 3. SAFETY OF HEMOCLEAN®

#### (1) Biocompatibility

Biocompatibility of **HEMOCLEAN®** was tested by Institute for Environment Health and Related Product Safety (IEHS), Chinese Center for Disease Control & Prevention. The result was as follows, the acute oral toxicity, LD<sub>50</sub> is 2,710 mg/kg. This is 54% level of LD<sub>50</sub>, oral, of citric acid<sup>8)</sup>city and **HEMOCLEAN®** was not cause deformity depended on the results of Mouse bone marrow polychromatic erythrocytes (PCE) micronucleus test and Mouse sperm malformation test.

Table 3. Toxicity result of **HEMOCLEAN®**

Institute	Test	Laboratory animal	Toxicity
CCDC*	Acute oral toxicity test	Mouse	Female LD <sub>50</sub> = 2,330 mg/kg Male LD <sub>50</sub> = 3,690 mg/kg
	Acute oral toxicity test (5% sol)	Mouse	Non toxicity
	Mouse bone marrow polychromatic erythrocytes (PCE) micronucleus test	Mouse	No malformation-producing effects
	Mouse sperm malformation test	Mouse	No teratogenic effects
	Acute oral toxicity test	Mouse	LD <sub>50</sub> = 2710 mg/kg Low toxicity
Nelson**	Primary skin (ISO10993)	Rabbit	No irritation
	Skin sensitization	Guinea pig	No sensitization
Toxikon***	Acute dermal irritation (OECD405)	Rabbit	No irritation
	Acute skin irritation (28 days Repeated Dose)	Rabbit	No irritation
	Ocular irritation (OECD402)	Rabbit	Mild irritant
	Acute oral toxicity (OECD401)	Rat	LD <sub>50</sub> ≥ 2000 mg/kg

\*CCDC: Chinese Center for Disease Control and prevention

\*Nelson: Nelson Laboratories, Inc. Salt Lake in the US

\*\*ToxiKon: Toxikon Corp. Massachusetts in the US

## (2) Residues

For the purpose of **HEMOCLEAN®** residual test after cleaning the hemodialysis machine, we took draining water samples every 2 minutes for 30 minutes from the hemodialysis machine and checked the pH. The draining water pH equaled to supplying water (pH 5.4) and that's satisfied the effluent standard (pH 5~9).

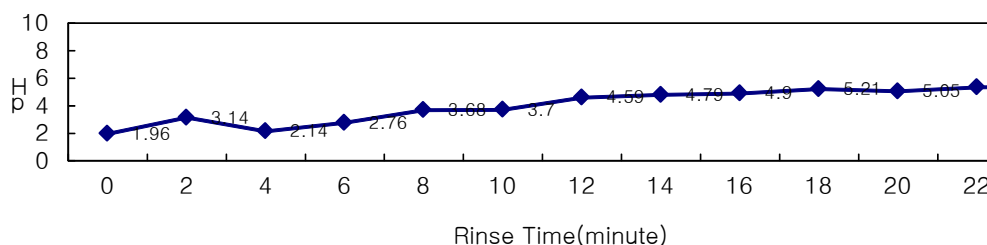
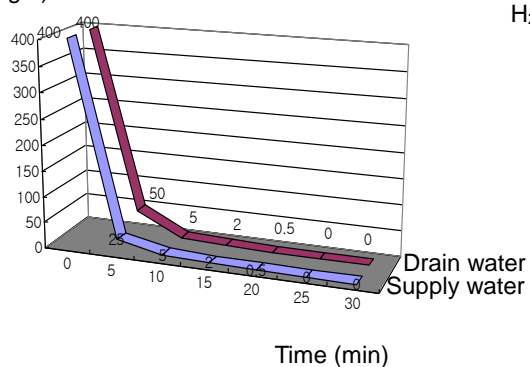


Figure 14. The change of pH during washing after the disinfectant treatment

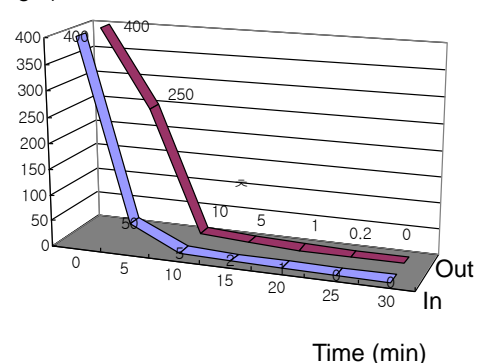
Follow materials were presented by Mr. N. Ono at JSDT in 2002. As we can see **HEMOCLEAN®**'s main ingredient- hydrogen peroxide didn't remained even in a short time.<sup>9)</sup>

H<sub>2</sub>O<sub>2</sub>(mg/L)



Supply water and drain water

H<sub>2</sub>O<sub>2</sub>(mg/L)



In and Out of ET filter

Figure 15. Residual of hydrogen peroxide during post rinse

### (3) Material compatibility

For examining the safety of **HEMOCLEAN®**, we observed **HEMOCLEAN®**'s corrosiveness to materials in hemodialysis machine's like metals, synthetic resins and components etc. We picked samples which area is 10~30 cm<sup>2</sup> and we cut or did acid treatment if scale was adhered on the surface of samples. All samples were dipped in undiluted, 10 times diluted, 35 times diluted **HEMOCLEAN®** at 25°C for 5 days then measure sample's each weight and compare the before and after. The test was based on KS-D0222. O-ring, spring, pipes and PVC tube were also tested with same method with undiluted **HEMOCLEAN®**.

Table 4. Compatibility of components (Unit: g)

Parts types	Before	After	Variation
L-tube	4.36	4.36	0.00
O-ring	0.08	0.08	0.00
Spring	0.25	0.25	0.00
Cap	28.29	28.29	0.00
Pipe	13.37	13.37	0.00
PVC tube	10.87	10.87	0.00
Nipple	12.14	12.14	0.00

Table 5. Compatibility of materials (Unit: g)

Material type	3%	5%
Aluminum 99.5	0.00	0.00
Stainless Steel	0.00	0.00
Tinned Iron	0.00	0.00
Galvanized Iron	0.00	0.00
PVC	0.00	0.00
PP	0.00	0.00
PE	0.00	0.00
Silicon	0.00	0.00
Polyurethane	0.00	0.00
Teflon	0.00	0.00



#### 4. DIRECTIONS OF HEMOCLEAN®

- (1) **HEMOCLEAN®** is intended for Sterilization or high-level disinfection of artificial kidney machines (hemodialysis machines) and dialyzer reprocessing. It should be used under the following the dilution rate and contact condition:

The purpose in use	Dilution rate	Contact time
Hemodialysis machines	1:9~1:50	Min. 10 min ~ Max. 72 hrs

- (2) The dilution ratio and cleaning period should be followed machine manual.

Table 6. Using examples by machines

	Type	Dilution rate	Consumption (ml)	Pre rinse (min)	Infusion (min)	Contact time (min)	Post rinse (min)
Gambro	WRO membrane (polyamide)	1/25~1/50	Set	10	Set	10~40	~240
	AK 90/95	1/20~1/30	~100	10	7	30~40	40 ~
	AK 100	1/35	60	10	App. 3	Over night	30 ~
	AK 200 Ultra	1/35	60	10	7	Over night	30 ~
	COBE C-3	1/9	250	-	9:45	-	18:30
		1/9	250	5	10	90	35
FMC	Phoenix	1/25	220	-		15	15
	2008/4008	1/25	~ 50	-	-	15	25
Nikkiso	DBB22B/26B	-	60 ~ 80	30		30	30
	DBB27B	-	60	20	0.5	50	50
Nipro	SURDIAL / II	1/43~1/45	100 ~ 110	10	10 ~ 15	60	30
	NCU 12	1/43~1/45	100 ~ 110	10	20	60	30
Toray	TR-321EVX (Taiwan)	1/22.33	150	10	15	30	40
	TR-321/322 TR-01 (Japan)	1/35	-	30	15	99	60
	TR-3000	1/50*	150	10	15	25	30
	TR-8000	1/50*	217	10	15	25	25
	TR-FX	1/50	210	10	15	30	40
Baxter	550/Meridian	1/35	255	2	16:05	30	6:25
JMS	SID2001	1/35	200	20	10~15	40~60	35
	SDS2000/3000						
	SDS20						
MED-TECH	GSD-2000	1/35	250	set	set	5 h	15~150
	NHD-2000	1/35	250	10	20	20	60
B. Braun	Dialog	-	90		30		25
Bellco	Formula	1/30	~120	-		11	30

Above methods were just the recommendations. And consumption of **HEMOCLEAN®** and disinfection conditions can be adjusted by using circumstance.

\* General recommended dilution rate is 1/20~1/35 and in cased this contact time is 30~60 minutes. If the dilution rate was lower (using concentrate was lower) than the recommended dilution rate (ex, TR3000, TR8000), we may recommend additional treatments for perfect disinfection/cleaning. Call the service center of machine or us, KRD, for more information.

- (3) Do the residual test of peracetic acid with *Peracetic Acid Potency Test Kit* after machine disinfect and confirm the result is less than 0.5 ppm.

Bellow table is about the recommended dilution ratio and cleaning period from each hemodialysis machine manual. As time as the sterilize mode finished, do the residual test to confirm the chemical residue is not remained in the machine. Disinfectant residual tests could be followed machine manual.

- ☐ HEMCOCHECK® PEROXCIDE25 (MACHERE-NAGEL GmbH & Co. KG, Germany)

0.5~25 mg/L H<sub>2</sub>O<sub>2</sub>

- ☐ Peroxide Merckoquant strip (MERCK, Germany, #110011)

\* 0.1% = 1000 ppm = 100 mg/L

## 5. STORAGE AND PRECAUTION

### (1) Warning

- Do not use for the human body science it's not apply to human body.

### (2) Do not apply the HEMOCLEAN® used hemodialysis machine to follow patient

- The patients who are allergies to hydrogen peroxide and peracetic acid

### (3) Precaution

- Do not use HEMOCLEAN® for other purpose.
- HEMOCLEAN® may cause stimulus to eye and skin for its corrosiveness, deal with caution when using HEMOCLEAN®. Wash thoroughly after use, when contacted with eye or skin immediately wash with large quantities of water.
- All users must master the medical instrument pollution control and toxicity medical treatment like disinfection and chemical disinfectant. Before use HEMOCLEAN®, be sure to fully aware of its precaution, directions and dosage. Especially rinse-process after dialysis session must follow equipment manual in the purpose of fully showing HEMOCLEAN®'s efficacy.
- When handling, avoid contact with skin and eye, wear proper protective devices like gloves, safety glasses and clothes.
- Users must follow HEMOCLEAN®'s instruction, if not it will cause efficacy reduction or safety problems.
- Do not swallow, if swallowed immediately drink large quantities of water to dilute, never try to vomit then see a doctor. Do not wash out the stomach for it may cause mucous membrane damage.

### (4) Interaction

- Do not mix HEMOCLEAN® with aldehyde for it may cause the mucous membrane damage or reduce its efficacy.

### (5) Storage

- Keep out of reach of children.
- Do not store in direct sunlight or high temperature.
- Do not contact HEMOCLEAN® with an oxidizer like an inflammable material.
- For keep the efficacy of HEMOCLEAN®, store in original container, and never tamper with vent.
- Do not pour back the used HEMOCLEAN® into its container.

### (6) Package / Storage condition/ Shelf life

- Package: 5 L X 2 /Box
- Storage condition: room temperature(1~30℃)
- Shelf life: 24 months(in original, sealed package)

### III. CONCLUSION

Environmental pollutant and toxicity of aldehyde type and chlorine type disinfectants were being reported by many international institutes. Especially aldehyde type disinfectants were widely used for hemodialysis equipment, water purification systems and purified water supply systems because of economic problems, but aldehyde type disinfectants couldn't fully remove scales (calcium carbonate etc), iron corrosion, biofilm but cause equipment corrosion and shorten the equipment use life. Further more it reacted with organics and produced a carcinogenic substance-THM and organic halogen compounds-trichloroethylene, tetra ethylene which cause 2<sup>nd</sup> environmental pollution. Aldehyde type disinfectants have high toxicity, need long contact time and produce carcinogenic substance from reaction with chloride.

**HEMOCLEAN®**, as a kind of acidic disinfectant with its main ingredients of peracetic acid and hydrogen peroxide has fast disinfection rate, excellent disinfection power and cleaning power, easy concentration control in various condition, superior stability for long lasting efficacy, environmental friendly for complete natural decomposition, long lasting and effective scale removal power and restraint to equipment and pipes etc. During using **HEMOCLEAN®** to hemodialysis machine, the water purification systems and purified water supply systems for cleaning & disinfection, it has superior economical efficiency for the reduction of electricity, water and time since it's no need to use extra chemicals, it is convenient and safe for the users.

The excellence of **HEMOCLEAN®** had been proved through all of the tests. According to the test results, **HEMOCLEAN®** has a wide-range sterilize power (including spore) at low temperature in low concentration, biofilm removal power, removing calcium carbonate scale in equipment and pipes and also shows perfect corrosion restraint efficacy. Further more, **HEMOCLEAN®** can finally decompose into water and carbon dioxide during drainage and that's proved its environmental friendly. Disinfection & cleaning efficacy were proved depend on the actual using results from about 120 university hospitals, specialty clinics and general hospitals where have various types of hemodialysis machine, water purification systems and purified water supply systems for HD and HDF during some years months by users.

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