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Measurement Report On Behalf Of STURDY INDUSTRIAL CO.,LTD

LARYNGOSCOPE Model # :SLN-020

Prepared for: STURDY INDUSTRIAL CO.,LTD No. 15, Lane 142, Suwei Road, Wu-Ku Hsiang, Taipei Hsien, Taiwan, R.O.C.

Review By :DET NORSKE VERITAS AS Taiwan Branch

International Trade Bldg. Room 2102 21F, 333, Keelung Rd., Sec. 1, Taipei, Taiwan, R.O.C. Tel : 886-2-2757-6817 Fax : 886-2-2757-6840 GesTek Report No#995035E

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1. Test Report Certification

Applicant: STURDY INDUSTRIAL CO.,LTDEUT Description: LARYNGOSCOPE

ECT Description	
Model Number	: SLN-020
Serial Number	: N/A
Power Supply	C Size battery 1.5V*2

MEASUREMENT PROCEDURE USED :

EN60601-1-2/1993 RULES AND EN55011/1991 RULES

EN60601-1-2/1993 RULES AND IEC 801 SERIES REGULATIONS

For EN60601-1-2/1993 and EN55011/1991:

The measurement shown in the attachment where made in accordance with the procedures indicated, and the maximum energy emitted by the equipment was found to be within the EN55011/1991 limits applicable.

For <u>EN60601-1-2/1993</u> Rules and <u>IEC 801</u> Series Regulations:

The device described above was evaluated by Global EMC Standard Tech. Corp. to determine the severity levels of the device, and the severity levels of the device can endure and its performance criterion. The measurement results are contained in this test report and show that the EUT to be technically compliant with EN60601-1-2/1993/IEC 801 Series regulations. Global EMC Standard Tech. Corp. recommends that the measurement results can pass performance criterion of above regulations.

GENERAL REMARK:

The tests were performed according to the technical requirement of EUT .

- Electron-magnetic Radiated Emission Interference (55011)
- Electron-magnetic Conduction Emission Interference (EN55022/55011/55014)
- Disturbance Measurement (EN60555-2 & 3/ EN61000-3-2,-3)
- ⊠ ESD Measurement (IEC801-2/ IEC1000-4-2/EN61000-4-2)
- ⊠ RF Field strength Susceptibility Measurement(IEC801-3/ IEC1000-4-3/ EN61000-4-3)
- □ Electrical Fast Transient/Burst Measurement (IEC801-4/ IEC1000-4-4/EN61000-4-4)
- □ Surge Measurement (IEC801-5/IEC1000-4-5/EN61000-4-5)
- □ Low Frequency Signals Immunity (IEC1000-2-2)
- ☐ Magnetic Field Measurement (EN61000-4-8)
- □ Voltage Dips/Interruption Measurement (EN61000-4-11)

Sample Received Date : <u>May 17, 1999</u>

Final Test Date	: <u>May 20, 1999</u>
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Documented By : Irene Lin

Test Engineer :

Approve & Authorized Signer :

Reviewed by DNV:

HANS LIN

TERRY CHUNG

DENNIS LIN

2. General Information

2.1 Production Description

Description	: LARYNGOSCOPE
Model Number	: SLN-020
Serial Number	: N/A
Applicant	: STURDY INDUSTRIAL CO., LTD.
Address	: No. 15, Lane 142, Suwei Road, Wu-Ku Hsiang,
	Taipei Hsien, Taiwan, R.O.C.
Manufacturer	: STURDY INDUSTRIAL CO., LTD.
Address	: No. 15, Lane 142, Suwei Road, Wu-Ku Hsiang,
	Taipei Hsien, Taiwan, R.O.C.
Power Cord	: N/A

2.2 Results:

The EUT(s) **met** the EN55011 Class B requirements.

(1). The Worst Emission data was found as following:

Emission	Worst Emission Frequency (MHz)	Emission Level Limit		Height of Antenna, Angel of Turntable	
Radiation	32.34	20.85dBuV,	30.0dBuV	$4m,186^{\circ}$	
	52.54	Horinontal	30.00Bu v	4111,100	

Immunity	Requested	Passed	passed with modification	not passed
Electrostatic Contact/AIR Discharge (ESD)	3kV / 8Kv	\boxtimes		
RF field strength Susceptibility	3 V/m	\boxtimes		

(2). The data that show in this test report reflects the worst-case data as above.

(3). Equipment for Medical, Laryngoscope, 6 kind Disposable Blades.

Laryngoscope Set (Made by PC plastic) with :

Handle (water proof) *1pc

Disposable Blades :	Macintosh	SLN-003	6-1/2"	*1 pc.
	Macintosh	SLN-002	4"	*1 pc.
	Macintosh	SLN-001	3"	*1 pc.
	Miller	SLN-013	5-1/4"	*1 pc.
	Miller	SLN-012	4-1/2"	*1 pc.
	Miller	SLN-011	3-1/4"	*1 pc.

2.3 Tested System Details

The FCC IDs/TYPEs for all equipment, plus descriptions of all cables used in the tested system (including inserted cards, which have grants) are:

🗵 EUT	: LARYNGOSCOPE
Model No.	: SLN-020
Manufacturer	: STURDY INDUSTRIAL CO.,LTD
Power Cord	: N/A

2.4 Test Methodology

EMI Test:

Both conducted and radiated testing were performed according to the procedures in EN55011/1991. Radiated Power testing was performed at an antenna to EUT distance of <u>10</u> meters.

EMS Test:

Performed according to procedures in EN 61000-4(IEC 801/IEC1000-4 Series Regulations)

2.5 Test Facility

Ambient conditions in the laboratory:

Items	Required (IEC 68-1)	Actual
Temperature (°C)	15-35	20-35
Humidity (%RH)	25-75	50-65 for ESD
	(45-75 for ESD, 1 st , ed.)	55-70 for others
	(30-60 for ESD, 2 nd . Ed)	
Barometric pressure (mbar)	860-1060	950-1000

Site Description	: March 13, 1998 File on NEMKO EMC Laboratory Authorization			
	Gaustadalleen 30, Postboks 73 Blindern, 0314 Oslo, Aut. No.: ELA 126			
	Recognition of Det Norske Veritas AS effective through De c. 2001			

Statement No:510-96-1017

Accreditation on NVLAP effective through Sep. 30, 1999 For CISPR22, FCC Method and AS/NZS 3548 Measurement. NVLAP Lab Code: 200085-0

Registration on VCCI effective through March 31, 2002. Registration No.: R-291 and C-305

- Name of firm : Global EMC Standard Tech. Corp.
- Site location : No. 3 Pau-Tou-Tsuo Valley, Chia-Pau Tsuen, Lin Kou Hsiang, Taipei County, Taiwan, R.O.C.

3. Radiation Emission Test

3.1 Test Equipment

The following test equipments are used during the radiated emission tests:

Item	Instrument	Manufacturer	Type /Serial No.	Last Cal.	Site #1	Site #2
1	Test Receiver	Rohde & Schwarz	ESVS 30 / 829007/014	Nov. 23,1998	~	
2	Spectrum Analyzer	HP	8594E / 3543A02689	N/A	V	
3	Pre-Amplifier	HP	8447D / 2944A08272	N/A	V	
4	Test Receiver	Rohde & Schwarz	ESCS 30/825022/003	Jul. 08,1998		V
5	Spectrum Analyzer	HP	8591E/3543A05040	N/A		V
6	Pre Amplifier	HP	8447D/2944A08273	N/A		V
7	BILOG ANTENNA	Chase	CBL6112B/2417	May. 15,1999	V	
8	BILOG ANTENNA	Chase	CBL6112B/2416	May. 15,1999		V
9	Pre Amplifier	HP	8347A/3307A01401	N/A	~	V
10	Open Site	GesTek	GTK-RF-S01	Jan. 05, 1999	V	
11	Open Site	GesTek	GTK-RF-S02	Jan. 03, 1999		V
12	RF Cable	GesTek	GTK-RF-C01	May. 15,1999	~	
13	RF Cable	GesTek	GTK-RF-C02	May. 15,1999	~	
14	RF Cable	GesTek	GTK-RF-C03	Mar. 26,1999		~
15	Test Program Software	GesTek	GTK-RF-P01	N/A	V	
16	Test Program Software	GesTek	GTK-RF-P02	N/A		V

Radiated test was performed on : \square Site #1 \square Site #2

Note: All equipment upon which need to calibrated are with calibration period of 1 year.

- 3.2 Test Setup
- 3.2.1 Block Diagram of Connections between EUT and simulators



3.2.2 Open Test Site & Anechoic Chamber Setup Diagram

Note: This is a representive setup diagram for Table-top EUT.

For Floor-standing EUT, the table will be removed with all others setup condition remain the same.



3.3 Radiated Emission Limit

Frequency	Distance	Field Strength
MHz	Meter	dB(uV/M)
30 - 230	10	30
230 - 1000	10	37

Class B Limits

Class A Limits

Frequency	Distance	Field Strength
MHz	Meter	dB(uV/M)
30 - 230	30	30
230 - 1000	30	37

Remark: 1. The tighter limit shall apply at the edge between two frequency bands.

2. Distance refers to the distance in meters between the measuring instrument antenna and the closed point of any part of the device or system.

3.4 EUT Configuration

The equipments which is listed 3.2.2 are installed on Radiated Emission Test to meet the Commission requirement and operating in a manner which tends to maximize its emission characteristics in a normal application.

The device under test, installed in a representative system as described in section 4.2.2, was placed on a non-conductive table whose total height equaled 80 cm. This table can be rotated 360 degree. The measurement antenna was mounted to a non-conductive mast capable of moving the antenna vertically. Antenna height was varied from 1 meter to 4 meters and the system under test was rotated from 0 degree through 360 degrees relative to the antenna position and polarization (Horizontal and Vertical). Also the I/O cable position was investigated to find the maximum emission condition.

3.5 Operating Condition of EUT

Same as Conducted Power Line Test which is listed in 2.5.

3.6 Radiated Emission Data

The measurement range of radiated emission which is from 30 MHz to 1 GHz was investigated. The initial step in collecting conducted data is a spectrum analyzer peak scan of the measurement range for all the test modes. Then the worst modes were reported the following data pages .

The total uncertainty for this test is as follows:

• Uncertainty in the field strength measured (3m antenna distance): $< \pm 4.0 \text{ dB}$

• Uncertainty in the field strength measured (10m antenna distance): $< \pm 4.0 \text{ dB}$

The uncertainty is calculated in accordance with NAMAS document NIS 81, and is given as 2 standard deviations.

Radiated Emission Data

Date of Test	:05-17,1999 Mon	Temperature	:27 deg/C
EUT	: LARYNGOSCOPE	Humidity	:70 %RH
Working Cond	.:Mode 1	Display Pattern	n :

Fr	equency [MHz]	Cable Loss [dB]	Antenna Factor [dB/m]	Reading Level Horizontal [dB(uV)]	Emission Level Horizontal [dB(uV/m)]	Limit [dB(uV/m)]
*	32.340	0.16	18.22	2.47	20.85	30.00
	113.410	0.87	10.63	2.10	13.60	30.00
	143.310	0.84	10.64	4.90	16.38	30.00
	162.030	1.10	10.00	3.97	15.07	30.00
	190.120	1.15	9.20	5.70	16.05	30.00
	207.350	1.23	9.80	2.39	13.43	30.00
	290.960	1.48	12.89	4.99	19.37	37.00

Remarks:	1.	A11	Rea	adings	below	1GHz	are	e Quas	i -Pea	k, above	are	average	value.
	2.	· · *	"	means	this	data	is v	worse	case	emission	lev	el.	

- 3. Emission Level = Reading Level + Antenna Factor + Cable loss
- 4. Deviations from the specifications: None.

Date of Test	:05-17,1999 Mon	Temperature	:27 deg/C
EUT	: LARYNGOSCOPE	Humidity	:70 %RH
Working Cond	.:Mode 1	Display Patter:	n:

F	Grequency (MHz)	Cable Loss (dB)	Antenna Factor (dB)	Reading Level Vertical (dBuV/m)	Emission Level Vertical (dBuV/m)	Limits (dBuV/m)
*	32.270 112.520 143.720 162.020 190.820	0.16 0.87 0.87 1.10 1.15	18.22 10.63 10.58 10.00 9.20	2.08 2.26 5.73 4.41 6.13	20.46 13.76 17.18 15.51 16.48	30.00 30.00 30.00 30.00 30.00 30.00
	206.590 290.690	1.13 1.23 1.48	9.80 12.89	2.38 4.95	13.42 19.33	30.00 37.00

Remarks:	1.	Al	1	Rea	ndings	below	1GHz	ar	e Quas	i-Pea	ık,	above	are	average	value.
	2.	"	*	",	means	this	data	i s	worse	case	emi	ssion	lev	el.	

- 3. Emission Level = Reading Level + Antenna Factor + Cable loss
- 4. Deviations from the specifications: None.

4. ESD Measurement

4.1 Test Equipment

The following test equipments are used during the ESD tests:

Item	Instrument	Manufacturer	Type No.	Last Calibration	
1	ESD Simulator System	HAEFELY	PSD25B/083427-11	Jul. 15, 1998	
2	Shielded Room	GesTek	GTK-RF-S05	N/A	

Note: All equipment upon which need to calibrated are with calibration period of 1 year.

4.2 Test Setup

4.2.1 Block Diagram of Connections between EUT and simulators



For Floor-standing EUT, the table will be removed with all others setup condition remain the same.

4.3 Severity Levels

LEVEL	TEST VOLTAGE CONTACT DISCHARGE	TEST VOLTAGE AIR DISCHARGE
1	2KV	2KV
2	4KV	4KV
3	3KV	8KV
4	8KV	15KV
Х	SPECIAL	SPECIAL

Pursuant to EN60601-1-2/1993:

Required Performance Criteria	:	В
Limit	:	±3Kv (Contact Discharge)

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±8Kv (Air Discharge)
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4.4 EUT Operating Condition

1. Setup the EUT and Test Equipment as shown on 3.5

4.5 Test Procedure

Direct ESD :

Single discharge at > 1 second interval, 10 positive & 10 negative.

Air discharges to surfaces of the EUT.

Air Discharge:

This test was done above a non-conductive surfaces. The round discharge electrode about 30cm away will approach as fast as possible to touch test points of the EUT. Discharge happens before the contact. This procedure is repeated ten times on one selected location.

Indirect ESD : (Horizontal Coupling Plane under the EUT & Vertical Coupling Plane beside EUT)

Vertical Coupling Plane shall be positioned at a distance of 0.1m from the EUT, with the Discharge Electrode touching the coupling plane.

Apply ESD to the earth reference plane on each accessible side of the EUT.

Single discharge at > 1 second interval, 10 positive & 10 negative

4.6 Test Method

According to IEC801-2/1984/1991, IEC1000-4-2/1995.

4.7 Test Result

ITEM	AMOUNT OF DISCHARGE	VOLTAGE	REQUIRED CRITERIA	COMPLIED TO CRITERIA (A,B,C)	RESULTS
Direct Discharge Air	20 20	+8KV -8KV	B B	A A	PASS PASS
Direct Discharge Contact	20 20	+3KV -3KV	B B	A A	PASS PASS
Indirect Discharge VCP	20 20	+3KV -3KV	B B	A A	PASS PASS
Indirect Discharge HCP	20 20	+3KV -3KV	B B	A A	PASS PASS

NR: No Requirement

- \boxtimes Meet criteria A: Operate as intended during and after the test
- Meet criteria B: Operate as intended after the test
- ☐ Meet criteria C: Loss/Error of function
- □ Additional Information
 - EUT stopped operation and <u>could</u> / <u>could not</u> be reset by operator at _____ KV of mode _____.
 - \boxtimes No false alarms or other malfunctions were observed during or after the test. The acceptance criteria were met, and the EUT passed the test.

5. RF Field Strength Susceptibility Measurement

5.1 Test Equipment

The following test equipments are used during the RS tests:

Item	Instrument	Manufacturer	Type No.	Last Calibration
1	Signal Generator	Marconi	2030/3110196	Dec. 15,1998
2	Power Amplifier	A & R	100W1000M1/17108	Aug. 18, 1998
3	Field Strength Meter	A & R	FM2000/16837	N/A
4	Field Strength Sensor	A & R	FP2000/16895	Jun. 12, 1998
5	Broadband Antenna	Chase	CBL6111A/1620	Nov. 12, 1998
6	Power Amplifier	A & R	75A220/17044	Aug. 18, 1998
7	Spectrum	Advantest	R3261CN/41720195	N/A
8	Pre-Amplifier	HP	8447F/3113A04487	N/A
9	Arbitary Waveform Generator	НР	33120A/US3602015 5	Jan. 10,1999
10	Shielded Room	GesTek	GTK-RF-S03	Mar. 18,1999
11	EMI & EMS Program Software	GesTek	GTK-RF-P03	N/A
12	RF Cable	GesTek	GTK-RF-C04	Apr. 11,1999
13	RF Cable	GesTek	GTK-RF-C05	Apr. 11,1999
14	RF Cable	GesTek	GTK-RF-C06	Apr. 11, 1999
15	Power Amplifier	A & R	150A100A/25056	Mar. 31, 1999

Note: All equipment upon which need to calibrated are with calibration period of 1 year.

5.2 Block Diagram of Test Setup



Note: This is a representive setup diagram for Table-top EUT. For Floor-standing EUT, the table will be removed with all others setup condition remain the same.

5.3 Severity Levels

LEVEL	FIELD STRENGTH V/M
1	1
2	3
3	10
X SPECIAL	

Pursuant to EN60601-1-2:

Required Performance Criteria	:	А
Limit	:	3.0V/m

5.4 EUT Operating Condition

Same as section 3.5.

5.5 Test Procedure

5.6

The EUT and load are placed on a table which is 0.8 meter above ground. The field sensor is also placed on the same table to monitor field strength from transmitting antenna. EUT is set 3 meter away from the transmitting antenna which is mounted on an antenna each time. The antenna is fixed 1 meter above ground. Both horizontal and vertical polarization of the antenna are set on measurement. In order to judge the EUT performance, a CCD camera is used to monitor EUT screen.

All the scanning conditions are as follows:

Condition of Test	Remarks
A 1. Field Strength	3 V/m Level 2
2. Radiated Signal	1K AM 80% Unmodulation
3. Scanning Frequency	26MHz-1000MHz
4. Frequency step size Δf :	$\Delta f = f n - f (n-1) = \frac{1}{Q} f (n-1)$
where: Δf	= frequency step size
f(n-1) = previous test	frequency
f n = next test free	quency
Q	= ratio center frequency to bandwidth
B 1. Test Frequencies : 895 – 905 M	Hz
2. Rep. Frequency : 200Hz	
3. 50% Duty cycle	
4. Pulse modulation : Signal 50% mo	odulated by 200Hz pulses of equal mark/space ratio.
Test Method	

According to IEC801-3/1984, IEC1000-4-3/1995 Basic immunity standard;

Radiated radio-frequency electromagnetic field; Immunity test.

5.7 Test Result

Freq. Range (MHz)	Position (Angle)	Polarity (H or V)	Field Strength (V/M)	Performance Criteria Complied to	Results
26-1000	0	Н	3	A	PASS
900±5	0	Н	3	A	PASS
26-1000	90	Н	3	А	PASS
900±5	90	Н	3	А	PASS
26-1000	180	Н	3	А	PASS
900±5	180	Н	3	A	PASS
26-1000	270	Н	3	A	PASS
900±5	270	Н	3	A	PASS
26-1000	0	V	3	A	PASS
900±5	0	V	3	A	PASS
26-1000	90	V	3	А	PASS
900±5	90	V	3	A	PASS
26-1000	180	V	3	A	PASS
900±5	180	V	3	A	PASS
26-1000	270	V	3	А	PASS
900±5	270	V	3	A	PASS

Meet criteria A: Operate as intended during and after the test

- ☐ Meet criteria B: Operate as intended after the test
- ☐ Meet criteria C: Loss/Error of function
- \boxtimes Additional Information
 - \boxtimes There was no observable degradation in performance.
 - □ EUT stopped operation and <u>could</u> / <u>could not</u> be reset by operator at _____ V/m at frequency _____MHz.
 - □ No false alarms or other malfunctions were observed during or after the test. The acceptance criteria were met, and the EUT passed the test.

The total uncertainty for this test is as follows:

• Uncertainty in applied field strength (3m antenna distance): -2.1/+2.9 dB

The uncertainty is calculated in accordance with NAMAS document NIS 81, and is given as 2 standard deviations.

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6.

The following test photographs shown maximum emission configuration condition for each test mode.

- Photographs CO FRONT VIEW OF RADIATION TEST 1.
- 2. BACK VIEW OF RADIATION TEST

- 3. FRONT VIEW OF ESD TEST SETUP
- 4. BACK VIEW OF ESD TEST SETUP

- 5. FRONT VIEW OF ESD TEST POINT
- 6. BACK VIEW OF ESD TEST POINT

- 7. FRONT VIEW OF RS TEST SETUP
- 8. BACK VIEW OF RS TEST SETUP

FRONT VIEW OF LARYNGOSCOPE
BACK VIEW OF LARYNGOSCOPE

11. INNER VIEW OF LARYNGOSCOPE
12. INNER VIEW OF LARYNGOSCOPE

13. FRONT VIEW OF LARYNGOSCOPE
14. BACK VIEW OF LARYNGOSCOPE

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7. EMI/EMS Reduction Method During Compliance Testing