

Biological safety and data on operational environment. Material Compatibility with Endoscopes

Safety Data

Biological safety

Toxic data at 50 ppm of chlorine content

Results of biological safety test performed by the Japan Food Analysis Center are as follows:

Acute oral toxicity test (limiting test)	Fatal dose by single oral administration is 50ml/kg or more for both male and female.
Skin primary stimulation test	It was evaluated as "weak irritant" in the test which used rabbits.
Eye stimulation test	It was evaluated as "non irritant" in the test which used rabbits.
Stimulation test of oral mucous membrane	Micro abscess on the oral mucous membrane and cellular infiltration on the submucosa were recognized in some cases. However, the incidence rate was low and individual difference was large, and stimulation is supposed to be very weak.
Atavism test	Increase of atavism colony number was not induced. As a result, induction of atavism was judged to be negative.
Inhibition test of colony forming	Colony forming rate did not fall specially compared with the non-processed test liquid, and it was considered to have no cytotoxic effect.

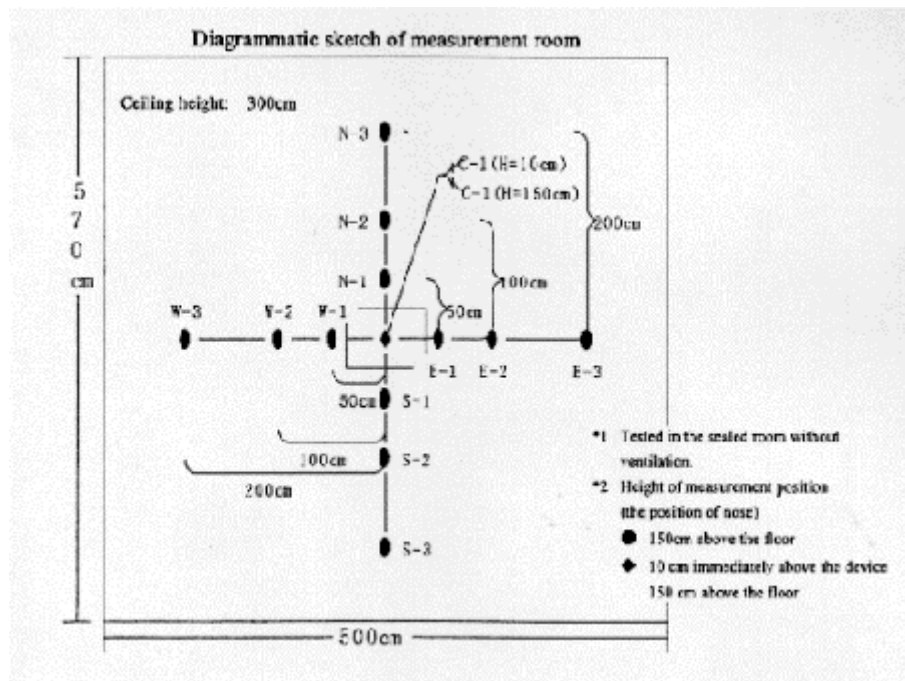
Data for operational environment - chlorine gas concentration in the air

CLEANTOP WM-S performs electrolysis of tap water with a small amount of sodium chloride dissolved to produce electrolyzed acid water with optimum quality to clean and sterilize gastrointestinal endoscopes. The concentration of chlorine gas produced by the electrolysis was measured in the working environment.

Test methods:

Following 40 minutes electrolysis by CLEAN TOP WM-S according to the operational instructions electrolyzed acid water was produced to reach the optimum conditions. At this stage, 2.5l of the air was collected for five minutes by an air sample AL-410, Yuasa Shoji at the points shown in the figure below collected at the height of 150 cm above the floor as considered for the average position of human nostrils.

The collected chlorine gas was measured for concentration by the absorptionmetric analysis.



Test results

Concentration of chlorine gas: volppm

1	Pre-electrolysis concentration of chlorine gas		Pre-electrolysis concentration : 4.80 ppm pH : 2.36 ORP : 1092mV							
	C-1(1)	0.77	S-1(1)	<0.05	N-1(1)	<0.05	E-1(1)	<0.05	W-1(1)	<0.05
C-2(1)	<0.05	S-2(1)	<0.05	N-2(1)	<0.05	E-2(1)	<0.05	W-2(1)	<0.05	
		S-3(1)	<0.05	N-3(1)	<0.05	E-3(1)	<0.05	W-3(1)	<0.05	
2	Pre-electrolysis concentration of chlorine gas		Pre-electrolysis concentration : 5.20 ppm pH : 2.30 ORP : 1101mV							
	C-1(2)	1.80	S-1(2)	<0.05	N-1(2)	0.09	E-1(2)	<0.05	W-1(2)	<0.05
C-2(2)	<0.05	S-2(2)	<0.05	N-2(2)	<0.05	E-2(2)	<0.05	W-2(2)	<0.05	
		S-3(2)	<0.05	N-3(2)	<0.05	E-3(2)	<0.05	W-3(2)	<0.05	
3	Pre-electrolysis concentration of chlorine gas		Pre-electrolysis concentration : 4.95 ppm pH : 2.32 ORP : 1107mV							
	C-1(3)	1.20	S-1(3)	<0.05	N-1(3)	0.05	E-1(3)	<0.05	W-1(3)	<0.05
C-2(3)	<0.05	S-2(3)	<0.05	N-2(3)	<0.05	E-2(3)	<0.05	W-2(3)	<0.05	
		S-3(3)	<0.05	N-3(3)	<0.05	E-3(3)	<0.05	W-3(3)	<0.05	

The concentrations were 0.5 vol. ppm at all points of nostril position 150 cm above the floor except the position 10 cm immediately above the device. Chlorine gas concentrations before and during electrolysis were measured as preliminary tests. The results were 0.5 vol. ppm or less as shown in the table below.

Before test	30 minutes after the start of electrolysis	At the end of electrolysis 40 minutes later	During sterilization
< 0.05 volppm	< 0.05 volppm	<0.05 volppm	0.44 volppm

From the results shown above, chlorine gas concentrations at the nostril position 150 cm above the floor were 0.5 vol. ppm or less to meet the regulatory control standard defined for indoor working environment by the Industrial Safety and Health Law-Working Condition Evaluation Standard. However, the concentration at 10 cm immediately above the device exceeded the standard value, and it is necessary not to keep the face closer to the top of the device, not to reach within 150 cm from the floor on the spot.

Degradation test of materials used for gastrointestinal endoscopes

Test were made to evaluate the effect which the electrolyzed acid water produced by CLEANTOP WM S has on the materials used for gastrointestinal endoscopes.

Test methods:

The test materials shown below were put in the cleaning / sterilizing bath and observed for degradation by repeating cleaning and sterilizing of seven minutes each by CLEANTOP WM S for 1000 times.

Test materials:

Used materials	Used part
Stainless steel (SUS303)	Metal parts of gastrointestinal endoscope
Synthetic rubber (NBR)	Protection cover of connecting area such as the control block as well as elastic parts
Phosphor bronze gold-plated	Electric contacts
Polyurethane tube	Sheath of elastic area of the inserting section
Alumite proofing	Case of the control block and connector parts
Brass (BS)	Inside of the control block and connector parts
Araldite (adhesive)	Bonding area
Rubber tube (EPDM)	Sheath of winding area of the insertion section

Test results:

Degradation caused by electrolytic acid water was not noticed.