TELEDYNE INSTRUMENTS
Analytical Instruments
Risk Analysis

Concern Level & Definitions

The table lists the established concern levels and their corresponding definitions for hardware and software risk hazards. The risk analysis elements were generated using EN/IEC 60601-1, EN 60601-4, EN 1441 and Center for Devices and Radiological Health (CDRH) FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices as guidance.

Concern Level	Concern Category	Definition
1	Minor	Failures or latent design flaws that would not be expected to result in any injury to the patient and/or operator.
2	Moderate	Operation of the hardware/software associated with device functions directly affects the patient and/or operator so that failures or latent flaws could result in non-serious injury to the patient or operator, or if it indirectly affects the patient and/or operator (e.g. through the action of a care provider) where incorrect or delayed information could result in non-serious injury of the patient and/or operator.
3	Major	Operation of the hardware/software associated with device function directly affects the patient and/or operator so that failures or latent flaws could result in death or serious injury to the patient and/or operator, or if it indirectly affects the patient and/or operator (e.g. through the action of a care provider) where incorrect or delayed information could result in serious injury of the patient and/or operator.

TELEDYNE INSTRUMENTS
Analytical Instruments
Device Hazard Analysis

Hazardous Event	Level of Concern	Cause of Hazard	Method of Control	Corrective Measures To Reduce Hazard	Testing Method To Ensure Control
Hardware Failure	Minor	Subsystem, component or interconnection failure (i.e. defective component broken conductor)	ESD product handling methods, material procurement & manufacturing process control	"Watchdog*" timer circuit	Induce failures during product design and qualification to verify proper performance of "watchdog" timer circuit
Hardware Design Flaw	Minor	Exceeding set up and old times for device	Device operating at low clock rate	"Watchdog" timer circuit	Induce failures during product design and qualification to verify proper performance of "watchdog" timer circuit
Software "Bug"	Minor	Unexpected execution of software logic sequence	Software validation during final product software release	"Watchdog" timer circuit	Extensive software testing using various and numerous test conditions to induce failures.

*"Watchdog" timer circuit – Timing circuit that expects to see a reset pulse from the microprocessor, typically 1 to 2 seconds on a cyclical basis prior to the period in which the timing circuit would in absence of that pulse strobe an alarm signal.

TELEDYNE INSTRUMENTS
Analytical Instruments
Risk Evaluation Sheet

Product Line: **OXYGEN MONITOR, Model MX300**

Item #	Description of Hazard	Parts or Equipment which pose this hazard	Initial Risk Level	Design Solutions adopted to reduce the hazard	Residual Risk Level	Documents referred to	Location
1.0	**ENERGY HAZARDS**		Risk Level 1 to 3				
1.1	Electrical Shock	RS232 Port	2	Caution Statement added to Instruction Manual	1	Instruction Manual	Section B.4
1.2	Excessive Heat	NONE	1	N/A	1	N/A	N/A
1.3	Mechanical Force	NONE	1	N/A	1	N/A	N/A
1.4	Ionizing Radiation	NONE	1	N/A	1	N/A	N/A
1.5	Non-ionizing Radiation	NONE	1	N/A	1	N/A	N/A
1.6	Electromagnetic Fields	NONE	1	N/A	1	N/A	N/A
1.7	Moving Parts	NONE	1	N/A	1	N/A	N/A
1.8	Suspended Masses Falling	NONE	1	N/A	1	N/A	N/A
1.9	Patient Support Device Failure	NONE	1	N/A	1	N/A	N/A
1.10	Pressure Vessel Rupture	NONE	1	N/A	1	N/A	N/A
1.11	Excessive Acoustic Pressure	NONE	1	N/A	1	N/A	N/A
1.12	Excessive Vibration	NONE	1	N/A	1	N/A	N/A
2.0	**BIOLOGICAL HAZARDS**						
2.1	High Level Mechanical Field	NONE	1	N/A	1	N/A	N/A
2.2	Bio-burden	Lead (Lead Oxide)	2	Leaflet (MSDS)	1	Leaflet	Section B.3
2.3	Bio-contamination	Potassium Hydroxide KOH (Electrolyte Leaking)	2	Process Control (Leak Check Procedure) & Leaflet	1	Instruction for Use & Test Procedure	Section B.3, B.4 & D.5
2.4	Bio-incompatibility	Electrolyte KOH	2	Sensor's Leaflet (MSDS section)	1	Sensor's Leaflet	Section B.3

TELEDYNE INSTRUMENTS
Analytical Instruments
Risk Evaluation Sheet

Product Line: **OXYGEN MONITOR, Model TED MX300**

Item #	Description of Hazard	Parts or Equipment which pose this hazard	Initial Risk Level	Design Solutions adopted to reduce the hazard	Residual Risk Level	Documents referred to	Location
2.0	**BIOLOGICAL HAZARDS**		Risk Level 1 to 3				
2.5	Incorrect Output (Substance/Energy)	R17MED Sensor	2	Leaflet (Calibrate prior to use)	1	Sensor's Leaflet	Section B.3
2.6	Incorrect Formulation (Chemical Composition)	Sensor's Electrolyte	2	Functional Test Procedure (Final Assembly Output)	1	Test Procedure	Section D.5
2.7	Toxicity	Potassium Hydroxide	2	Leak Testing Procedure (Potassium Hydroxide) KOH	1	Leak Test Procedure	Section D.5
2.8	Chemical Nature of the Materials	Potassium Hydroxide	2	Leak Testing Procedure (Potassium Hydroxide) KOH	1	Leak Test Procedure	Section D.5
2.9	Prior Use of the Materials	N/A because the unit is not used previous to being delivered	1	N/A	1	N/A	N/A
2.10	Cross Infection	Sensor & Accessories	2	Sensor's Leaflet & User Manual Cleaning Instructions	1	Sensor's Leaflet & User Manual	Section B.3 and B.4
2.11	Pyrogenicity	N/A because this unit has no tendency to burn under any conditions	1	N/A	1	N/A	N/A
2.12	Inability to Maintain Hygienic Safety	Sensor & Accessories	2	Sensor's Leaflet & User Manual Cleaning Instructions	1	Instructions for Use (Leaflet & User Manual)	Section B.3 and B.4

TELEDYNE INSTRUMENTS
Analytical Instruments
Risk Evaluation Sheet

Product Line: **OXYGEN MONITOR, Model TED MX300**

Item #	Description of Hazard	Parts or Equipment which pose this hazard	Initial Risk Level	Design Solutions adopted to reduce the hazard	Residual Risk Level	Documents referred to	Location
2.0	**BIOLOGICAL HAZARDS**		Risk Level 1 to 3				
2.13	Degradation	Sensor & Accessories	1	Product Design and Material Selection	1	Risk of Degradation Analysis	Section D.7
3.0	**ENVIRONMENTAL HAZARDS**						
3.1	Electromagnetic Interference	System PCB	2	EMC shielding EN61000-4-2,3,4,6&8, EN/IEC60601-1-2, IEC1000-4-2,3,4,6&8, EN55011	1	EMC Test Report	Section F.2
3.2	Inadequate Supply of power or coolant	3 - AA Alkaline Battery	2	Battery Life Indicator	1	Instruction Manual	Section B.4
3.3	Restriction of cooling	N/A because this unit generates no appreciable heat	1	N/A	1	N/A	N/A
3.4	Likelihood of Operation Outside prescribed environmental conditions	Monitor & Sensor	2	Product Qualification Testing	1	Qualification Test Reports	Section F and Exhibits
3.5	Incompatibility with other devices	N/A because this device is not normally used with other devices	1	N/A	1	N/A	N/A
3.6	Accidental Mechanical Damage	Monitor & Sensor	2	EN/IEC60601-1, UL2601-1 and CSA 601-1	1	Test Reports	Section F.1
3.15	Reasonably Foreseeable Misuse	N/A	1	Labels & User Manual	1	Labels & User Manual	Section B.2 and B.4
3.16	Insufficient Warning of Side Effects	N/A because this unit is not ingested in any way	1	N/A	1	N/A	N/A

TELEDYNE INSTRUMENTS
Analytical Instruments
Risk Evaluation Sheet

Product Line: **OXYGEN MONITOR, Model MX300**

Item #	Description of Hazard	Parts or Equipment which pose this hazard	Initial Risk Level	Design Solutions adopted to reduce the hazard	Residual Risk Level	Documents referred to	Location
3.0	**ENVIRONMENTAL HAZARDS**		Risk Level 1 to 3				
3.17	Inadequate Warning of Hazards likely with Re-use of single use devices.	N/A	1	N/A	1	N/A	N/A
3.18	Incorrect Measurement and other Meteorological Aspects	N/A	1	N/A	1	N/A	N/A
3.19	Incorrect Diagnosis	N/A because this unit is not used for diagnostic purposes	1	N/A	1	N/A	N/A
3.20	Erroneous Data Transfer	RS232 connection	2	Use of parity bit in communication protocol. Slow rate of data transfer (2400 baud).	1	Integrated into the design	N/A
3.21	Misrepresentation of Results	N/A	1	N/A	1	N/A	N/A
3.22	Incompatibility with Consumable/ Accessories/Other Devices	N/A	1	N/A	1	N/A	N/A
4.0	**HAZARDS arising from Functional Failure, Maintenance and Aging**						
4.1	Inadequacy of performance characteristics for the Intended use	Instruction Manual	1	Labels & User Manual	1	Labels and Manual	Section B.2 and B.4
4.2	Lack of, or inadequate specification for maintenance including inadequate Specification of post maintenance functional checks	Instruction Manual Maintenance & Troubleshooting	1	Instruction Manual	1	Instruction Manual	Section B.4
4.3	Inadequate Maintenance	NONE	1	N/A	1	N/A	N/A

TELEDYNE INSTRUMENTS
Analytical Instruments
Risk Evaluation Sheet

Product Line: **OXYGEN MONITOR, Model MX300**

Item #	Description of Hazard	Parts or Equipment which pose this hazard	Initial Risk Level	Design Solutions adopted to reduce the hazard	Residual Risk Level	Documents referred to	Location
4.0	**HAZARDS arising from Functional Failure, Maintenance and Aging**		Risk Level 1 to 3				
4.4	Lack of Adequate determination of end of device life	NONE	1	N/A	1	N/A	N/A
4.5	Loss of Mechanical Integrity	NONE	1	N/A	1	N/A	N/A
4.6	Inadequate Packaging (Contamination and/or deterioration of the device).	NONE	1	N/A	1	N/A	N/A
4.7	Improper re-use	NONE	1	N/A	1	N/A	N/A

TELEDYNE
INSTRUMENTS
Analytical Instruments
A Teledyne Technologies Company

MEMORANDUM

DATE: 12 / 4 / 02

TO: MX300 / AX 300 Technical File

FROM: Steve Broy, Director of Engineering

CC:

SUBJECT: Risk of Degradation

Regarding the Risk of Degradation on the materials within the analyzer, which might eventually cause a risk due to bio incompatibility one, can say the following:

- The product is made up of the following materials

a) ABS plastic case
b) Glass Epoxy Circuit Board
c) Lexan Viewing Window
d) Metal Contacts
e) Off the Shelf AA Alkaline Batteries
f) Packaged Integrated Circuits and Passive Electronic components
g) Coiled rubberized cable
h) Microfuel Cell Oxygen Sensor

Of these components, a) through g) have excellent long term stability and are inert with regard to the possibility of degrading into a form which exhibits bio-incompatibility

Item h), the micro fuel cell sensor, which are manufactured by Teledyne for the O2 concentration measurement, contain an electrolyte and a lead anode, which is later oxidized for a lead oxide.

The lead and electrolyte solution is encapsulated in a cylindrical two layer (inner polyethylene and outer polypropylene) plastic material assembly. This material is inert and provides robust and sound structural integrity for its intended applications and is resistant to routine mechanical stresses and not general susceptible be to material fracture.

The electrolyte, Potassium hydroxide (KOH), and lead oxide formed cannot permeate through the cell body; therefore, it does not allow the opportunity for lead exposure.

Therefore, the risk associated with this is negligible as well.

TELEDYNE INSTRUMENTS
Analytical Instruments
Performance Standards

There are no performance standards set by the Food and Drug Administration. This medical device is designed to meet and has been tested to meet the following voluntary standards:

Standard	Description
ISO 7767	Oxygen Monitors for monitoring patient breathing mixtures – Safety requirements
EN 55011, Class B	Conducted RF Interference
EN 61000-4-2/IEC1000-4-2	Electrostatic Discharge Test
EN 61000-4-3/ IEC1000-4-3	Radiated RF Field
EN 61000-4-4/ IEC1000-4-4	Electrical Fast Transient
EN 61000-4-6/ IEC1000-4-6	Conducted Susceptibility
EN 61000-4-8/ IEC1000-4-8	Magnetic Field Immunity
EN/IEC 60601-1/CSA 601.1/ UL2601-1	Medical Electrical Equipment (General requirements for safety)
EN/IEC 60601-1-2	Medical Electrical Equipment General requirements for safety) – Electromagnetic Compatibility

TELEDYNE INSTRUMENTS
Analytical Instruments
Qualification Test Reports

This section contains the significant test reports that demonstrate the product has successfully passed all of the following voluntary safety and performance standards. Approved independent test laboratories conducted the tests and produced the Qualification Test reports. The test reports are as follows:

Test Laboratory	Test Report Number	Performance Standards
Intertek Testing Service (ITS)	3026020-001	EN/IEC 60601-1 CSA 601-1 UL2601-1
DNB Engineering	RV28108	EN/IEC 60601-1-2 EN 55011 EN 61000-4-2/IEC1000-4-2 EN 61000-4-3/IEC1000-4-3 EN 61000-4-4/IEC1000-4-4 EN 61000-4-6/IEC1000-4-6 EN 61000-4-8/IEC1000-4-8
Wyle Laboratory	D47885	ISO 7767 (Shock)

Test Report

ITS Intertek Testing Services

TEST REPORT

IEC 60601-1

Medical electric equipment
Part 1: General requirements for safety

Report

Reference No. ..... : 3026020-001

Compiled by (+ signature) ..... : Sayeed Abassi

Approved by (+ signature) ..... : Nathan Shivers

Date of issue ..... : 06-30-02

Contents ..... : Pages: 42

..... :

This report is based on a blank test report that was prepared by KEMA using information obtained from the TRF originator (see below).

Testing laboratory

Name ..... : Intertek Testing Services

Address ..... : 27611 La Paz Road, Suite C, Laguna Niguel, CA 92677

Testing location ..... : Same as above

..... :

Client

Name ..... : Teledyne Analytical Instrument

Address ..... : 16830 Chestnut St.

..... : P.O Box 1580

City of Industry, CA 91749

Test specification

Standard ..... : IEC 60601-1:1988 + A1:1991 + A2:1995

Test procedure ..... : CB-scheme

Procedure deviation ..... : N.A.

Non-standard test method ..... : N.A.

Test Report Form/blank test report

Test Report Form No. ..... : I601-1_C/97-07

TRF originator ..... : UL

Master TRF ..... : dated 97-04

Test item

Description ..... : Oxygen Monitor

Trademark ..... : none

Model and/or type reference ..... : MX300 and AX 300

Manufacturer ..... : Teledyne

Rating(s) ..... : 4.5 V DC

IEC 601-1			
Clause	Requirement – Test	Result - Remark	Verdict

.....:

Particulars: test item vs. test requirements

Classification of installation and use .....: Hand-held

Supply connection .....: internally powered

Test case verdicts

Test case does not apply to the test object .....: N(.A.)

Test item does meet the requirement.....: P(ass)

Test item does not meet the requirement .....: F(ail)

.....:

Testing

Date of receipt of test item .....: 05-20-02

Date(s) of performance of test.....: 06-30-02

.....:

General remarks

This test report shall not be reproduced except in full without the written approval of the testing laboratory.

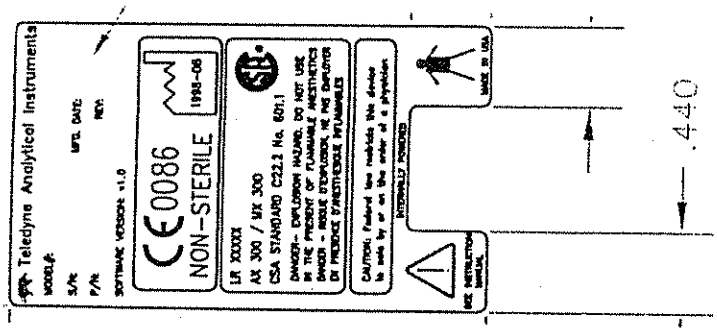
The test results presented in this report relate only to the item tested.

"(see remark #)" refers to a remark appended to the report.

"(see appended table)" refers to a table appended to the report.

Throughout this report a comma is used as the decimal separator.

Copy of marking plate

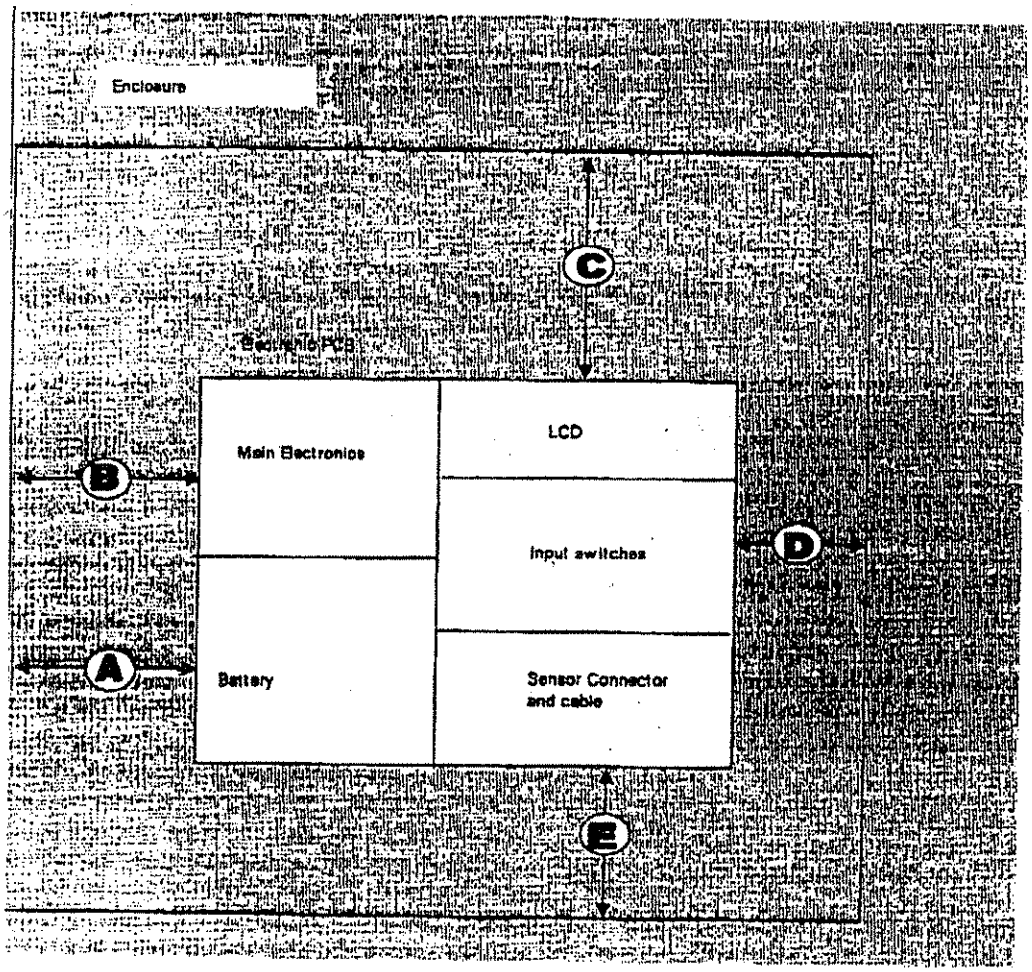


IEC 601-1			
Clause	Requirement – Test	Result - Remark	Verdict
3.	GENERAL REQUIREMENTS		
3.1	Equipment when transported, stored, installed, operated in normal use and maintained according to the instructions of the manufacturer, causes no safety hazard which could reasonably be foreseen and which is not connected with its intended application in normal condition (N.C.) and in single fault condition (S.F.C.)	Equipment will not cause safety hazards when used according to manufacturer instruction.	P
3.4	An alternative means of construction is used to that detailed in this standard and it can be demonstrated that an equivalent degree of safety is obtained	No alternative construction	N
5.	CLASSIFICATION		
5.1	Type of protection against electric shock		
	Class I equipment	Not a class I	N
	Class II equipment	Not a class II	N
	Internally powered equipment	Powered by 3 x 1.3 V batteries	P
	Degree of protection against electric shock	Ordinary	P
5.2	Type B applied part	Type B Applied parts	P
	Type BF applied part	No a BF	N
	Type CF applied part	Not a CF	N
	Not classified, no applied parts	Type B applied parts	N
5.3	Classification according to the degree of protection against ingress of water as detailed in the current edition of IEC 529 (see 6.1.1) ... :	IPX0	P
5.4	Methods of sterilization or disinfection	Instruction Provided	P
5.5	Equipment not suitable for use in the presence of flammable mixtures	Marking provided to warn the user against the use if the equipment in the presence of flammable gas mixtures	P
	Category AP equipment	Not an AP type	N
	Category APG equipment	Not an APG type	N
5.6	Mode of operation:		
	continuous operation	Continuous	P

IEC 601-1			
Clause	Requirement – Test	Result - Remark	Verdict
	short-time operation, specified operation; period ..... :	No short-time operation	–
	intermittent operation, specified operation; rest period ..... :	No intermittent operation	–
	continuous operation with short-time, stated permissible loading time ..... :	No short-time operation	–
	continuous operation with intermittent, stated permissible loading/rest time ..... :	No intermittent operation	–

	Table: insulation diagram	P
	Protection against electric shock - Block diagram of system	

INSULATION DIAGRAM



IEC 601-1			
Clause	Requirement – Test	Result - Remark	Verdict

Table: to insulation diagram

area	insulation type: operational/basic/ supplementary/ double/reinforced	reference voltage (V)	required creepage (mm)	required clearance (mm)	measured creepage (mm)	measured clearance (mm)	remarks
A	A-a2	4.5	3.4	1.8	> 3.4	3.01	
B	A-a2	4.5	3.4	1.8	> 3.4	3.01	
C	A-a2	4.5	3.4	1.8	> 3.4	3.01	
D	A-a2	4.5	3.4	1.8	> 3.4	3.01	
E	A-a2	4.5	3.4	1.8	> 3.4	3.01	
F							
G							
H							
I							
J							
K							
L							
M							
N							
O							

INSULATION DIAGRAM CONVENTIONS

Insulation diagram is a graphical representation of equipment insulation barriers, protective impedance and protective earthing. If feasible, use the following conventions to generate the diagram:

1. All isolation barriers are identified by letters between separate parts of diagram, for example separate transformer windings, optocouplers, wire insulation, creepage and clearance distances.

2. Parts connected to earth with large dots are protectively earthed. Other connections to earth are functional.

3. Applied parts are extended beyond the equipment enclosure and terminated with an arrow.

4. Parts accessible to the operator only are extended outside of the enclosure, but are not terminated with an arrow.

5. Blocks containing the letter "Z" indicate protective impedance.

6. Operational Insulation (OP) - indicates insulation that may be required for function of the equipment, but is not required or relied on for compliance with requirements of Cl. 17., 20. and 57.

IEC 601-1			
Clause	Requirement – Test	Result - Remark	Verdict

6.	IDENTIFICATION, MARKING AND DOCUMENTS		
6.1	Marking on the outside of equipment or equipment parts		P
	c) Markings of the specific power supply are affixed	No specific Power Supply	N
	d) If marking is not practicable due to size or nature of enclosure, information is included in accompanying documents	Marking is on the enclosure of the unit	P
	e) Name and/or trademark of the manufacturer or supplier .....:	Teledyne Analytical Instrument	P
	f) Model or type reference .....:	AX300 / MX 300	P
	g) Rated supply voltages or voltage range(s)	Internally powered equipment	N
	Number of phases .....:	Internally powered equipment	N
	Type of current .....:	Internally powered equipment	N
	h) Rated frequency or rated frequency range(s) (Hz) .....:	Internally powered equipment	N
	j) Rated power input (VA, W or A) .....:	Internally powered equipment	N
	k) Power output of auxiliary mains socket-outlets	Internally powered equipment	N
	l) Class II symbol	Not a class II unit	N
	Symbol for degree of protection against ingress of water provided .....:	IPX0	N
	Symbol for protection against electric shock ...:	Type B	N
	If equipment has more than one applied part with different degrees of protection, the relevant symbols are clearly marked on such applied parts, or on or near relevant outlets		N
	Symbol for protection of defibrillation-proof applied parts .....:		N
	Symbol 14 from Table DI for defibrillation-proof with protection partly in patient cable		N
	m) Mode of operation (if no marking, suitable for continuous operation		N
	n) Types and rating of external accessible fuses .....:	No fuses provided	N
	p) Ratings of external output .....:	No external output	N
	q) Symbol for physiological effect(s):		N

IEC 601-1			
Clause	Requirement – Test	Result - Remark	Verdict
	attention, consult accompanying documents	Symbol 14 of table D1 is provided	P
	non-ionizing radiation, or symbols as adopted by ISO or IEC 417	No radiation provided	N
	r) Anaesthetic-proof symbol: AP or APG .....:	Not an AP or APG	N
	s) Dangerous voltage symbol	Internally power equipment	N
	t) Special cooling requirements	No special cooling requirement	N
	u) Limited mechanical stability	No limited mechanical stability	N
	v) Protective packing requirement(s)	No protective packing	N
	Marking(s) for unpacking safety hazard(s)	No such hazard	N
	Equipment or accessories supplied sterile, marked as sterile	Non Sterile type of unit	N
	y) Potential equalization terminal	No potential equalisation provided	N
	Functional earth terminal	No Functional earth	N
	z) Removable protective means	No alternative applications	N
	Durability of marking test	(see appended table)	P
6.2	Marking on the inside of equipment or equipment parts		
	a) Nominal voltage of permanently installed equipment	Not a permanently installed unit	N
	b) Maximum power loading for heating elements or holders for heating lamps	No heating element	N
	c) Dangerous voltage symbol	No hazardous voltages	N
	d) Type of battery and mode of insertion	Symbol 14 of table D1 is provided in the unit which instructs the user of the type of the battery that needs to be used	P
	Marking referring to accompanying documents used for battery not intended to be changed by the operator	Marking is provided	P
	e) Fuses accessible with a tool identified either by type and rating or by a reference to diagram	No fuses in the unit	N
	f) Protective earth terminal	No protective earth terminal	N
	g) Functional earth terminal	No Functional earth	N

IEC 601-1			
Clause	Requirement – Test	Result - Remark	Verdict
	h) Supply neutral conductor in permanently installed equipment (N)	Internally power equipment	N
	j) Markings required in 6.2 f), h), k) ,and l) remain visible after connection and are not affixed to parts which have to be removed	Internally powered equipment	N
	Markings comply with IEC 445		N
	k) For permanently connected devices the supply connections are clearly marked adjacent to the terminals (or in accompanying documents for small equipment)	Not permanently connected unit	N
	l) Statement for suitable wiring materials at temperatures over 75 °C	Internally powered equipment	N
	n) Capacitors and/or circuit parts are marked as required in Cl. 15. c)	No caps	N
6.3	Marking of controls and instruments		
	a) Mains switch clearly identified		P
	ON and OFF positions marked according to Symbols 15 and 16 of Table D1 or indicated by an adjacent indicator light	ON and OFF positions are marked	P
	b) Indications of different positions of control devices and switches	All different position controls have been marked	P
	c) Indication of the direction in which the magnitude of the function changes, or an indicting device	Marked	P
	f) The functions of operator controls and indicators are identified	All operator control indicators have been identified.	P
	g) Numeric indications of parameters are in SI units except for units listed in A2	No parameters	N
6.4	Symbols		
	Symbols used comply with Appendix D or IEC 417 and/or IEC 878 or ISO publications (if applicable)	All symbols conform to appendix D	P
6.5	Colours of insulation of conductors		
	a) Protective earth conductor has green/yellow insulation	Internally powered equipment	N
	b) All insulations of internal protective earth conductors are green/yellow at least at their terminations	Internally powered equipment	N
	c) Only protective or functional earthing, or	No Functional earth	N

IEC 601-1			
Clause	Requirement – Test	Result - Remark	Verdict
	potential equalization conductors are green/yellow		
	d) Colour of neutral conductor .....:	Internally powered equipment	N
	e) Colours of phase conductors .....:	Internally powered equipment	N
	Compliance with IEC 227 and IEC 245	Internally powered equipment	N
	f) Additional protective earthing in multi-conductor, cords are marked green/yellow at the ends of the additional conductors	Internally powered equipment	N
6.6	Medical gas cylinders and connections		N
	a) In accordance with ISO/R 32	No gas connections	N
	b) Identification of connection point	No gas connections	N
6.7	Indicator lights and push-buttons		
	a) Red indicator lights used exclusively to indicate a warning of danger and/or a need for urgent action	No indicator lights on the unit	N
	Yellow used to indicate caution or attention required	No indicator lights on the unit	N
	Green used to indicate ready for action	No indicator lights on the unit	N
	b) Colour red used only for push-buttons by which a function is interrupted in case of emergency	No such push buttons	N
6.8	Accompanying documents		
6.8.1	Equipment is accompanied by documents containing at least instructions for use, a technical description and an address to which the user can refer	Provided	P
	Classifications specified in Cl. 5. are included in both the instructions for use and the technical description	Provided	P
	Markings specified in 6.1 included in the accompanying documents if they have not been permanently affixed to equipment	Provided	P
	Warning statements and the explanation of warning symbols provided in the accompanying documents	Provided in the unit	P
6.8.2	Instructions for use		
	a) General information provided in instructions for use:		
	- state the function and intended application of	Provided	P

IEC 601-1			
Clause	Requirement – Test	Result - Remark	Verdict
	the equipment		
	- include an explanation of: the function of controls, displays and signals	Provided	P
	- the sequence of operation	Provided	P
	- the connection and disconnection of detachable parts and accessories	Provided	P
	- the replacement of material which is consumed during operation	Provided	P
	- information regarding potential electromagnetic or other interference and advice regarding avoidance	Provided	P
	- include: indications of recognized accessories, detachable parts and materials, if the use of other parts or materials can degrade minimum safety	A list of spare parts have provided	P
	- instructions concerning cleaning, preventive inspection and maintenance to be performed including the frequency of such maintenance	Provided	P
	General information provided in instructions:		P
	- information for the safe performance or routine maintenance	Provided	P
	- parts on which preventive inspection and maintenance shall be performed by other persons including the periods to be applied	Provided	P
	- explanation of figures, symbols, warning statements and abbreviations on the equipment	Provided	P
	c) Signal output or signal input parts intended only for connection to specified equipment described	Input out marking provided	P
	d) Details about acceptable cleaning, disinfection or sterilization methods included	Provided	P
	e) Warning statement for mains operated equipment with additional power source	Internally powered equipment	P
	f) A warning to remove primary batteries if equipment is not likely to be used for some time	Provided	P
	g) Instructions to ensure safe use and adequate maintenance of rechargeable batteries	No rechargeable batteries	P
	h) Identification of specified external power supplies or battery chargers necessary to ensure compliance with the requirements of IEC 601-1	No such components	N

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Clause	Requirement – Test	Result - Remark	Verdict
	j) Identification of any risks associated with the disposal of waste products, residues, etc.	No such residue	N
	Advice in minimizing these risks	Provided	P
6.8.3	Technical description		
	a) All characteristics essential for safe operation provided	Provided	P
	b) Required type and rating of fuses utilized in the mains supply circuit external to permanently installed equipment	Internally powered unit	P
	Instructions for replacement of interchangeable and/or detachable parts which are subject to deterioration during normal use	Provided	P
	c) Instructions or reference information for repair of equipment parts designated by the manufacturer as repairable provided	Provided	P
	d) Environmental conditions for transport and storage specified in accompanying documents and marked on packaging	Provided	P
7.	POWER INPUT		
	Power input measurements	(see appended table)	N
10.	ENVIRONMENTAL CONDITIONS		
10.1	Equipment is capable while packed for transport or storage of being exposed to the conditions stated by the manufacturer	The unit is capable of storage for –40 to 70 °C	P
10.2.2	a) Rated voltage not exceeding 250 V for hand-held equipment	Internally powered rated at 4.5V	N
	Rated voltage not exceeding 250 V d.c. or single-phase a.c. or 500 V polyphase a.c. for equipment up to 4 kVA	Internally powered	N
	Rated voltage not exceeding 500 V for all other equipment	Internally powered	N
	Rated input frequency not more than 1 kHz	Internally powered	N
	b) Internal replaceable electric power source specified	3 AA batteries	P
14.	REQUIREMENTS RELATED TO CLASSIFICATION		

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Clause	Requirement – Test	Result - Remark	Verdict
14.4	a) Class I and Class II equipment in addition to basic insulation provided with an additional protection	Internally powered equipment	N
	b) Equipment supplied from external d.c. source of reverse polarity results in no safety hazard	Internally powered equipment	N
14.5	b) Internally powered equipment complies with requirements for Class I or Class II equipment while connected to supply mains, and with requirements for internally powered equipment when not connected	Can not be connected to supply mains	N
14.6	c) Applied parts intended for direct cardiac application are of type CF	Not for direct cardiac application	N
15.	LIMITATION OF VOLTAGE AND/OR ENERGY		
	b) Voltage measured one sec after disconnection of the mains plug does not exceed 60 V	(see appended table)	N
	c) For live parts accessible after equipment has been de-energized the residual voltage does not exceed 60 V nor residual energy exceeds 2 mJ	(see appended table)	N
	Marking provided for manual discharging		N
16.	ENCLOSURES AND PROTECTIVE COVERS		
	a) Equipment enclosed to protect against contact with live parts, and with parts which can become live (finger, pin, hook test)	No hazardous live parts	N
	Insertion or removal of lamps: protection against contact with live parts provided	No hazardous live parts	N
	b) Opening in a top cover so positioned that accessibility of live parts by a test rod is prevented	No hazardous live parts	N
	c) Conductive parts accessible after the removal of handles, knobs, levers:		N
	- have a resistance of not more than 0,2 Ω	(see appended table 18)	N
	- separated from live parts by one of the means described in Cl. 17. g)	No hazardous live parts	N
	d) Parts with voltage exceeding 25 V a.c. or 60 V d.c. which cannot be disconnected by external mains switch or plug protected against contact	No voltages of 25V ac	N

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Clause	Requirement – Test	Result - Remark	Verdict
	e) Removable enclosures protecting against contact with live parts	No hazardous live parts	N
	Removal possible only with the aid of a tool	Enclosure is secured by screws that needs to be opened	P
	Use of automatic device making parts not live when the enclosure is opened or removed	No automatic devices used	N
	Exception 16 e) applied to the following parts .:	No openings in the equipment	N
	f) Openings for the adjustment of controls using a tool. The tool not able to touch basic insulation or any live parts	No openings	N
17.	SEPARATION		
	a) Separation method of the applied part from live parts:		P
	1) basic insulation: applied part earthed		N
	2) by protectively earthed conductive part (e.g. screen)		N
	3) by separate earthed intermediate circuit limiting leakage current to applied part in event of insulation failure		N
	4) by double or reinforced insulation	Provided.	P
	5) by protective impedances limiting current to applied part		N
	Additional leakage current test in single fault conditions	(see appended table 19)	N
	c) There is no conductive connection between applied parts and accessible conductive parts, which are not protectively earthed		N
	d) Supplementary insulation between hand-held flexible shafts and motor shafts (Class I)		N
	g) Separation method of accessible parts other than applied parts from live parts:		
	1) basic insulation: accessible part earthed		N
	2) by protectively earthed conductive part (e.g. screen)		N
	3) by separate earthed intermediate circuit limiting leakage current to enclosure in event of		N

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Clause	Requirement – Test	Result - Remark	Verdict
	insulation failure		
	4) by double or reinforced insulation		N
	5) by protective impedances limiting current to accessible part		N
	Additional leakage current test in single fault conditions	(see appended table 19)	N
	h) Arrangements used to isolate defibrillation-proof applied parts so designed that:		N
	- no hazardous electrical energies appear during a discharge of a cardiac defibrillator	(see appended table 17h1)	N
	- after exposure to the defibrillation voltage, the equipment continues to perform its intended function	(see appended table 17h2)	N
18.	PROTECTIVE EARTHING, FUNCTIONAL EARTHING AND POTENTIAL EQUALIZATION		
	a) Accessible parts of Class I equipment separated from live parts by basic insulation connected to the protective earth terminal	No protective earthing. The unit is internally powered	N
	b) Protective earth terminals suitable for connection to the protective earth conductor		N
	e) Potential equalization conductor:		N
	- readily accessible		N
	- accidental disconnection prevented in normal use		N
	- conductor detachable without the use of a tool		N
	- power supply cord does not incorporate a potential equalization conductor		N
	- connection means marked with Symbol 9, Table DI		N
	f) For equipment without power supply cord, impedance between protective earth terminal and accessible metal part ≤ 0,1 Ω	(see appended table)	N
	For equipment with an appliance inlet, impedance between protective earth contact and any accessible metal part ≤ 0,1 Ω	(see appended table)	N
	For equipment with a non-detachable power supply cord, impedance between protective	(see appended table)	N

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Clause	Requirement – Test	Result - Remark	Verdict
	earth pin in mains plug and accessible metal part ≤ 0,2 Ω		
	g) If the impedance of protective earth connections other than in Cl. 18. f) exceeds 0,1 Ω, the allowable value of the enclosure leakage current is not exceeded in single fault condition	(see appended table 19)	N
	k) Functional earth terminal not used to provide protective earthing		N
	l) Class II equipment with isolated internal screens		N
	- insulation of screens and all internal wiring connected to them is double insulation or reinforced insulation		N
	- functional earth terminal clearly marked		N
	- explanation of functional earth terminal provided in the accompanying documents		N
19.	CONTINUOUS LEAKAGE CURRENTS AND PATIENT AUXILIARY CURRENTS		
19.1	b) Leakage currents	(see appended table)	
	Earth leakage current	No earth Leakage	N
	Enclosure leakage current	Refer to the test data sheet	P
	Patient leakage current	No patient leakage test	N
	Patient auxiliary current	No patient auxiliary current	N
20.	DIELECTRIC STRENGTH AT OPERATING TEMPERATURE		
	Overall compliance with Cl. 20.	(see appended table)	P
21.	MECHANICAL STRENGTH		
	a) Sufficient rigidity of enclosure tested by: force of 45 N	The equipment is powered by three 1.5V batteries. No hazardous live parts	N
	b) Sufficient strength of an enclosure tested by: impact hammer		N
	c) Portable equipment carrying handles or grips withstand the requirements of the loading test	(see appended table)	N
21.3	No damage to parts of patient support and/or immobilization system after the loading test	(see appended table 21)	N

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Clause	Requirement – Test	Result - Remark	Verdict
21.5	Hand-held equipment or equipment parts are safe after drop test	(see appended table 21)	N
21.6	Portable and mobile equipment is able to withstand rough handling	(see appended table 21)	N
22.	MOVING PARTS		
22.2	a) Moving parts of a transportable equipment are provided with guards which form an integral part of the equipment	No moving parts	N
	b) Moving parts of a stationary equipment are provided with similar guards as above, unless it is evident that equivalent protection is separately provided during installation	No moving parts	N
22.3	Cords (ropes), chains and bands are provided with guides to prevent them from running off or from jumping out of their guiding devices	No moving parts	N
	Guides or other safeguards are removable only with a tool	No moving parts	N
22.4	Dangerous movements of equipment parts, which may cause physical injury to the patient, are possible only by the continuous activation of the control by the operator	No moving parts	N
22.6	Parts of equipment subject to mechanical wear are accessible for inspection	No moving parts	N
22.7	Means provided for emergency switching of an electrically produced mechanical movement which could cause a safety hazard	No moving parts	N
	The means for emergency switching is readily identifiable and accessible and does not introduce a further safety hazard	No moving parts	N
	Devices for emergency stopping able to break the full load current of the relevant circuit, taken into account possible stalled motor currents	No moving parts	N
	Means for stopping of movements operate as a result of one single action	No moving parts	N
23.	SURFACES, CORNERS AND EDGES		
	Rough surfaces, sharp corners and edges which may cause injury or damage avoided or covered	No sharp edges or corners	P

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Clause	Requirement – Test	Result - Remark	Verdict
24.	STABILITY IN NORMAL USE (see appended table)		
24.1	Equipment does not overbalance during normal use when tilted trough an angle of 10°	The equipment is handheld	N
24.3	Equipment overbalances when tilted through an angle of 10°:		N
	- does not overbalance when tilted through an angle of 5° in any position excluding transport		N
	- carry a warning notice stating that transport should only be undertaken in a certain position		N
	- in the position specified for transport does not overbalance when tilted to an angle of 10°		N
24.6	a) Equipment or its parts with a mass of more than 20 kg is provided with:		N
	- suitable handling devices (grips etc.), or	Not more than 20Kg	N
	- instructions for lifting and handling during assembly		N
	b) On portable equipment with a mass of more than 20 kg carrying handle(s) is (are) so situated that equipment may be carried by 2 or more persons		N
25.	EXPELLED PARTS		
25.1	Protective means are provided where expelled parts of the equipment could be a hazard	No expelled parts	N
25.2	Display vacuum tubes with a face dimension exceeding 16 cm are provided with adequate protection against implosion		N
28.	SUSPENDED MASSES		
28.3	Suspension system with safety device:		N
	Safety device provided where the integrity of a suspension depends on parts which may have hidden defects, or on parts having safety factors not complying with 28.4	No suspended masses	N
	Safety device has safety factors complying with 28.4.2		N
	Clear indication to the operator that the safety device has been activated after failure of suspension means		N

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Clause	Requirement – Test	Result - Remark	Verdict
28.4	Suspension systems of metal without safety devices:		
	1) the total load does not exceed the safe working load	No such metals in the unit	N
	2) safety factors not less than 4 where it is unlikely that supporting characteristics will be impaired		N
	3) safety factors not less than 8 where impairment is expected		N
	4) safety factors multiplied by 1,5 for metal having an elongation at break of less than 5%		N
	5) sheaves, sprockets, bandwheels and guides so constructed that the safety factors shall be maintained till replacement		N
29.	X-RADIATION		N
29.2	Equipment not intended to produce X-radiation produces an exposure ≤ 130 nC/kg (0,5 mR)	(see appended table)	N
36.	ELECTROMAGNETIC COMPATIBILITY		P
	Equipment complies wit IEC 601-1-2	EMC reports provided	P
37.	COMMON REQUIREMENTS FOR CATEGORY AP AND CATEGORY APG EQUIPMENT		N
	Requirements for category AP and APG equipment (Cl. 37. - 41.)	Not an APG type of equipment	N
42.	EXCESSIVE TEMPERATURES		
42.1	Equipment does not attain temperatures exceeding the values given in Table Xa over the range of ambient temperatures specified in 10.2.1	(see appended table)	P
42.2	Equipment does not attain temperatures exceeding the values given in Table Xb at 25 °C ambient	Refer to the test data sheet	P
42.3	Applied parts not intended to supply heat have surface temperatures not exceeding 41 °C	Refer to the test temp.	N
42.5	Guards to prevent contact with hot surfaces removable only with a tool	No such hot surfaces	N

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Clause	Requirement – Test	Result - Remark	Verdict
43.	FIRE PREVENTION		
	Strength and rigidity necessary to avoid a fire hazard	The enclosure has a flammability of UL94HB.	P
44.	OVERFLOW, SPILLAGE, LEAKAGE, HUMIDITY, INGRESS OF LIQUIDS, CLEANING, STERILIZATION, DISINFECTION (see appended table)		
44.2	If equipment contains a liquid reservoir:		
	- the equipment is electrically safe after 15% overfill steadily over a period of 1 min	No liquids used with the equipment	N
	- transportable equipment is electrically safe after additionally having been tilted through an angle of 15° in the least favourable direction(s) (if necessary with refilling)	Handheld equipment	N
44.3	Electrical properties of the equipment do not change in connection of spillage test (200 ml of water)	No liquids used with the equipment	N
44.4	Liquid which might escape in a single fault condition does not wet parts which may cause a safety hazard	No liquids used with the equipment	N
44.5	Equipment sufficiently protected against the effects of humidity	No liquids used with the equipment	N
44.6	Enclosures designed to give a protection against harmful ingress of water classified according to IEC Publication 529	No liquids used with the equipment	N
44.7	Equipment capable of withstanding cleaning, sterilization or disinfection without deterioration of safety provisions	Equipment is capable of cleaning and sterilization.	P
45.	PRESSURE VESSELS AND PARTS SUBJECT TO PRESSURE		
45.2	Pressure vessel with pressure volume greater than 200 kPa x l and pressure greater than 50 kPa withstand the hydraulic test pressure	(see appended table)	N
45.3	The maximum pressure does not exceed the maximum permissible working pressure for individual parts	No pressure parts or vessels	N
45.7	Unless excessive pressure cannot occur, pressure-relief device provided	No pressure parts or vessels	N

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Clause	Requirement – Test	Result - Remark	Verdict
	a) Pressure-relief device connected as close as possible to the pressure vessel	No pressure parts or vessels	N
	b) Readily accessible for inspection	No pressure parts or vessels	N
	c) Not capable of being adjusted or rendered inoperative without a tool	No pressure parts or vessels	N
	d) Discharge opening so located that the released material is not directed towards any person	No pressure parts or vessels	N
	e) Discharge opening so located that operation will not deposit material which may cause a safety hazard	No pressure parts or vessels	N
	f) Adequate discharge capacity to ensure that pressure does not exceed the maximum permissible working pressure	No pressure parts or vessels	N
	g) No shut-off valve between the pressure-relief device and the parts intended to be protected	No pressure parts or vessels	N
	h) Minimum number of cycles of operation is 100 000	(see appended table 45)	N
48.	BIOCOMPATIBILITY		
	Parts of equipment and accessories intended to come into contact with biological tissues, cells or body fluids are evaluated in accordance with ISO 10993-1	No such parts	N
49.	INTERRUPTION OF THE POWER SUPPLY		
49.1	Thermal cut-outs and over-current releases with automatic resetting not used if they may give a safety hazard	Internally powered unit	N
49.2	Interruption and restoration of the power supply shall not result in a safety hazard other than interruption of its intended function	Internally powered unit	N
49.3	Means are provided for removal of mechanical constraints on a patient in case of a supply mains failure	Internally powered unit	N
51.	PROTECTION AGAINST HAZARDOUS OUTPUT		
51.4	Equipment providing both low-intensity and high-intensity outputs provided with means minimizing the possibility of a high-intensity	No hazardous outputs	N

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Clause	Requirement – Test	Result - Remark	Verdict
	output being selected accidentally		

52.	ABNORMAL OPERATION AND FAULT CONDITIONS (see appended table)		
52.1	Equipment is so designed and manufactured that even in single fault condition no safety hazard as described under 52.4 exists (see 3.1 and Cl. 13.)	The equipment meet the requirement of section 3 of the standard	P
	The safety of equipment incorporating programmable electronic systems is checked by applying IEC 601-1-4	No such parts	N
52.5.2	Failure of thermostat presents no safety hazard	No thermostat	N
52.5.3	Short-circuiting of either constituent part of double insulation presents no safety hazard	(see appended table 19)	N
52.5.5	Impairment of cooling: temperatures not exceeding 1,7 times the values of Cl. 42. minus 17,5 °C	No cooling system	N
52.5.6	Locking of moving parts presents no safety hazard	No locking or moving parts	N
52.5.7	Interruption and short-circuiting of motor capacitors presents no safety hazard	No caps	N
52.5.8	Duration of motors locked rotor test in compliance with 52.5.8	No motors	N
52.5.9	Failure of one component at a time presents no safety hazard	No hazardous component	N
52.5.10	Overload of heating elements presents no safety hazard	No heating elements	N
	f) Motors intended to be remotely controlled, automatically controlled, or liable to be operated continuously provided with running overload protection	No motors	N
	h) Equipment with three-phase motors can safely operate with one phase disconnected	No motors	N

56.	COMPONENTS AND GENERAL ASSEMBLY		
	List of critical components	(see appended table)	
56.1	b) Ratings of components not in conflict with the conditions of use in equipment	Rating of components does not conflict with the use of the equipment	P
	Ratings of mains components are identified	No mains components	N

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Clause	Requirement – Test	Result - Remark	Verdict
	d) Components, movements of which could result in a safety hazard mounted securely	No moving components	N
	f) Conductors and connectors are secured and/or insulated to prevent accidental detachment resulting in a safety hazard	All connectors secured appropriately	P
56.3	a) Connectors provide separation required by Cl. 17. g)	Seperation is appropriate	P
	Plugs for connection of patient circuit leads can not be connected to other outlets on the same equipment	Plugs for connection of the patient can not be connected to other outlets	P
	Medical gas connections not interchangeable	No medical gas connections	N
	b) Accessible metal parts cannot become live when detachable interconnection cord between different parts of equipment is loosened or broken	No accessible metal parts	N
	c) Leads with conductive connection to a patient are constructed such that no conductive connection remote from the patient can contact earth or hazardous voltages	No hazardous voltages can be contacted	P
56.4	Connections of capacitors		
	Not connected between live parts and non-protectively earthed accessible parts	No such caps.	N
	If connected between mains part and protectively earthed metal parts, comply with IEC 384-14	No such caps.	N
	Enclosure of capacitors connected to mains part and providing only basic insulation is not secured to non-protectively earthed metal parts	No such caps.	N
	Capacitors or other spark-suppression devices are not connected between the contacts of thermal cut-outs	No such caps.	N
56.5	Protective devices which cause disconnection from the supply mains by producing a short-circuit not provided in equipment	Not mains supplied unit	N
56.6	Temperature and overload control devices		
	a) Thermal cut-outs which have to be reset by a soldering not fitted in equipment	No thermal cut-out in the unit	N
	Thermal safety devices provided where necessary to prevent operating temperatures exceeding the limits	No thermal safety devices	N

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Clause	Requirement – Test	Result - Remark	Verdict
	Independent non-self-resetting thermal cut-out provided where a failure of a thermostat could constitute a safety hazard	No thermal cut-outs	N
	Audible warning provided where the loss of function caused by operation of a thermal cut-out presents a safety hazard	No thermal cut-outs	N
	Self-resetting thermal cut-outs and self-resetting over-current releases operated 200 times	No thermal cut-outs	N
	Non-self-resetting over-current releases operated 10 times	No thermal cut-outs	N
	b) Thermostats with varying temperature settings clearly indicated	No thermal cut-outs	N
	Operating temperature of cut-outs is clearly indicated	No thermal cut-outs	N
56.7	Batteries		
	a) Battery compartments are:		
	- adequately ventilated	The unit uses 3 AA alkline	N
	- accidentally short-circuiting is prevented	Refer to the test data	P
	b) Incorrect polarity of connection prevented	Refer to the test data	P
56.8	Indicators, unless indication is provided by other means (from the normal operation position), indicator lights are used (colour see 6.7)		N
	- to indicate that equipment is energized	No indicator lights	N
	- to indicate the operation of non-luminous heaters if a safety hazard could result	No heaters provided	N
	- to indicate when output exists if a safety hazard could result	No hazardous output	N
	- charging mode indicator is provided	No charging mode	N
56.10	Actuating parts of controls	(see appended table)	N
	b) Actuating parts are adequately secured to prevent them from working loose during normal use	Actuating parts secured	P
	Controls are secured to prevent the movement relative to scale marking (safety related only)	All the push buttons secured appropriately	P
	Detachable indicating devices are prevented from incorrect connection without the use of a tool	No detachable connections	N
	c) Stops are provided on rotating controls:		

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Clause	Requirement – Test	Result - Remark	Verdict
	- to prevent an unexpected change from maximum to minimum or vice versa where this could produce a safety hazard	No moving parts	N
	- to prevent damage to wiring	No moving parts	N
56.11	Cord-connected hand-held and foot-operated control devices		
	a) Contain voltages not exceeding 25 V a.c. or 60 V d.c. and isolated from the mains part by Cl. 17. g)	Not cord connected. Handheld control device.	N
	b) Hand-held devices comply with the requirement and test of 21.5	Not cord connected. Handheld control device.	N
	Foot-operated control devices designed to support the weight of an adult human being	Not cord connected. Handheld control device.	N
	c) Devices shall not change their setting when inadvertently placed	Not cord connected. Handheld control device.	N
	d) Foot-operated control devices are at least IPX1	Not cord connected. Handheld control device.	N
	For surgical use, electrical switching parts are IPX8	Not cord connected. Handheld control device.	N
	e) Adequate strain relief at the cord entry provided	Not cord connected. Handheld control device.	N

57.	MAINS PARTS, COMPONENTS AND LAYOUT		
57.1	Isolation from supply mains		
	a) Equipment provides means to isolate its circuits electrically from the supply mains on all poles simultaneously	Internally powered equipment	N
	Means for isolation incorporated in equipment or, if external, specified in the accompanying documents	Internally powered equipment	N
	d) Switches used to comply with 57.1 a) comply with the creepage distances and air clearances as specified in IEC 328	Internally powered equipment	N
	f) Mains switches not incorporated in a power supply cord	Internally powered equipment	N
	h) Appliance couplers and flexible cords with mains plugs provide compliance with 57.1 a)	Internally powered equipment	N
	m) Fuses and semiconductor devices are not used as isolating devices	Internally powered equipment	N

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Clause	Requirement – Test	Result - Remark	Verdict
57.2	Mains connectors and appliance inlets		
	e) Auxiliary mains socket-outlets on non-permanently installed equipment of a type that cannot accept a mains plug	Internally powered equipment	N
	g) Unless functional earth needs to be provided, Class I appliance inlet is not used in Class II equipment	Internally powered equipment	N
57.3	Power supply cords		
	a) Not more than one connection to a particular supply mains	Internally powered equipment	N
	If alternative supply allowed, no safety hazards when more than one connection is made simultaneously	Internally powered equipment	N
	The mains plug has only one power supply cord	Internally powered equipment	N
	Non-permanently connected equipment provided with power supply cord or appliance inlet	Internally powered equipment	N
	b) Power supply cords sufficiently robust to comply with the requirements of IEC 227, designation 53 and IEC 245, designation 53	Internally powered equipment	N
	Polyvinyl chloride insulated power supply cords not used for equipment having external metal parts with a temperature exceeding 75 °C	Internally powered equipment	N
	c) Nominal cross-sectional area of conductors of power supply cords not less than in Table XV	Internally powered equipment	N
	d) Stranded conductors not soldered if fixed by any clamping means	Internally powered equipment	N
57.4	Connection of power supply cords		N
	a) Cord anchorages:		N
	Equipment provided with power supply cords has cord anchorages such that the conductors are relieved from strain, including twisting	(see appended table)	N
	Tying the cord into a knot or tying the ends with string not used	Internally powered equipment	N
	Cord anchorages made of insulating material or metal insulated from unearthed accessible metal parts by supplementary insulation	Internally powered equipment	N
	Cord anchorages made of metal provided with an insulating lining	Internally powered equipment	N

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Clause	Requirement – Test	Result - Remark	Verdict
	Clamping screws do not bear directly on the cord insulation	Internally powered equipment	N
	Screws associated with cable replacement are not used to secure other components	Internally powered equipment	N
	Conductors of the power supply cord so arranged that the protective earth conductor is not subject to strain as long as the phase conductors are in contact with their terminals	Internally powered equipment	N
	b) Power supply cord protected against excessive bending	(see appended table 57.4 b))	N
	c) Adequate space inside equipment to allow the supply cable conductors to be introduced and connected	Internally powered equipment	N
57.5	Mains terminal devices and wiring of mains part		N
	a) Mains connected equipment other than those with a detachable supply cord is provided with mains terminals, where connections are made with screws, nuts or equally effective methods	Internally powered equipment	N
	If a conductor breaks away, barriers are provided such that creepage distances and air clearances cannot be reduced	Internally powered equipment	N
	Screws and nuts which clamp external conductors shall not serve to fix any other component	Internally powered equipment	N
	b) Terminals closely grouped with any protective earth terminal	Internally powered equipment	N
	Mains terminal devices accessible only with use of a tool	Internally powered equipment	N
	Mains terminal devices located or shielded so that, should a wire of a stranded conductor escape when the conductors are fitted, there is no risk of accidental contact	Internally powered equipment	N
	c) Internal wiring not subjected to stress when the means for clamping the conductors are tightened or loosened	Internally powered equipment	N
	d) Cord terminals shall not require special preparation of the conductor	Internally powered equipment	N
57.6	Mains fuses and over-current releases		
	Fuses or over-current releases provided accordingly for Class I and Class II	No fuses in the unit	N

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Clause	Requirement – Test	Result - Remark	Verdict
	Current rating of mains fuses and over-current releases such that they reliably carry the normal operating current	No fuses in the unit	N
	Protective earth conductor not fused	No fuses in the unit	N
	Neutral conductor not fused for permanently installed equipment	No fuses in the unit	N
57.8	Wiring of mains part		
	a) Individual conductors in the mains part with insulation not at least electrically equivalent to that of the individual conductors of flexible supply cords complying with IEC 227 or IEC 245, treated as bare conductor .....:	Internally powered equipment.	N
	b) Cross-sectional area of conductors up to protective device not less than the minimum required for the power supply	Internally powered equipment.	N
	Cross-sectional area of other wiring and the sizes of tracks on printed wiring circuits are sufficient to prevent any fire hazard	Internally powered equipment.	N
57.9	Mains supply transformers		N
57.9.1	Overheating		N
	External to the transformer protective devices connected in such a way that failure of any component cannot render the protective devices inoperative	No mains transformers.	N
	a) Short-circuit of secondary windings not caused excessive temperature	No mains transformers.	N
	b) Overload of secondary windings not caused excessive temperature	No mains transformers.	N
57.9.2	The dielectric strength of the electrical insulation of a mains supply transformer such that it passes tests	No mains transformers.	N
57.9.4	Construction		N
	a) Separation of primary and secondary windings:		N
	- separate bobbins or formers	No mains transformers.	N
	- one bobbin with insulating partition	No mains transformers.	N
	- one bobbin with concentric windings and having copper screen with a thickness of not less than 0,13 mm	No mains transformers.	N
	- concentrically wound on one bobbin with	No mains transformers.	N

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Clause	Requirement – Test	Result - Remark	Verdict
	windings separated by double insulation		
	c) Means provided to prevent displacement of end turns	No mains transformers.	N
	d) Insulated overlap of not less than 3 mm if a protective earth screen has only one turn	No mains transformers.	N
	e) Insulation between the primary and secondary winding in transformers with double insulation:		N
	- 1 insulation layer having a thickness of at least 1 mm	No mains transformers.	N
	- at least 2 insulation layers with a total thickness of at least 0,3 mm	No mains transformers.	N
	- 3 layers provided that each combination of 2 layers can withstand the dielectric strength test for reinforced insulation	No mains transformers.	N
	g) Exit of the wires of toroidal transformers provided with double sleeving complying with requirements for double insulation and having a total thickness at least 0,3 mm extending at least 20 mm outside the winding	No mains transformers.	N
57.10	Creepage distances and air clearances		
	a) Values: compliance with at least the values of Table XVI	(see table for insulation diagram)	P
	Creepage distances for slot insulation of motors are at least 50% of the specified values	No motors	N
	b) Minimum creepage distances and air clearances in the mains part between parts of opposite polarity not required if short-circuiting does not produce a safety hazard	(see appended table 52)	N
	c) Creepage distances or clearances of at least 4 mm are maintained between defibrillation-proof applied parts and other parts	No defibrillation proof applied parts.	N

IEC 601-1			
Clause	Requirement – Test	Result - Remark	Verdict

58.	PROTECTIVE EARTHING - TERMINALS AND CONNECTIONS		
58.1	Clamping means of the protective earth terminal	No protective earth terminal. Internally powered.	N
	Not be able to loosen without the aid of a tool	No protective earth terminal. Internally powered.	N
	Screws for internal earth connections are covered or protected against loosening from outside	No protective earth terminal. Internally powered.	N
58.7	Earth pin of the appliance inlet regarded as the protective earth terminal	No protective earth terminal. Internally powered.	N
58.8	The protective earth terminal is not used for the mechanical connection or the fixing of any component not related to earthing	No protective earth terminal. Internally powered.	N
58.9	Where the protective earth connections are made via a plug or socket device the protective earth connection is made before and interrupted after the supply connections during connection and interrupting	No protective earth terminal. Internally powered.	N

59.	CONSTRUCTION AND LAYOUT		
59.1	Internal wiring		
	a) Cables and wiring protected against contact with a moving part	No moving parts or cables	N
	Wiring having basic insulation only protected by additional fixed sleeving	Double insulation	N
	Components are not likely to be damaged in the normal assembly or replacement of covers	No assembly required	N
	b) Movable leads are not bent around a radius of less than five times the outer diameter of the lead	No movable leads	N
	c) Insulating sleeving adequately secured	No sleeving	N
	If the sheath of a flexible cable or cord is used as supplementary insulation it complies with requirements of IEC 227 and IEC 245 and dielectric strength test	(see appended table 20)	
	Conductors subjected to temperatures exceeding 70 °C, have an insulation of heat-resistant material	The unit does not obtain such a high temperature	N

IEC 601-1			
Clause	Requirement – Test	Result - Remark	Verdict
	d) Aluminium wires of less than 16 mm² cross-section not used	No aluminium wires have been used	N
	f) Connecting cords between equipment parts considered as belonging to the equipment	Connecting cabling do belong to the equipment.	P
59.2	Insulation		
	b) Mechanical strength and resistance to heat and fires retained by all types of insulation	Wires insulation are appropriate	P
	c) Insulation not likely to be impaired by deposition of dirt or dust resulting from wear of parts	Insulation will not be impaired by dirt or decomposition	P
	Parts of rubber resistant to ageing	No rubber used parts	N
59.3	Excessive current and voltage protection		
	Internal electrical power source provided with device for protection against fire hazard	Suitably sized traces provided.	N
	Fuse elements replaceable without opening the enclosure fully enclosed in a fuseholder	No fuses used.	N
	Protective devices between an isolated applied part and the body of the equipment do not operate below 500 V r.m.s.	Not an F type applied part	N
59.4	Oil containers		
	Oil containers adequately sealed	No oil containers in the unit	N
	Container design shall allow for the expansion of the oil	No oil containers in the unit	N
	Oil containers in mobile equipment sealed to prevent the loss of oil during transport	No oil containers in the unit	N
	Partially sealed oil-filled equipment or equipment parts provided with means for checking the oil level	No oil containers in the unit	N

	ANNEX I, NATIONAL DIFFERENCES		
	AUSTRALIA: see CB Bulletin 89A I, December 1996		
	CANADA: see CB Bulletin 89A I, December 1996		
	UNITED STATES: see CB Bulletin 89A I, December 1996		
2.4.1	UNITED STATES: see CB Bulletin 89A I, December 1996		

IEC 601-1			
Clause	Requirement – Test	Result - Remark	Verdict
2.10.100	UNITED STATES: see CB Bulletin 89A I, December 1996		
2.10.101	UNITED STATES: see CB Bulletin 89A I, December 1996		
10.2.2	UNITED STATES: see CB Bulletin 89A I, December 1996		
6.21	UNITED STATES: see CB Bulletin 89A I, December 1996		
14.	UNITED STATES: see CB Bulletin 89A I, December 1996		
18.	UNITED STATES: see CB Bulletin 89A I, December 1996		
57.	UNITED STATES: see CB Bulletin 89A I, December 1996		
57.2	UNITED STATES: see CB Bulletin 89A I, December 1996		
57.3	UNITED STATES: see CB Bulletin 89A I, December 1996		
59.1	UNITED STATES: see CB Bulletin 89A I, December 1996		
	UNITED STATES: see CB Bulletin 89A I, December 1996		
1.1	UNITED STATES: see CB Bulletin 89A I, December 1996		
2.12.100	UNITED STATES: see CB Bulletin 89A I, December 1996		
2.12.101	UNITED STATES: see CB Bulletin 89A I, December 1996		
19.	UNITED STATES: see CB Bulletin 89A I, December 1996		
3.	UNITED STATES: see CB Bulletin 89A I, December 1996		
3.100	UNITED STATES: see CB Bulletin 89A I, December 1996		
3.100.1	UNITED STATES: see CB Bulletin 89A I, December 1996		
3.101	UNITED STATES: see CB Bulletin 89A I, December 1996		
3.101.1	UNITED STATES: see CB Bulletin 89A I,		

IEC 601-1			
Clause	Requirement – Test	Result - Remark	Verdict
	December 1996		
3.101.2	UNITED STATES: see CB Bulletin 89A I, December 1996		
3.102	UNITED STATES: see CB Bulletin 89A I, December 1996		
57.5	UNITED STATES: see CB Bulletin 89A I, December 1996		
6.	UNITED STATES: see CB Bulletin 89A I, December 1996		
22.	UNITED STATES: see CB Bulletin 89A I, December 1996		
28.	UNITED STATES: see CB Bulletin 89A I, December 1996		
42.	UNITED STATES: see CB Bulletin 89A I, December 1996		
55.	UNITED STATES: see CB Bulletin 89A I, December 1996		
56.3	UNITED STATES: see CB Bulletin 89A I, December 1996		
58.2	UNITED STATES: see CB Bulletin 89A I, December 1996		
400	UNITED STATES: see CB Bulletin 89A I, December 1996		
600	UNITED STATES: see CB Bulletin 89A I, December 1996		

6.1	TABLE: marking durability	P
marking tested		Remarks
Refer to test data sheet		

IEC 601-1			
Clause	Requirement – Test	Result - Remark	Verdict

7.	TABLE: power input					N
operating condition	voltage	frequency	current	power	Remarks	
Internally Powered unit						

15. b)	TABLE: residual voltage in attachment plugs										N
voltage measured between:	measurements (V)										remarks
	1	2	3	4	5	6	7	8	9	10	
Not cord connected											

15. c)	TABLE: residual voltage or energy in capacitors				N
capacitor and its location	residual voltage (V)	time after disconnection (s)	capacitance value (µF)	residual energy (mJ)	remarks

IEC 601-1			
Clause	Requirement – Test	Result - Remark	Verdict

17. h1)	TABLE: defibrillation-proof applied parts				N
test condition: fig. 50 or 51	accessible part of measurement:	applied part with test voltage	test voltage polarity	measured voltage between Y1 and Y2 (mV)	remarks

17. h2)	TABLE: defibrillation-proof recovery time				N
applied part with test voltage		test voltage polarity	recovery time from accompanying document(s)	measured recovery time (s)	Remarks

18.	TABLE: protective earthing			N
test location	test current (A)	measured voltage (V)	resistance (Ω)	remarks

IEC 601-1			
Clause	Requirement – Test	Result - Remark	Verdict

19.	TABLE: leakage current				P
type of leakage current and test condition (including single faults)	supply voltage	supply frequency	measured max. value	remarks	
Refer to test data sheet					

(Record at least maximum measured value for each test required by Cl._19. and the specific conditions of the test circuit and equipment).

Abbreviations used:
ER - Earth leakage current
EN - Enclosure leakage current
P - Patient leakage current
PM - Patient leakage current with mains on the the applied parts
PA - Patient auxiliary current
Fig. 15 - refers to Fig. 15 in IEC 601-1
MD - Measuring device
A - After humidity conditioning
B - Before humidity condtioning
1 - Switch closed or set to normal polarity
0 - Switch open or set to reversed polarity
NC - Normal condition
SFC - Single fault condition

IEC 601-1			
Clause	Requirement – Test	Result - Remark	Verdict

20.	TABLE: dielectric strength			P
insulation under test (area from insulation diagram)	insulation type: (OP-operational/BI-basic/ SI-supplementary/DI-double/ RI-reinforced	reference voltage (V)	test voltage (V)	remarks
Refer to test data sheet				

21.	TABLE: mechanical strength	N
part under test	test (impact, drop, force, handle, rough handling, mobile)	remarks

24.	TABLE: stability	N
part under test	test condition	Remarks

IEC 601-1			
Clause	Requirement – Test	Result - Remark	Verdict

29.	TABLE: X-radiation			N
part under test	test condition	measured radiation (mR)	Remarks	
No X-radiation				

42.	TABLE: normal temperature		P
	supply voltage ..... :	Refer to test data sheet	—
	ambient temperature °C ..... :		—
	test condition ..... :		—

measuring location	measured temperature (°C)	remarks
Refer to test data sheet		

COR - indicates measurements taken using change-of-resitance method

IEC 601-1			
Clause	Requirement – Test	Result - Remark	Verdict

44.	TABLE: overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection	N

test type and condition	part under test	remarks

45.	TABLE: hydrostatic pressure and pressure-relief device cycling test	N

test type and condition	part under test	test pressure	remarks

52.	TABLE: abnormal operation	N

test type, condition and clause reference	observed results	Remarks

56.1	TABLE: lists of critical component parts				

object/part No.	manufac-turer/trademark	type/model	technical data	standard	mark(s) of conformity[1]
Enclosure material	Boedeker plastics Inc.	ABS Acrylonitrile Butadiene Styrene	94HB, max. operating temp. of 140/60 °F/°C		UL

IEC 601-1			
Clause	Requirement – Test	Result - Remark	Verdict

PWB	Teledyne Analytical instrument	C73880	94V-0		UL
Oxygen Sensor	Sensor Technologies	C43690-R17med	7-13mv output		
Insulating plastic above the battery Contacts	BPI		94HB		UL
[1]) an asterisk indicates a mark which assures the agreed level of surveillance					

56.10	TABLE: actuating parts and controls	N
part under test	torque applied	Remarks

56.11 b)	TABLE: foot-operated control devices loading	N
part under test	observed results	Remarks

57.4	TABLE: cord anchorages				N
cord under test	mass of equipment	pull	torque	remarks	Verdict

IEC 601-1			
Clause	Requirement – Test	Result - Remark	Verdict

57.4 b)	TABLE: cord bending			N
cord under test	test mass	measured curvature	remarks	

57.9.1 a)	TABLE: transformers short-circuit					N
winding under test	protection	measured temperatures (°C)			test duration	remarks
		primary	secondary	ambient		

57.9.1 b)	TABLE: overload						N
winding under test	protection	measured temperatures (°C)			test duration	test current or thermal cut-out temp	remarks
		primary	secondary	ambient			

IEC 601-1			
Clause	Requirement – Test	Result - Remark	Verdict

57.9.2	TABLE: transformer dielectric strength				N
transformer under test	test voltage applied to	test voltage	test frequency	remarks	

	TABLE: additional tests		N
Clause	test type and condition	remarks and observed results	verdict

DATA SHEETS

Company:	Teledyne Analytical	Project Engineer:	Sayeed Abassi
Project #:	3026020-108	Tested By:	Sayeed Abassi
Model:	AX/MX 300	Date:	6/30/02
Product Name:	OXYGEN MONITOR SYSTEM	Sample Condition:	prototype
Standard:	IEC60601-1		

TEST PERFORMED	Section	PASS	FAIL
Leakage Current Before Humidity	19	✓	
Dielectric Withstand Test Before Humidity	20	✓	
Temperatures- Fire Prevention	42-43	✓	

Tested By: **Sayeed Abassi** Initials: SA

Reviewed By: Nathin Shivers Initials: NS

DATA SHEETS

Company:	Teledyne Analytical	Project Engineer:	Sayeed Abassi
Project #:	3026020-108	Tested By:	Sayeed Abassi
Model:	AX/MX 300	Date:	6/30/02
Product Name:	OXYGEN MONITOR SYSTEM	Sample Condition:	prototype
Standard:	IEC60601-1		

TEST EQUIPMENT LIST

Item	Equipment Type	Make	Model No.	Serial No.	Cal. Date
1	Hi Pot Tester	Biddle	230425	ETL61	07/23/01
2	Multimeter	Fluke	87	ETL34	08/31/01
3	Tegam Therometer	Tegam	819	ETL156	07-10-01

DATA SHEETS

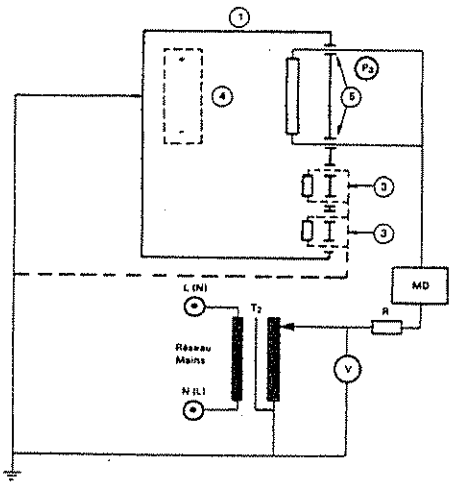
Company:	Teledyne Analytical	Project Engineer:	Sayeed Abassi
Project #:	3026020-108	Tested By:	Sayeed Abassi
Model:	AX/MX 300	Date:	6/30/02
Product Name:	OXYGEN MONITOR SYSTEM	Sample Condition:	prototype
Standard:	IEC60601-1		

PATIENT LEAKAGE CURRENT A.C. OF INTERNALLY POWERED EQUIPMENT WITH AN F-TYPE APPLIED PART (19.4.h, Fig. 24, as shown below):

Applied part measured:

Operating Conditions: Normal

A13	TABLE: Measurement of patient leakage current a.c. (19.4.h)			
State of Unit	Normal Condition Measured µA		Single Fault Condition* Measured µA	
	Before 1)	After 2)	Before 1)	After 2)
ON	18.1uA		N	N
OFF	.01uA		N	N
1) and 2) before and after humidity preconditioning treatment Remarks: * = Describe additional SFC according to 17.a				



TESTED BY:	SA	REVIEWED BY:	MS
Sayeed Abassi		DATE PERFORMED:	6/30/02
		PASS ✓	FAIL

EQUIPMENT USED : 1 (2) 3 4 5 6 7 8 9 10 11 12 13 14 15 or N/A

DATA SHEETS

Company:	Teledyne Analytical	Project Engineer:	Sayeed Abassi
Project #:	3026020-108	Tested By:	Sayeed Abassi
Model:	AX/MX 300	Date:	6/30/02
Product Name:	OXYGEN MONITOR SYSTEM	Sample Condition:	prototype
Standard:	IEC60601-1		

DIELECTRIC WITHSTAND TEST (Section 20):

Method

A dielectric withstand potential was applied between the points indicated below. For this test, all switches were set so that all circuits were energized. In each case, the test potential was gradually achieved starting from zero and held at the indicated value for a period of one minute.

Results:

20	TABLE: Dielectric done at operating temperature.				
Insulation under test	Insulation Type	Reference voltage	Test voltage	Remarks	Verdict
Equipment: all types					
A-a1	D	Live parts to enclosure	500 VAC		Pass

TESTED BY:	Sayeed Abassi	REVIEWED BY:	
		DATE PERFORMED:	6/30/02
		PASS ✓	FAIL

EQUIPMENT USED: (1) 2 3 4 5 6 7 8 9 10 11 12 13 14 15 or N/A

DATA SHEETS

Company:	Teledyne Analytical	Project Engineer:	Sayeed Abassi
Project #:	3026020-108	Tested By:	Sayeed Abassi
Model:	AX/MX 300	Date:	6/30/02
Product Name:	OXYGEN MONITOR SYSTEM	Sample Condition:	prototype
Standard:	IEC60601-1		

NORMAL TEMPERATURE TEST (Section 42):

Method

The sample was operated at the conditions described below to represent a maximum normal load. The temperature test shall be terminated upon thermal stabilization.

TEST #	TEST CONDITION	VOLTAGE (V)	FREQUENCY (Hz)
1	Normal Condition	4.5V DC	N

#	Test A Thermocouple Locations	Measured Temperature C	Complies Yes	Complies No
1	Ambient	25.1		
2	Oxygen Sensor	25.1	X	
3	PWB	26.5	X	

TESTED BY:	Sayeed Abassi	REVIEWED BY:	
		DATE PERFORMED:	6/30/07
		PASS ✓	FAIL

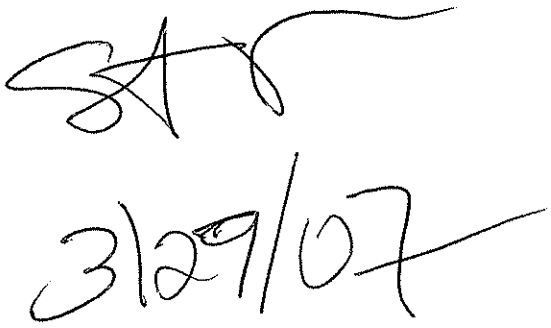
EQUIPMENT USED : 1 2 (3) 4 5 6 7 8 9 10 11 12 13 14 15 or N/A

Teledyne was considering switching vendors of cables used in the MX300 to System Connection and also using a slightly different cable construction from Wing Tat

In order to validate the EMC testing was not affected by the change, we subjected the cables to EMC testing per the attached.

Based on this it is okay to use the cable in production units

Steve Broy



Date 3/29/07 Purchase Order Inquiry **Inquiry** AM61A4 EI

Order Addresses

Order **P057815** Status 40 Revision 2

Vendor name SYSTEM CONNECTION
Address 441 EASY BAY BLVD
PROVO UT 84606
UNITED STATES

Ship to name TELEDYNE ANALYTICAL INSTRUMENTS
Address 16830 CHESTNUT STREET
CITY OF INDUSTRY CA 91748
UNITED STATES

Bill to name TELEDYNE ANALYTICAL INSTRUMENTS
Address P.O. BOX 1580
CITY OF INDUSTRY CA 91749-1580
UNITED STATES

F13 Order summary
F19 Reselect options
F24 End of job

Date 3/29/07 Purchase Order History Inquiry **Inquiry** AM61A4 EI

Order Addresses

Order **P052388** Status 60 Revision

Vendor name WING TAT DEVELOPMENT LTD
Address UNIT D, 23/F, INFOTECH CENTRE
21 HUNG TO ROAD
KWUN TONG, KOWLOON, HONG KONG
HONG KONG

Ship to name TELEDYNE ANALYTICAL INSTRUMENTS
Address 16830 CHESTNUT STREET
CITY OF INDUSTRY CA 91748
UNITED STATES

Bill to name TELEDYNE ANALYTICAL INSTRUMENTS
Address P.O. BOX 1580
CITY OF INDUSTRY CA 91749-1580
UNITED STATES

F13 Order summary
F19 Reselect options
F24 End of job

5969 Robinson Avenue
Riverside, CA 92503
(951) 637-2630
FAX (951) 637-2704

Certificate of Test

Application of Council Directive:	Customer Requirements
Standards by which conformity has been established:	Radiated Susceptibility Evaluation **Radiated RF Susceptibility** The EUT was subjected to a radiated E-field while being monitored for signs of susceptibility. To generate the required level of field strength in the appropriate frequency range a Kalmus 100W Power Amplifier M/N 757LCB-CE and aTEM Cell were used. The required field strength was monitored with an Amplifier Research Isotropic Field Probe model # FP1000 along with an Amplifier Research Isotropic Field Monitor model # FM1000. Maximum allowable deviation per customer is +/- 2%
Customer	Teledyne Instruments 16830 Chestnut Street City of Industry, CA 91748
Equipment Description	Portable Oxygen Analyzer
Type / Model No:	AX300

The equipment as listed above was tested to the stated standards and directives and was found to be **COMPLIANT** with the applicable standards

Test Facility	DNB Engineering Inc 5969 Robinson Avenue Riverside, CA 92503-8620	**NEMKO ELA:115** DNB Job: 78092	
Test Engineer	*Thomas Elders*	Date:	26 Feb 2007
Sr Engineering Manager	*C L Payne III*	Date:	26 Feb 2007

DNB
5969 Robinson Avenue
Riverside, CA 92503
(951) 637-2630
FAX (951) 637-2704

Radiated Susceptibility Evaluation

DNB Job Number:	78092	Date: 26 Feb 2007	**Conformance Standard** EN60601-1-2
Customer:	Teledyne Instruments		
Model Number:	AX300		
Description:	Portable Oxygen Analyzer Cable # 1		**Basic Standard** EN61000-4-3

X or A During testing, normal performance within specification limits.

B During testing, temporary degradation or loss of function or performance which is self-recoverable.

C During testing, temporary degradation or loss of function or performance which requires operator intervention or system reset.

D Degradation or loss of function which is not recoverable due to damage of the equipment, components, software, or loss of data.

Performance Criterion	A
Ambient Temperature (°C)	20
Relative Humidity (%)	39
Atmospheric Pressure (kPa)	98.8

EN61000-4-3 using TEM Cell

Axis ⇓	Level 1	Level 2	Level 3	Special	Notes:
	1 V/M	3 V/M	10 V/M		
X		X			80MHz-2.5Ghz 80%AM 1KHz Sine wave
Y		X			80MHz-2.5Ghz 80%AM 1KHz Sine wave
Z		X			80MHz-2.5Ghz 80%AM 1KHz Sine wave

EN61000-4-3 using Antenna

Antenna faces ⇓	Level 1		Level 2		Level 3		Special		Notes:
	1 V/M		3 V/M		10 V/M				(1) Required only if accessible during normal operation.
	H	V	H	V	H	V	H	V	
Front									
Right									
Rear									
Left									
Top (1)									
Bottom (1)									

Maximum allowable deviation is 2% per customer requirements

EUT performed within the requirements of the applicable Standard(s)	X	YES		NO	Signed	Thomas Elders

5969 Robinson Avenue
Riverside, CA 92503
(951) 637-2630
FAX (951) 637-2704

Radiated Susceptibility Evaluation

DNB Job Number:	78092	Date: 26 Feb 2007	**Conformance Standard** EN60601-1-2
Customer:	Teledyne Instruments		
Model Number:	AX300		
Description:	Portable Oxygen Analyzer Cable # 2		**Basic Standard** EN61000-4-3

X or A During testing, normal performance within specification limits.

B During testing, temporary degradation or loss of function or performance which is self-recoverable.

C During testing, temporary degradation or loss of function or performance which requires operator intervention or system reset.

D Degradation or loss of function which is not recoverable due to damage of the equipment, components, software, or loss of data.

Performance Criterion	A
Ambient Temperature (°C)	20
Relative Humidity (%)	39
Atmospheric Pressure (kPa)	98.8

EN61000-4-3 using TEM Cell

Axis ⇓	Level 1	Level 2	Level 3	Special	Notes:
	1 V/M	3 V/M	10 V/M		
X		X			80MHz-2.5Ghz 80%AM 1KHz Sine wave
Y		X			80MHz-2.5Ghz 80%AM 1KHz Sine wave
Z		X			80MHz-2.5Ghz 80%AM 1KHz Sine wave

EN61000-4-3 using Antenna

Antenna faces ⇓	Level 1		Level 2		Level 3		Special		Notes:
	1 V/M		3 V/M		10 V/M				(1) Required only if accessible during normal operation.
	H	V	H	V	H	V	H	V	
Front									
Right									
Rear									
Left									
Top (1)									
Bottom (1)									

Maximum allowable deviation is 2% per customer requirements
Note: Cable # 2 is more susceptible than cable # 1 at the following frequencies 84 MHz, 93MHz, and 117MHz where levels of 5% can cause a deviation greater than 2% on the output.

EUT performed within the requirements of the applicable Standard(s)	X	YES		NO	Signed	Thomas Elders

DNB ENGINEERING, INC.
"One World, One EMC Solution"
DNB ENGINEERING, INC.
EMI CONSULTANTS-FCC RFI TESTING
3535 W. COMMONWEALTH AVENUE
FULLERTON, CALIFORNIA 92833
(714) 870-7781

Invoice

DATE	INVOICE #
2/23/2007	17235

MAR 0 2 2007

BILL TO

Teledyne Analytical Instruments
16830 Chestnut Street
City Of Industry, CA 91749
ATT: Jeff Burks

P.O. NUMBER	TERMS	PROJECT
PO59857	Net 30	78092

QUANTITY	DESCRIPTION	RATE	AMOUNT
1	CE-Mark-EMC Limited testing on the Oxygen Analyzer.	1,320.00	1,320.00
	CE-Mark-EMC Test data (Pass/Fail Criteria)	100.00	100.00

Any unpaid amount will accrue interest at a rate of 1 1/2% monthly after 30 days.

BALANCES SUBJECT TO 1 1/2% MONTHLY INTEREST & LEGAL/ATTORNEY FEES IF COLLECTION REQUIRED.

TOTAL $1,420.00

TELEDYNE
INSTRUMENTS
Analytical Instruments
A Teledyne Technologies Company
PO BOX 1580 CITY OF INDUSTRY, CA 91749-1580
TELEPHONES (626) 934-1500 FAX: (626) 934-1599
www.teledyne-ai.com

...VISION NO.	PURCHASE ORDER NUMBER
	[illegible]

PURCHASE ORDER NO: P059857
PAGE: 1
PO REV DATE:

PO REV:
ORIGINAL PO DATE: 2/13/07
CONTRACT NUMBER:
CONTACT: 714-870-7781

PURCHASE ORDER

IMPORTANT NOTICE: ITEM NO., PART NO., AND PURCHASE ORDER NO. MUST APPEAR ON ALL CONTAINERS, LABELS, PACK SHEETS, INVOICE AND CORRESPONDENCE.
SEND DUPLICATE INVOICES TO: ATTN: ACCOUNTS PAYABLE

VENDOR ID: DN2077
DNB ENGINEERING INC
3535 W COMMONWEALTH AVE
FULLERTON CA 92833
UNITED STATES

SHIP TO:
TELEDYNE ANALYTICAL INSTRUMENTS
16830 CHESTNUT STREET
CITY OF INDUSTRY CA 91748
UNITED STATES

TRANSPORT VIA:
FOB POINT: DESTINATION
PAYMENT TERMS: NET 45 DAYS

TAX EXEMPT NUMBER: SR AP 97-860650

ITEM/ I#	DESCRIPTION	UM	REV	ORDER QUANTITY	BALANCE DUE	PROMISED DOCK	UNIT PRICE	EXTENDED PRICE	T X
1	EXPENSE2 MISCELLANEOUS ITEM	EA		1.000	1.000	3/05/08	1420.0000	1420.00	

G/L ACCT- 6020280

Limited EMC Evaluation of Model AX300
with two different cable assemblies per
attached DNB quote R0061891

TERMS AND CONDITIONS ARE LOCATED AT WEBSITE WWW.TELPURCHASING.COM

IZED BY:
6000 Jeff Burn[illegible]

THICS LINE 1-877-666-6969

TOTAL EXTENDED AMOUNT
THIS PURCHASE ORDER: 1420.00

TELEDYNE

DNB Engineering, Inc.

Teledyne Analytical Instruments
Electromagnetic Compatibility Report
M/N# MX300 (Inclusive of AX300)
RV28108

Electromagnetic Compatibility

Test Report
for the

O2 Analyzer

Model # MX300 (Inclusive of M/N AX300)

Test Report Number 28108

Prepared For:
Teledyne Analytical Instruments
16830 Chestnut Street
City of Industry, CA 91748

Prepared by:

DNB Engineering, Inc.
5969 Robinson Avenue
Riverside, CA 92503

Prepared By		Date	6 Jun 2002
Test Engineer		Date	6 Jun 2002
Facility Manager		Date	6 Jun 2002

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DOCUMENT HISTORY

Revision	Number of Pages	Revised Pages	Description	Date
-001	All	All	Document Release	6 Jun 2002
-002	All	All	Corrections to original report	7 Jun 2002

CERTIFICATION OF TEST DATA

This report, containing electromagnetic immunity and emissions test data and evaluations, has been prepared by an independent electromagnetic compatibility laboratory, DNB ENGINEERING, in accordance with the applicable specifications and instructions required per the Introduction. NEMKO has evaluated DNB Engineering to perform these tests for Laboratory Accreditation.

NEMKO EMC Laboratory Authorization No.: ELA 115

The data evaluation and equipment configuration presented herein are a true and accurate representation of the measurements of the test sample's electromagnetic immunity and emissions characteristics as of the dates and at the times of the test under the conditions herein specified.

This report shall not be reproduced, except in full, without the written approval of DNB ENGINEERING, INC. Results contained in this report relate only to the item tested.

Test Engineer		Date	6 Jun 2002
Facility Manager		Date	6 Jun 2002

Electromagnetic Compatibility Test Completion Record

for

Teledyne Analytical Instruments

O2 Analyzer

Model # MX300

Test Start Date: 21 Mar 2002 Test Completion Date: 15 Apr 2002

Test Completion Record:
The EUT was tested in accordance with the requirements of EN60601-1-2:2001 (IEC60601-1-2)

for use as [ ] Life Supporting [X] Non-Life Supporting *equipment.*

Shielded location required in accordance with EN60601-1-2:2001 Figure 201 Yes [ ] No [X]

Conducted Emissions (EN55011):	**Pass [ ]**	**Fail [ ]**	**N/A [X]**
Radiated Emissions (EN55011): Class B	**Pass [X]**	**Fail [ ]**	**N/A [ ]**
Harmonics:	**Pass [ ]**	**Fail [ ]**	**N/A [X]**
Flicker:	**Pass [ ]**	**Fail [ ]**	**N/A [X]**
Electrostatic Discharge:	**Pass [X]**	**Fail [ ]**	**N/A [ ]**
Radiated RF Susceptibility:	**Pass [X]**	**Fail [ ]**	**N/A [ ]**
Electrical Fast Transient:	**Pass [X]**	**Fail [ ]**	**N/A [ ]**
Conducted Susceptibility:	**Pass [X]**	**Fail [ ]**	**N/A [ ]**
Surge Immunity:	**Pass [ ]**	**Fail [ ]**	**N/A [X]**
Magnetic Field Immunity:	**Pass [X]**	**Fail [ ]**	**N/A [ ]**
Voltage Dips & Variations:	**Pass [ ]**	**Fail [ ]**	**N/A [X]**

Note: Items marked N/A were deemed unnecessary because the unit is a low power battery operated device and has no long line external cables or AC Mains connections.

Class A ISM is a category of all other ISM which satisfies the Class A ISM limits but not the Class B ISM limits. Such equipment should not be restricted in its sale but the following warning shall be included in the instructions for use.

> Warning:
> This is a Class A product in a domestic environment, this product may cause radio interference in which case, the user may be required to take adequate measures.

1.0 *INTRODUCTION*

Electromagnetic Compatibility (EMC) tests were performed on a representative sample of Teledyne Analytical Instruments, O2 Analyzer, Model # MX300 (Inclusive of M/N AX300). The purpose of this test was to demonstrate compliance of the EUT with the applicable limits listed in Section 4.0 of this report. The test results have been summarized herein, and all data sheets have been incorporated in Appendix D.

2.0 *TEST REQUIREMENTS*

The test requirements were defined by the applicable boxes checked in each Section of 4.0 Herein.

3.0 *TEST EQUIPMENT*

The test equipment utilized in the performance of this test, along with current calibration information, is listed in the Test Equipment Log of Appendix A.

4.0 *SUMMARY OF TEST REQUIREMENTS*

4.1 **Conducted RF Emissions,** Pass [ ] Fail [ ] N/A [X]

EN55011 [ ] Class A [ ] B[ ] Group 1[ ] 2[ ]
EN55013 [ ]
EN55014 [ ]
EN55015 [ ]
EN55022 [ ] Class A [ ] B[ ]

Conducted emissions generated by the EUT's power cables were measured in the frequency range 0.15 to 30 MHz using the spectrum analyzer and an Artificial Mains Network. All conducted data was recorded and is included in Appendix D.

4.2 **Radiated RF Interference** Pass [X] Fail [ ] N/A [ ]

EN55011 [ ] Class A [ ] B[X] Group 1[X] 2[ ]
EN55013 [ ] Freq Range 30-300MHz[ ] 30-1000MHz[ ]
EN55014 [ ]
EN55015 [ ]
EN55022 [ ] Class A [ ] B[ ]

Radiated emissions generated by the EUT were measured in the applicable frequency range on a 3 or 10 meter open area test site. All radiated data was recorded and is included in Appendix D.

4.3 **Harmonics** Pass [ ] Fail [ ] N/A [X]

Basic standard is EN61000-3-2 (IEC 1000-3-2) Class A[ ] B[ ] C[ ] D[ ]

TEST FREQ 50Hz[ ] 60Hz[ ] VOLT 115[ ] 230[ ]

Data sheets for this test were prepared and are included in Appendix D.

4.4 **Flicker** Pass [ ] Fail [ ] N/A [X]

Basic standard is EN61000-3-3 (IEC 1000-3-3)

TEST FREQ 50Hz[ ] 60Hz[ ] VOLT 115[ ] 230[ ]

Data sheets for this test were prepared and are included in Appendix D.

4.0 SUMMARY OF TEST REQUIREMENTS (Continued)

4.5 Electrostatic Discharge Test

Pass [X] Fail [ ] N/A [ ]

Basic standard is EN61000-4-2 (IEC 1000-4-2)

Test Values												
Used	Environment	Port	Contact (kV)					Air (kV)				
			2	4	6	8	S	2	4	8	15	S
X	All Equip	Enclosure	X	X	X			X	X	X		
	Other *	Enclosure										X

"*" these levels were used and the appropriate justification has been added to the report

"S" denotes special value used, refer to data sheet for exact value.

All data from this test was recorded and is included in Appendix D.

4.6 Radiated RF Field

Pass [X] Fail [ ] N/A [ ]

Basic standard is EN61000-4-3 (IEC 1000-4-3)

Test Values									
Used	Environment	Port	Freq Mhz	AM Mod	V/m				
					1	3	10	30	S
	Life Support	Enclosure	80-2500	80 %	X	X	X		
X	Non Life Support	Enclosure	80-2500	80 %	X	X			
	Other*	Enclosure	80-2500	80 %					X

"*" these levels were used and the appropriate justification has been added to the report

"S" denotes special value used, refer to data sheet for exact value.

All data from this test was recorded and is included in Appendix D.

4.0 SUMMARY OF TEST REQUIREMENTS (Continued)

4.7 Electrical Fast Transient

Pass [X] Fail [ ] N/A [ ]

Basic standard is EN61000-4-4 (IEC 1000-4-4)

Test Values							
Used	Environment	Port	Injected kV				
			0.5	1.0	2.0	4.0	S
X	All	AC power	X	X	X		
		DC Power	X	X	X		
		I/O signal/control	X	X			
	Other*	AC power					X
		DC Power					X
		I/O signal/control					X

"*" these levels were used and the appropriate justification has been added to the report

"S" denotes special value used, refer to data sheet for exact value.

All data from this test was recorded and is included in Appendix D.

4.0 SUMMARY OF TEST REQUIREMENTS (Continued)

4.8 Surge Susceptibility

Pass [ ] Fail [ ] N/A [X]

Basic standard is EN61000-4-5 (IEC 1000-4-5)

Test Values							
Used	Environment	Port	Injected kV				
			0.5	1.0	2.0	4.0	S
	All	AC power	X	L-L	L-G		
		DC Power	X	L-L	L-G		
	Other	AC power					X
		DC Power					X

"*" these levels were used and the appropriate justification has been added to the report

Each level is started at lowest level and then raised to the required level.
L-L denotes Line to Line injection (Differential)
L-G denotes Line to Earth (Ground) injection. (Common Mode)
"S" denotes special value used, refer to data sheet for exact value.
All data from this test was recorded and is included in Appendix D.

4.0 SUMMARY OF TEST REQUIREMENTS (Continued)

4.9 Conducted Susceptibility

Pass [X] Fail[ ] N/A[ ]

Basic standard is EN61000-4-6 (IEC 1000-4-6)

Test Values							
Used	Environment	Port	Injected V				
			1	3	10	30	S
	Life Support	AC power	X	X	ISM		
		DC Power	X	X	ISM		
		I/O signal/control	X	X	ISM		
X	Non-Life Support	AC power	X	X			
		DC Power	X	X			
		I/O signal/control	X	X			
	Other	AC power					X
		DC Power					X
		I/O signal/control					X

"ISM" denotes that this level is to be used within the ISM Bands as listed below:

6.765	to	6.795	MHz
13.553	to	13.567	MHz
26.957	to	27.283	MHz
40.660	to	40.700	MHz

"*" these levels were used and the appropriate justification has been added to the report

"S" denotes special value used, refer to data sheet for exact value.

All data from this test was recorded and is included in Appendix D.

4.0 SUMMARY OF TEST REQUIREMENTS (Continued)

4.10 Magnetic Field Immunity

Pass [X] Fail [ ] N/A [ ]

Basic standard is EN61000-4-8 (IEC 1000-4-8)

Test Values							
Used	Environment	Port	A/m				
			1	3	10	30	S
X	All	Enclosure	X	X			
	Other	Enclosure					X

"*" these levels were used and the appropriate justification has been added to the report

"S" denotes special value used, refer to data sheet for exact value.

All data from this test was recorded and is included in Appendix D

4.11 Voltage Dips & Variations

Pass [ ] Fail [ ] N/A [X]

Basic standard is EN61000-4-11 (IEC 1000-4-11)

Test Values			
Used	Environment	Port	Voltage Dip/Short Interruption
	All	AC Power	<5% Ut for 0.5 cycles 40% Ut for 5 cycles 70% Ut for 25 cycles <5% Ut for 5 seconds
	Other	AC Power	As specified

"*" these levels were used and the appropriate justification has been added to the report

All data from this test was recorded and is included in Appendix D.

5.0 *TEST DESCRIPTION*

5.1 **Conducted RF Emissions** (EN55011)

To measure conducted emissions, the EUT was set upon a wooden table in the shielded enclosure. AC power was fed into the EUT from the Artificial Mains Network. With the Artificial Mains Network connected to an HP 8568B Spectrum Analyzer, and using a Computer/Controller and the HP 85864B EMI Measurement Software or equivalent, the spectrum was searched from 0.15 - 30 MHz for emissions emanating from the EUT. A list of the equipment used in this test is included in Appendix A. A photograph of this test set up is included in Appendix B.

5.2 **Radiated RF Emissions** (EN55011)

To measure radiated emissions, the EUT was set up on the 10 meter open air test site. The EUT is placed on a wooden Table which rests on a wooden turntable. The top of the table is one meter above the ground, and the turntable can be rotated 360 degrees. For each frequency measured, the antenna is raised and lowered for both horizontal and vertical polarities to obtain the maximum reading on the analyzer. The turntable is also rotated throughout the 360 degrees in azimuth to determine the position of the maximum emissions. The applicable frequency range is searched using the antennas listed below. The respective antenna and preamplifier were connected to an HP 8568B Spectrum Analyzer or equivalent. Preamplifiers were used for all ranges to achieve the needed dynamic range. A list of the equipment used in this test is included in Appendix A. Photographs of this test set up are included in Appendix B.

5.3 **Harmonics**

The EUT was subjected to Power Supply Harmonics testing. Harmonics measurements were taken using the Combinova 300 Power Measurement System (or equivalent) and tabulated on the data sheet in Appendix C. A list of the equipment used in this test is included in Appendix B.

5.0 *TEST DESCRIPTION* (Continued)

5.4 Flicker

The EUT was subjected to a Flicker in Low - Voltage testing. Flicker measurements were taken and converted to percentages using the Combinova 300 Power Measurement System or equivalent. They were then recorded on the data sheet in Appendix C. The Evaluation Results include: Maximum relative voltage change (dmax), Maximum relative steady state voltage (dc), Duration of d(t)> 3% (t), Short term flicker severity (Pst), and Long term flicker severity (Plt). A list of the equipment used in this test is included in Appendix A.

5.5 Electrostatic Discharge Test

The EUT was placed upon a thin insulator which in turn was placed upon a metal plane. The plane was connected to Primary Earth through two 470 kohm resistors. The Haefely ESD Generator discharges from a 150 pfd Capacitor was applied through a 5K Resistor at the test point with the Haefely Discharge Electrode. The EUT was pulsed on the test points listed on the data sheets in Appendix D 10 times at each level in both polarities. A list of the equipment used in this test is included in Appendix A. A photograph of the test setup is included in Appendix B.

5.6 Radiated RF Susceptibility

The EUT was subjected to a radiated E-field while being monitored for signs of susceptibility. To generate the required level of field strength in the appropriate frequency range a Kalmus 100W Power Amplifier M/N 757LCB-CE and a Chase X-Wing Bilog M/N CBL6140 were used. The required field strength was monitored with two Amplifier Research Isotropic Field Probes model # FP1000 along with an Amplifier Research Isotropic Field Monitor model # FM1000. A list of the equipment used in this test is included in Appendix A.

5.0 *TEST DESCRIPTION* (Continued)

5.7 Electrical Fast Transient/Burst

The Electrical Fast Transient/Burst waveforms injected into the EUT were supplied by the Haefely 093 204.1 Transient Generator. The pulses were capacitively injected onto the I/O, Signal and Control lines using a Coupling Clamp injection probe. The pulses were directly injected into the power lines. A list of the equipment used in this test is included in Appendix A. Photographs of this test set up are included in Appendix B.

5.8 Surge Susceptibility

The Surge Susceptibility Test was performed on the EUT. The Combination Wave Generator (Differential Mode) delivers a 1.2/50 us voltage surge into an open circuit and a 8/20 us current surge into a short circuit (i.e. the generator has an effective output impedance of 2 ohm) are injected into selected pins of the EUT. Each Pin tested was subjected to 5 pulses each in both the positive and negative polarities. In addition, the EUT was subjected to Voltage phase shifts of 0°, 90°, and 270° in both the positive and negative polarities. The Combination Wave Generator (Common Mode) delivers a 1.2/50 us voltage surge into an open circuit and a 8/20 us current surge into a short circuit (i.e. the generator has an effective output impedance of 12 ohm) are injected into selected pins of the EUT. Each Pin tested was subjected to 5 pulses each in both the positive and negative polarities. In addition, the EUT was subjected to Voltage phase shifts of 0°, 90°, and 270° in both the positive and negative polarities. A list of the equipment used in this test is included in Appendix A. Photographs of this test set up appear in Appendix B.

5.9 Conducted RF Susceptibility

Conducted susceptibility signals were coupled into the input power leads and interconnecting cables using a current probe. Calibrated levels from 150 kHz to 80 MHz were injected while using a second probe to monitor the injected current. The radio frequency signal was supplied by a Marconi 2024 Signal Generator and a Kalmus 100 W Power Amplifier M/N 757LCB-CE. A Fischer Custom Communications Bulk Injection Probe M/N F-120-9B was used to inject the test level and a Solar 6741-1 was used to monitor the injected A list of the equipment used in this test is included in Appendix A. Photographs of this test set up appear in Appendix B.

5.0 *TEST DESCRIPTION* (Continued)

5.10 Magnetic Field Immunity Test

The EUT was placed upon a 0.1m insulator which in turn was placed upon a metal plane. The plane was connected to Primary Earth. A 1m loop antenna connected to a current transformer supplied from a 50Hz source was then placed around the EUT in the three axis. The applicable A/m was determined by monitoring the loops magnetic field with a Bell 640 Gaussmeter. A list of the equipment used in this test is included in Appendix A. A photograph of the test setup is included in Appendix B.

5.11 Voltage Dips, Short Interruptions, & Variations

The EUT was placed as close to the power source as possible with the manufacturer's supplied power cord. If no power cord was supplied the EUT was placed as close to the power source as possible. The power source was the controlled via GPIB bus to cause the required voltage dips and variations. The EUT was monitored after each test level. If required the EUT was reset to the applicable configuration. A list of the equipment used in this test is included in Appendix A. A photograph of the test setup is included in Appendix B.

6.0 CONCLUSIONS

The Teledyne Analytical Instruments. O2 Analyzer, Model # MX300 , was tested in accordance with the requirements listed herein and has been found to be COMPLIANT with the requirements of EN60601-1-2:2000. Pass/Fail status for each test is listed in Section 4.0. At the completion of testing the EUT and support equipment were returned to representatives of Teledyne Analytical Instruments.

In addition Model Number AX300 has also been qualified under this test report. M/n AX300 is similar in design and construction to M/n MX300 with the only difference being in software.

APPENDIX A

Test Equipment Log

Item No:	Description	Manufacturer	M/N	S/N	Calibration Due Date	Test Equip Used On
1	Push/Pull Scale	Imada	MF	70403	6/19/02	
2	Power Analyzer	Combinova	300	102	9/25/02	Harm / Flick
3	Digital MultiMeter	Chief Engineer	104	31220125	9/10/02	
4	Digital MultiMeter	Amprobe	AM-1250	330224	11/9/02	
5	LCR Meter	B & K Precision	878	23702237	11/9/02	
6	Digital MultiMeter	Amprobe	AM-1250	330139	8/22/02	
7	Dial Caliper	General MG	MG 6"	958	12/18/02	
8	Micrometer	General MG	1050C	959	12/18/02	
9	Impact Hammer	E.D. & D.	F22-50	9606235-3	11/6/02	
10	Process Meter	Newport	INFCP-210	4381880	4/4/02	
11	Process Meter	Newport	INFCP-210	6150730	4/4/02	
12	Oscilloscope	Tektronix	464	B133241	9/24/02	
13	Line Leakage Tester	Associated Research	510L	A130511	4/5/02	
14	Safety Compl Analyzer	Associated Research	7564SA	A100601	4/5/02	
15	AC/DC Current Probe	Amprobe	CT600	30301828	4/30/02	
16	Data Aquisition Unit	Hewlett Packard	34970A	US37017024	5/4/02	
17	Data Aquisition Unit	Hewlett Packard	34970A	US37016877	5/4/02	
18	Input Multiplexer	Hewlett Packard	34901A	US37017773	5/4/02	
19	Input Multiplexer	Hewlett Packard	34901A	US37017729	5/4/02	
20	Input Multiplexer	Hewlett Packard	34901A	US37019488	5/4/02	
21	Weather Station	Davis	7400	PC70804A01	1/22/02	All Tests
22	Safety Analyzer	Dynatech Nevada	431A	431A-1230	5/1/02	
23	SA - RF Section	Hewlett Packard	85680B	2330A02791	9/8/02	CE / RE / CS
24	SA - Display Section	Hewlett Packard	85662A	2318A05282	9/8/02	CE / RE / CS
25	RF Preselector	Hewlett Packard	85685A	2724A00659	9/8/02	CE / RE / CS
26	QP Adapter	Hewlett Packard	85650A	2811A01240	9/8/02	CE / RE / CS
27	SA - RF Section	Hewlett Packard	85680B	2049A01403	6/19/02	CE / RE / CS
28	SA - Display Section	Hewlett Packard	85662A	2112A02234	6/19/02	CE / RE / CS
29	QP Adapter	Hewlett Packard	85650A	2043A00184	6/19/02	CE / RE / CS
30	ESD Power Supply/Gun	Haefely	PSD 25 B	083 427-05	3/28/02	ESD
31	ESD Contact Finger	Haefely	093 579-1	083 071-11	3/28/02	ESD
32	Signal Source 9Khz-2Ghz	Marconi	2024	112231/034	12/22/02	RS / CS
33	Scale 300lb Capacity	Hanson	8930	1403	6/19/02	
34	Scale 25lb Capacity	Hanson	40	1402	5/17/02	
35	Precision Torque Gauge	SeeKonik	SL-12	967	7/27/02	
36	Precision Torque Wrench	Husky	39104	4980656019	7/27/02	
37	Step Attenuator 120dB	Hewlett Packard	355D	2522A43896	11/9/02	As Req'd
38	Step Attenuator 12dB	Hewlett Packard	355C	2524A42578	11/9/02	As Req'd
39	Oscillioscope	LeCroy	9400	85584	2/26/02	Surg / EFT/ ESD
40	Pressure Gauge	Ashcroft	0-30 PSI	1500	9/21/02	
41	Pressure Gauge	Ashcroft	0-30 PSI	1501	9/21/02	
42	Pressure Gauge	Ashcroft	0-30 PSI	1502	9/21/02	
43	Artificial Mains Network	Schwarzbeck	NNLA 8120	8120288	3/18/02	CE / CS
44	A.C. Leakage Current Tstr	Simpson	229-2	948	11/8/02	
45	Leakage Current tester	Simpson	228	709721	11/8/02	
46	Insulation Tester	Amprobe	AMB-1A	340055	11/9/02	
47	Hypot Tester	Beckman	P-2B	64999	11/8/02	
48	Ground Continuity Tester	Rod-I	M25	12485	11/8/02	
49	Digital MultiMeter	Di-log	DL-297T	23702237	11/13/02	
50	Probe	Omega	HX94V		4/4/02	
51	L I S N	ComPower Corp	L1-300	1331	5/25/02	CE / CS
52	L I S N	ComPower Corp	L1-300	1373	5/25/02	CE / CS

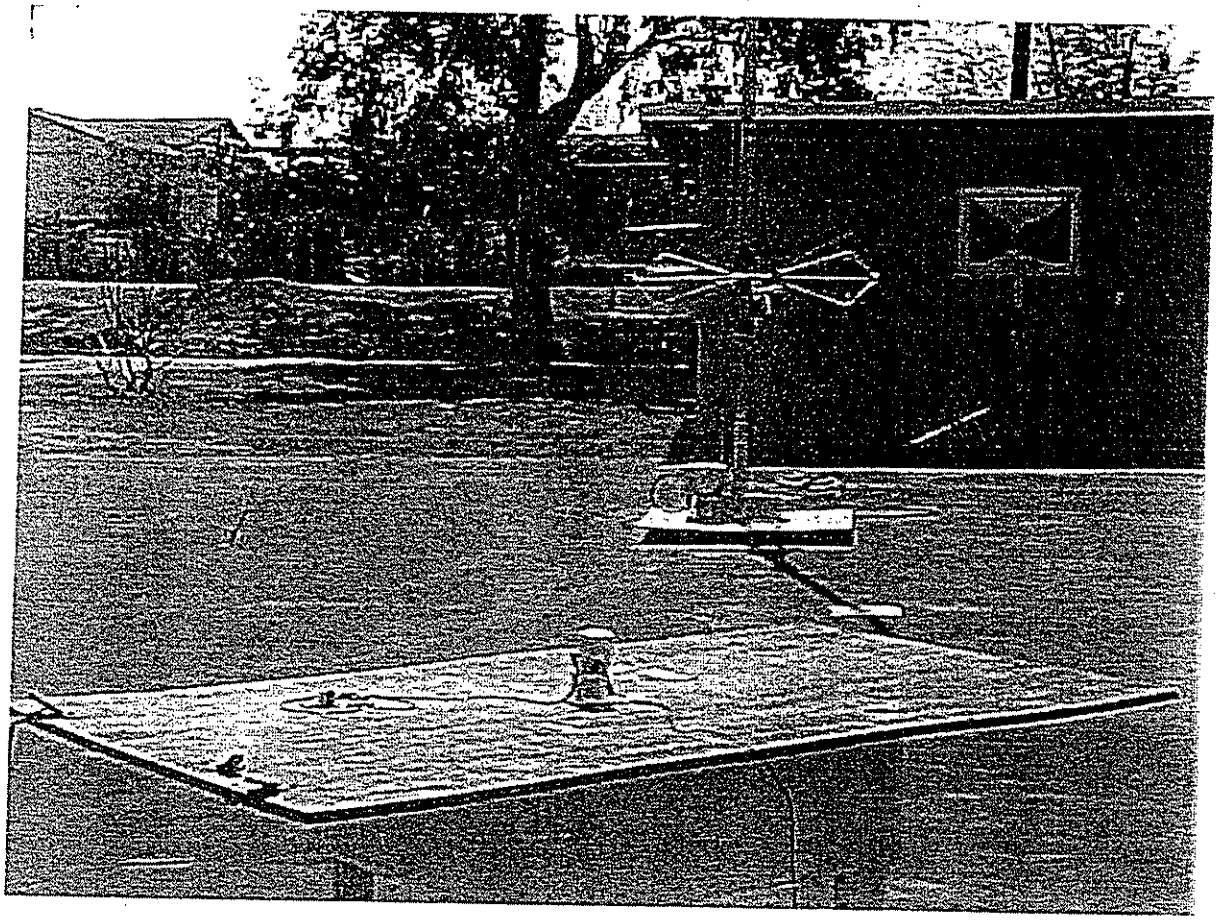
** When necessary, equivalent calibrated equipment may be substituted for the equipment listed here.*

APPENDIX B

Photographs

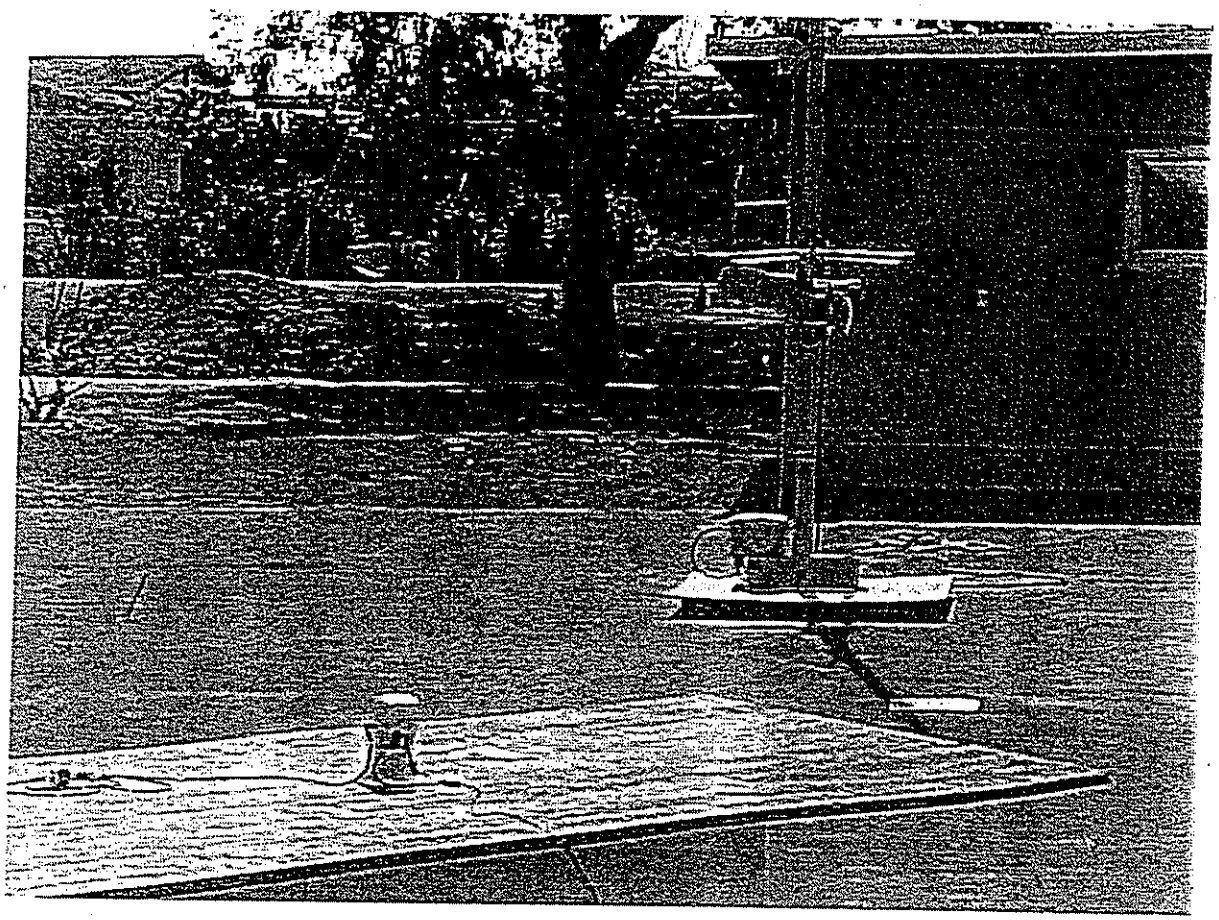
Photos — Radiated Emissions - Bicon

Notes:



Photos — Radiated Emissions - Log Periodic

Notes:



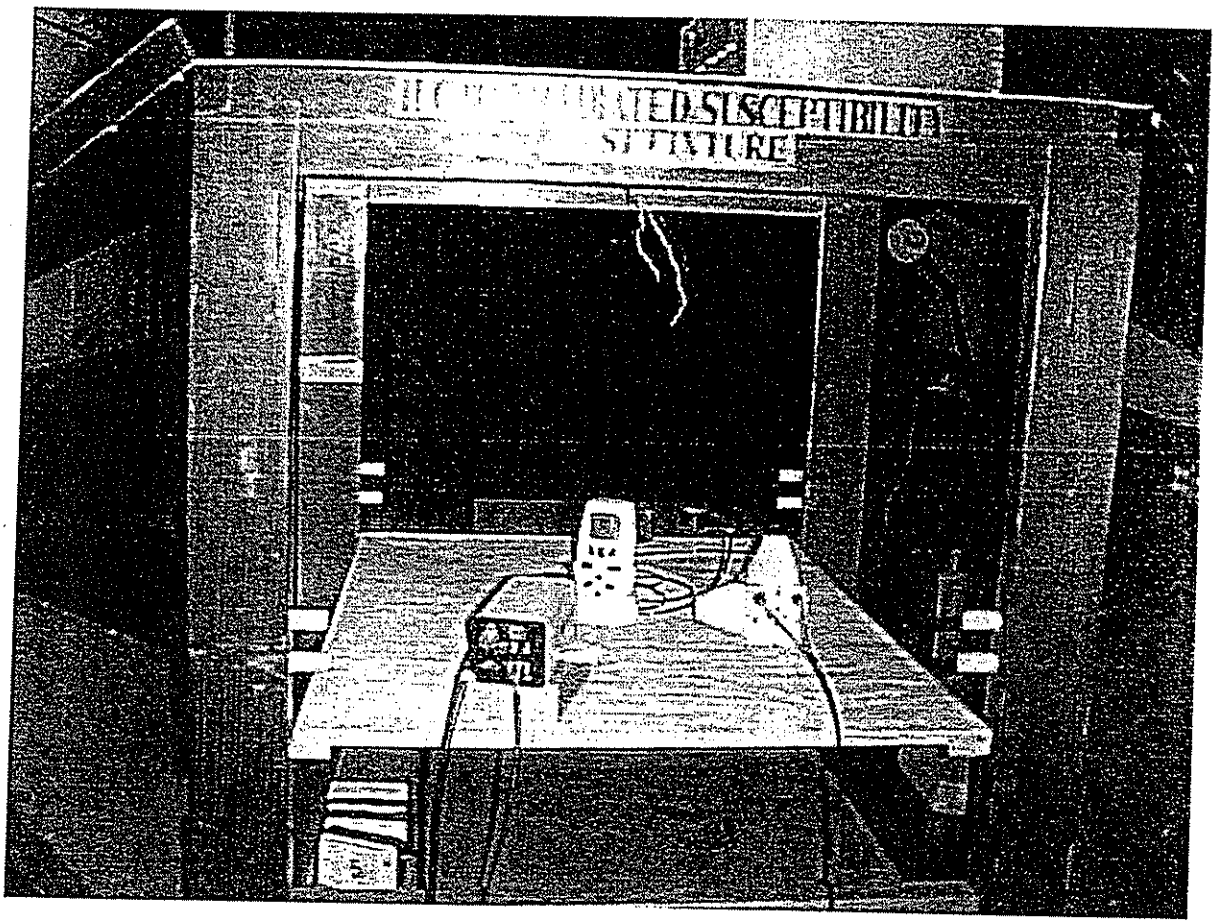
Photos — Electro-Static Discharge

Notes:

No Photograph is available for this set up.
EUT was tested in accordance with the applicable base standard set up.

Photos — Radiated Susceptibility

Notes:



Photos — Electrical Fast Transient

Notes:

No Photograph is available for this set up.
EUT was tested in accordance with the applicable base standard set up.

Photos — Conducted Susceptibility

Notes:

No Photograph is available for this set up.
EUT was tested in accordance with the applicable base standard set up.

Photos — Magnetic Field Immunity

Notes:

No Photograph is available for this set up.
EUT was tested in accordance with the applicable base standard set up.

APPENDIX C

Declaration(s) of Conformity

Declaration of Conformity

Application of Council Directive: 89/336/EEC

Standards To Which Conformity Is Declared:	EN60601-1-2:2001 EN55011 Class B Group 1 EN61000-4-2 EN61000-4-3 EN61000-4-4 EN61000-4-6 EN61000-4-8
Manufacturer's Name:	Teledyne Analytical Instruments
Manufacturer's Address:	16830 Chestnut Street City of Industry, CA 91748 (626) 934-1611
Equipment Description:	O_2 Analyzer
Equipment Class:	Medical Electrical Equipment (Non-Life Supporting)
Model Numbers:	MX300, AX300

I the undersigned, hereby declare that the equipment specified above, conforms to the above Directive(s) and Standard(s).

Place: _____

Signature: _____

Full Name: _____

Position: _____

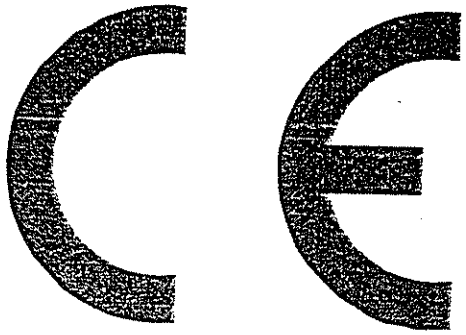
5969 Robinson Avenue
Riverside, CA 92503 USA
(909) 637-2630
FAX (909) 637-2704

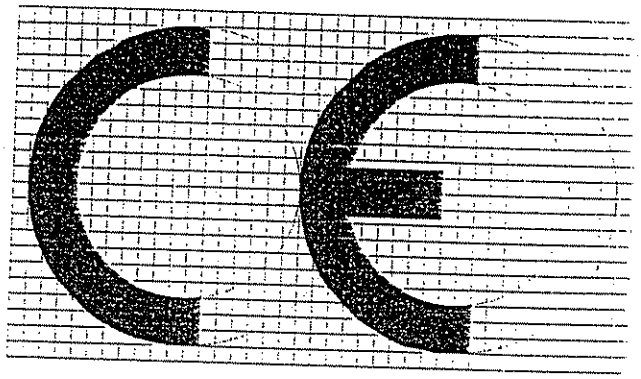
6 Jun 200
28108

CE Mark Information

DNB Job Number:	28108	Date: 6 Jun 2002	Council Directives
Customer:	Teledyne Analytical Instruments		[X] 89/336/EEC (EMC)
Model Number:	O2 Analyzer	Serial Number: N/A	[X] 92/31/EEC (EMC amend)
Description:	MX300		[X] 93/68/EEC (CE Mark)

The following Mark must appear on the body of each product shipped in a visible location. The only requirement is that it must have the same shape as depicted below and cannot be less than 5mm in height. The Mark to the left is how it should appear on your product. The Mark to right has been provided for your assistance in developing artwork. If the CE Mark is reduced or enlarged the proportions given in the graduated drawing must be respected.





NOTE: EMC Directive (89/336/EEC) required that the year that the CE Mark was affixed to the product be put adjacent to the CE Mark. Council Directive (93/68/EEC) no longer requires that the year be placed next to the CE Mark.

In addition to the Mark above the preceding ***Declaration of Conformity*** is to be supplied with each product shipped. This information can be applied to each unit in the form of a label, or placed in supporting documentation shipped with each product, (e.g., Owner's Manual, Instruction Manual, etc.)

- Description of the apparatus to which it refers.
- Reference to the specifications, standards, directives, that it conforms with.
- Identification of the signatory empowered to bind the manufacturer or his authorized representative.
- Where one or more Directives apply (during a transitional period) only those Directives to which conformity has been demonstrated may be applied. Failure to list actual Directives implies compliance with all applicable Directives.
- Where appropriate, reference to the EC Type-examination certificate issued by a notified body. Not required on most manufacturer self declaration products.

The attached sample Declaration of Conformity has been provided to assist you.

NOTE: MEDICAL DEVICES MUST ALSO COMPLY WITH THE SAFETY REQUIREMENTS OF THE MEDICAL DEVICES DIRECTIVE

APPENDIX D

Test Data

5969 Robinson Avenue
Riverside, CA 92503
(909) 637-2630
FAX (909) 637-2704

6 Jun 2002
RV28108

ESD Datasheet

DNB Job Number:	28108	Date: 4 -15 2002	**Conformance Standard** EN60601-1-2
Customer:	Teledyne Analytical		
Model Number:	MX300	Serial Number: N/A	
Description:	O2 Analyzer		**Basic Standard** EN61000-4-2
Notes:	Non-Life Supporting - Class I Medical		

EUT performed within the requirements of the applicable Standard(s) [X] YES [ ] NO Signed *Tom Elders*

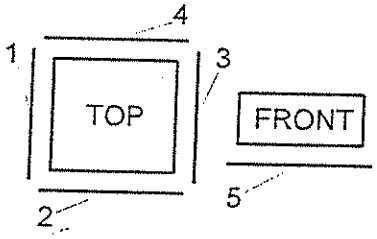
Ambient Temperature	23 °C	Relative Humidity	49 %	Atmospheric Pressure	98.0 kPa

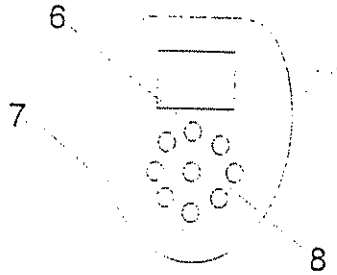
Requirements for ☞	EN50082-1:1998		EN50082-2		EN60601-1-2	
	Contact	Air	Contact	Air	Contact	Air
Enclosure Port	4KV	8KV	4KV	8KV	3KV(1)	8KV

PERFORMANCE CRITERION: EN50082-1 (B) and EN50082-2 (B)
The apparatus shall continue to operate as intended after the test. No degradation of performance or loss of function is allowed below a performance level specified by the manufacturer, when the apparatus is used as intended. In some cases the performance level may be replaced by a permissible loss of performance. During the test, degradation of performance is however allowed. No change of actual operating state or stored data is allowed. If the minimum performance level or the permissible performance loss is not specified by the manufacturer then either of these may be derived from the product description and documentation and what the user may reasonably expect from the apparatus if used as intended.

X or 0	Normal performance within specification limits.
1	Temporary degradation or loss of function or performance which is self-recoverable.
2	Temporary degradation or loss of function or performance which requires operator intervention or system reset.
3	Degradation or loss of function which is not recoverable due to damage of the equipment (components) or software, or loss of data.

A minimum of ten discharges
per injection point is required.
Location of injection points:





#	Injected Level																			
	Level 1				Level 2				Level 3				Level 4				Special			
	2KV Contact		2KV Air		4KV (1) Contact		4KV Air		6KV Contact		8KV Air		8KV Contact		15KV Air					
	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
1	X	X	X	X	X	X	X	X	X	X	X	X								
2	X	X	X	X	X	X	X	X	X	X	X	X								
3	X	X	X	X	X	X	X	X	X	X	X	X								
4	X	X	X	X	X	X	X	X	X	X	X	X								
5	X	X	X	X	X	X	X	X	X	X	X	X								
6	X	X	X	X	X	X	X	X	X	X	X	X								
7	X	X	X	X	X	X	X	X	X	X	X	X								
8	X	X	X	X	X	X	X	X	X	X	X	X								
9	X	X	X	X	X	X	X	X	X	X	X	X								

DNB
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6 Jun 2002
RV28108

Radiated Susceptibility Datasheet

DNB Job Number:	28108	Date: 21 Mar 2002	Conformance Standard
Customer:	Teledyne Analytical		EN60601-1-2
Model Number:	MX300	Serial Number: N/A	
Description:	O2 Analyzer		Basic Standard
	Non-Life Supporting - Class I Medical		EN61000-4-3
Transducer Type:	[X] TEM Cell [ ] Antennas		

PERFORMANCE CRITERION: EN50082-1 (A) and EN50082-2 (A)
The apparatus shall continue to operate as intended. No degradation of performance or loss of function is allowed below a performance level specified by the manufacturer, when the apparatus is used as intended. In some cases the performance level may be replaced by a permissible loss of performance. If the minimum performance level or the permissible performance loss is not specified by the manufacturer then either of these may be derived from the product description and documentation and what the user may reasonably expect from the apparatus if used as intended.

X or 0	Normal performance within specification limits.
1	Temporary degradation or loss of function or performance which is self-recoverable.
2	Temporary degradation or loss of function or performance which requires operator intervention or system reset.
3	Degradation or loss of function which is not recoverable due to damage of the equipment (components) or software, or loss of data.

Antenna faces ⇓	IEC 801-3:84								EN61000-4-3 and EN60601-1-2								TEM Cell Axis ⇓
	Level 1		Level 2		Level 3		Special		Level 1		Level 2		Level 3		Special		
	1 V/M		3 V/M		10 V/M				1 V/M		3 V/M		10 V/M				
	H	V	H	V	H	V	H	V	H	V	H	V	H	V	H	V	
Front									X	X	X	X					X
Right									X	X	X	X					Y
Rear									X	X	X	X					Z
Left									X	X	X	X					
Top (1)																	
Bottom (1)																	

(1) Required only if accessible during normal operation.

Antenna faces ⇓	ENV50204										TEM Cell Axis ⇓
	Level 1		Level 2		Level 3		Level 4		Special		
	1 V/M		3 V/M		10 V/M		30 V/M				
	H	V	H	V	H	V	H	V	H	V	
Front											X
Right											Y
Rear											Z
Left											
Top (1)											
Bottom (1)											

EN50082-1:1998
requires compliance to Level 2
1st Frequency 900 MHz ±5Mhz
2nd Frequency 1.89Ghz ± 10Mhz
1Khz unmodulated sine wave
Keyed carrier (200 Hz)
(50% duty cycle)
2.5ms on / 2.5ms off

Requirements	EN50082-1	EN50082-2							EN60601-1-2
Frequency MHz	80-1000	80-87	87-108	108-174	174-230	230-470	470-790	790-1000	80-2500
Level	2	3	2	3	2	3	2	3	2
Modulation	80%AM	80% AM							80% AM

Notes:

EUT performed within the requirements of the applicable Standard(s) [X] YES [ ] NO Signed *Tom Elders*

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6 Jun 2002
RV28108

EFT Datasheet

DNB Job Number:	28108	Date: 15 Apr 2002	**Conformance Standard**
Customer:	Teledyne Analytical		EN60601-1-2
Model Number:	MX300	Serial Number:	
Description:	O2 Analyzer		**Basic Standard**
	Non-Life Supporting - Class 1 Medical		EN61000-4-4

PERFORMANCE CRITERION: EN50082-1 (B) and EN50082-2 (B)
The apparatus shall continue to operate as intended after the test. No degradation of performance or loss of function is allowed below a performance level specified by the manufacturer, when the apparatus is used as intended. In some cases the performance level may be replaced by a permissible loss of performance. During the test, degradation of performance is however allowed. No change of actual operating state or stored data is allowed. If the minimum performance level or the permissible performance loss is not specified by the manufacturer then either of these may be derived from the product description and documentation and what the user may reasonably expect from the apparatus if used as intended.

X or 0	Normal performance within specification limits.
1	Temporary degradation or loss of function or performance which is self-recoverable.
2	Temporary degradation or loss of function or performance which requires operator intervention or system reset.
3	Degradation or loss of function which is not recoverable due to damage of the equipment (components) or software, or loss of data.

	Input and Output AC Power Ports									
	Level 1		Level 2		Level 3		Level 4		Special	
	0.5KV		1KV		2KV		4KV			
	+	-	+	-	+	-	+	-	+	-
L										
N										
PE										
L-N										
L-PE										
N-PE										
L-N-PE										

Cable Description	Input and Output DC Power Ports									
	Level 1		Level 2		Level 3		Level 4		Special	
	0.25KV		0.5KV		1KV		2KV			
	+	-	+	-	+	-	+	-	+	-

Cable Description	Process, measurement, control, & long buss									
	Level 1		Level 2		Level 3		Level 4		Special	
	0.25KV		0.5KV		1KV		2KV			
	+	-	+	-	+	-	+	-	+	-

Cable Description	I/O, signal, & data buss w/out process control									
	Level 1		Level 2		Level 3		Level 4		Special	
	0.25KV		0.5KV		1KV		2KV			
	+	-	+	-	+	-	+	-	+	-
O2 Sensor	X	X	X	X						

Requirements for ☞	EN50082-1	EN50082-2	EN60601-1-2
AC Power Ports	Level 2	Level 3	Plug connected: Level 2 Perm connected: Level 3
DC Power Ports	Level 2	Level 4	Level 2
Process control	Level 2	Level 4	Level 2
I/O, Signal, & Data	Level 2	Level 3	Level 2

Notes:

EUT performed within the requirements of the applicable Standard(s) [X] YES [ ] NO Signed *Mike Green*

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6 Jun 2002
RV28108

Conducted Susceptibility Datasheet

DNB Job Number:	28108	Date: 11 Apr 2002	**Conformance Standard**
Customer:	Teledyne Analytical		EN60601-1-2
Model Number:	MX300	Serial Number:	
Description:	O2 Analyzer		**Basic Standard**
	Non-Life Supporting - Class I Medical		EN61000-4-6

PERFORMANCE CRITERION: EN50082-1 (A) and EN50082-2 (A)
The apparatus shall continue to operate as intended. No degradation of performance or loss of function is allowed below a performance level specified by the manufacturer, when the apparatus is used as intended. In some cases the performance level may be replaced by a permissible loss of performance. If the minimum performance level or the permissible performance loss is not specified by the manufacturer then either of these may be derived from the product description and documentation and what the user may reasonably expect from the apparatus if used as intended.

X or 0	Normal performance within specification limits.
1	Temporary degradation or loss of function or performance which is self-recoverable.
2	Temporary degradation or loss of function or performance which requires operator intervention or system reset.
3	Degradation or loss of function which is not recoverable due to damage of the equipment (components) or software, or loss of data.

Cable Description	Input and Output AC Power Ports			
	Level 1	Level 2	Level 3	Special
	1V	3V	10V	

Cable Description	Input and Output DC Power Ports			
	Level 1	Level 2	Level 3	Special
	1V	3V	10V	

Cable Description	Process, measurement & control			
	Level 1	Level 2	Level 3	Special
	1V	3V	10V	

Cable Description	I/O, signal, & data buss			
	Level 1	Level 2	Level 3	Special
	1V	3V	10V	
O2 Sensor	X	X		

Requirements for ☞	EN50082-1	EN50082-2			EN60601-1-2
	0.15-80Mhz	0.15-47Mhz	47-68Mhz	68-80Mhz	.15-80Mhz
AC Power Ports	Level 2	Level 3	Level 2	Level 3	Level 2
DC Power Ports	Level 2	Level 3	Level 2	Level 3	Level 2
Process control	N/A	Level 3	Level 2	Level 3	Level 2
I/O, Signal, & Data	Level 2	Level 3	Level 2	Level 3	Level 2

Notes:

ISM denotes frequencies in the ISM bands were tested to 10V requirements

EUT performed within the requirements of the applicable Standard(s) [X] YES [ ] NO Signed *Tom Elders*

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6 Jun 2002
RV28108

Magnetic Field Immunity Datasheet

DNB Job Number:	28108	Date: 15 Apr 2002	**Conformance Standard**
Customer:	Teledyne Analytical		EN60601-1-2
Model Number:	MX300	Serial Number: N/A	
Description:	O2 Analyzer		**Basic Standard**
	Non-Life Supporting - Class 1 Medical		EN61000-4-8

PERFORMANCE CRITERION: EN50082-1 (A) and EN50082-2 (A)
The apparatus shall continue to operate as intended. No degradation of performance or loss of function is allowed below a performance level specified by the manufacturer, when the apparatus is used as intended. In some cases the performance level may be replaced by a permissible loss of performance. If the minimum performance level or the permissible performance loss is not specified by the manufacturer then either of these may be derived from the product description and documentation and what the user may reasonably expect from the apparatus if used as intended.

X or 0	Normal performance within specification limits.
1	Temporary degradation or loss of function or performance which is self-recoverable.
2	Temporary degradation or loss of function or performance which requires operator intervention or system reset.
3	Degradation or loss of function which is not recoverable due to damage of the equipment (components) or software, or loss of data.

	Induced magnetic field strength for continuous fields					
	Level 1	Level 2	Level 3	Level 4	Level 5	Special
	1 A/m	3 A/m	10 A/m	30 A/m	100 A/m	
X Axis	X	X				
Y Axis	X	X				
Z Axis	X	X				
	Induced magnetic field strength for short duration (1s to 3s)					
	Level 1	Level 2	Level 3	Level 4	Level 5	Special
	N/A	N/A	N/A	300 A/m	1000 A/m	
X Axis						
Y Axis						
Z Axis						

Requirements for ☞	EN50082-1:1998		EN50082-2		EN60601-1-2	
	Continuous	Short Duration	Continuous	Short Duration	Continuous	Short Duration
Compliance level no effect	Level 2	N/A	Level 4	N/A	Level 2	N/A
CRT interference allowed	Level 2	N/A	> Level 2	N/A	Level 2	N/A

Notes:

EUT performed within the requirements of the applicable Standard(s) [X] YES [ ] NO Signed *Les Payne*

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6 Jun 2002
RV28108

EMI Datasheet (ISM Devices)

DNB Job Number:	28108	Date: 21 Mar 2002	Specification
Customer:	Teledyne Analytical		[X] EN55011 Class B Group 1
Model Number:	MX300	Serial Number: N/A	
Description:	O2 Analyzer		
	Non-Life Supporting - Class 1 Medical		

EUT performed within the requirements of the applicable Standard(s) [X] YES [ ] NO Signed *Tom Elders*

Bcn = A.H. Systems SAS-200/540 Biconical Antenna S/N 138 (30-200 MHz)
Log = EMCO 3146 Log-Periodic Antenna S/N 1284 (200-1000 MHz)
Dcf = Distance Correction Factor = $20*LOG_{10}$(Test Distance/Specification Distance)
Typ = Type of reading
PK = Peak reading
QP = Quasi-peak reading

Cbl = Cable Loss
Amp = Preamplifier Gain
Pl = Antenna polarity
V = Vertical H = Horizontal
Hgt = Antenna height in meters
x.xx= 1.00 to 4.00 meters
Tbl = Table Position in degrees
xxx = 000 to 360 degrees
"*" = Readings taken with a res bandwidth of 10KHz do to nearby ambient signal

NOTES:

FREQ.	Meter	Bcn	Log	Cbl	Amp	Dcf	Corr	Lim	Delta	Corr	Lim	Delta	Typ	Tbl	Pl	Hgt
57.242	28.6	12.1	0	1.0	-24.0	0	17.7	30	-12.3	8	32	-24	PK	329	H	2.26
58.279	31.6	11.9	0	1.0	-24.0	0	20.5	30	-9.5	11	32	-21	PK	328	H	3.70
213.797	16.6	17.6	0	2.0	-24.0	0	12.2	30	-17.8	4	32	-28	PK	297	H	2.39
325.965	19.3	0	16.4	2.6	-24.4	0	13.9	37	-23.1	5	71	-66	PK	262	H	2.19
326.630	19.1	0	16.4	2.6	-24.4	0	13.7	37	-23.3	5	71	-66	PK	230	H	3.23
363.781	18.8	0	17.5	2.7	-24.4	0	14.6	37	-22.4	5	71	-66	PK	230	H	3.23
477.385	19.6	0	21.6	3.1	-24.7	0	19.6	37	-17.4	10	71	-61	PK	247	H	3.47
644.477	18.3	0	23.6	3.6	-25.0	0	20.5	37	-16.5	11	71	-60	PK	58	H	3.91
57.147	35.9	12.1	0	1.0	-24.0	0	25	30	-5	18	32	-14	QP	240	V	1.40
58.367	29.0	11.9	0	1.0	-24.0	0	17.9	30	-12.1	8	32	-24	PK	265	V	1.12
214.172	19.2	17.6	0	2.0	-24.0	0	14.8	30	-15.2	5	32	-27	PK	228	V	1.00
326.600	18.1	0	16.4	2.6	-24.4	0	12.7	37	-24.3	4	71	-67	PK	29	V	1.24
363.770	17.7	0	17.5	2.7	-24.4	0	13.5	37	-23.5	5	71	-66	PK	277	V	1.05
477.386	20.0	0	21.6	3.1	-24.7	0	20	37	-17	10	71	-61	PK	91	V	1.24
644.259	17.2	0	23.6	3.6	-25.0	0	19.4	37	-17.6	9	71	-62	PK	0	V	1.41

wyle laboratories

DATA SHEET REPORT NO. 47885

19 November 2002

TELEDYNE ANALYTICAL INSTRUMENTS
16830 Chestnut Street
City of Industry, CA 91748-1020

Attention: Victor Briseno
Test Title: Shock
References: Your Purchase Order No. 027871
Wyle Laboratories Job No. D47885

Sirs:

This is to certify that the enclosed Test Data Sheets contain true and correct data obtained in the performance of the test program as set forth in your Purchase Order No. 027871. Instrumentation used in obtaining this data has been calibrated using standards which are traceable to the National Institute of Standards and Technology. See the equipment lists included with the attachment.

Test Results:

One Oxygen Analyzer was subjected to a Shock Test in accordance with Teledyne Purchase Order No. 027871. A visual inspection of the specimen, as received, is presented in the Receiving Inspection Data Sheet of Attachment DYN-A. The specimen was received without apparent damage. The installation on the test plate is shown in Photograph 1. The test setups are shown in Photographs 2 through 4. **The specimen completed the three shocks in both directions of each axis, for a total of 18 applied shocks, without apparent damage.** The results of the 30 g, 11 millisecond half-sinusoidal Shock Test are presented in Attachment DYN-A. Acceleration response plots of each shock (time versus acceleration) are included with the data sheet.

Encl: Photographs (4 Pages); Attachment DYN-A (22 Pages)

STATE OF CALIFORNIA
COUNTY OF LOS ANGELES } SS.

R. SMITH, MNGR EL SEGUNDO DYNAMICS being duly sworn, deposes and says: That the information contained in this report is the result of complete and carefully conducted tests and is to the best of his knowledge true and correct in all respects.

J. Kasmarzyk FOR R. S.

SUBSCRIBED and sworn to before me this 20 day of NOV 20 02

PRAIRIE WITKAMP
Commission # 1236213
Notary Public - California
Los Angeles County
My Comm. Expires Oct 2, 2003

DEPARTMENT Dynamics

TEST ENGINEER K. Von Goerlitz

TEST WITNESS _____

(Not Applicable)

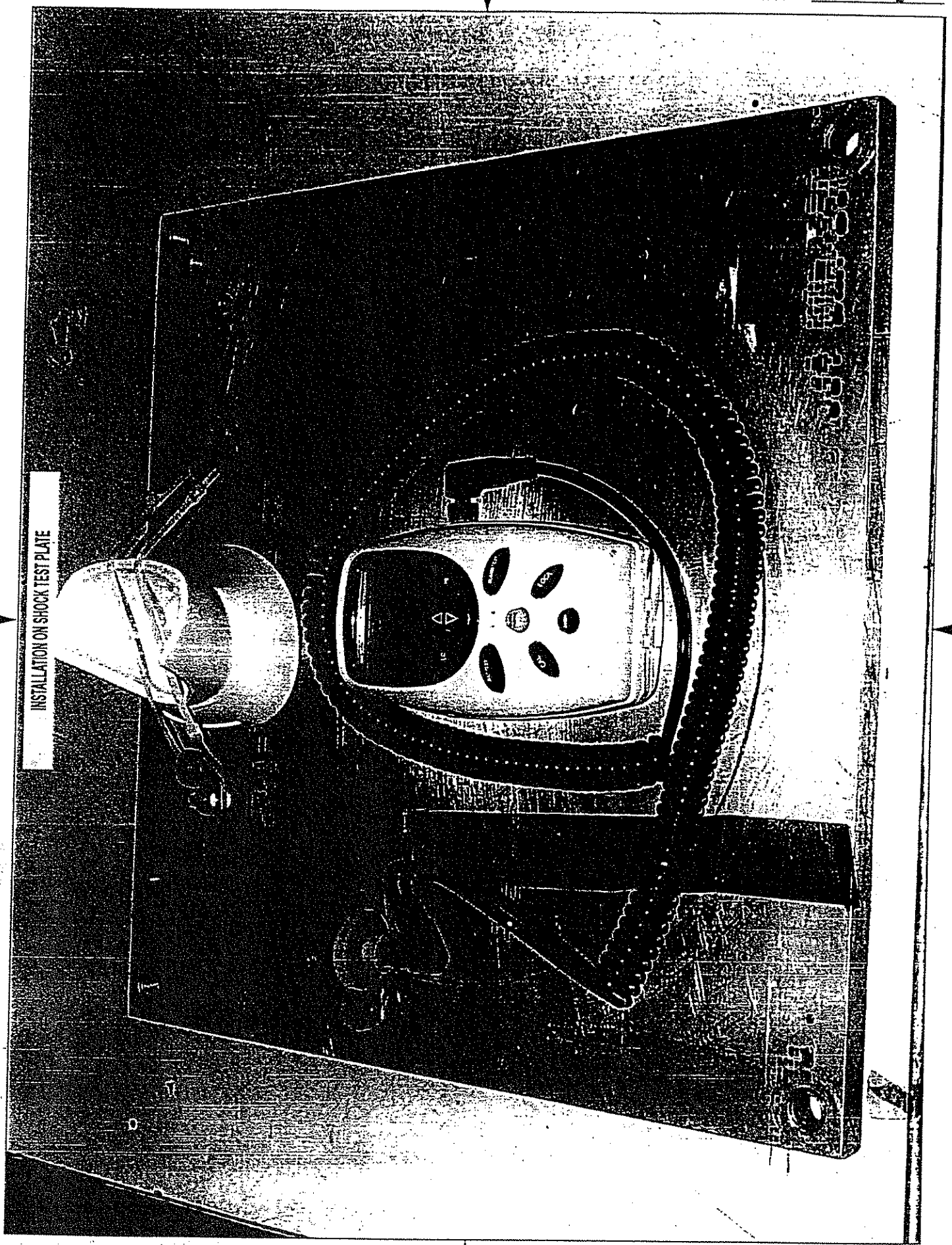
DCAS-QAR VERIFICATION

QUALITY ASSURANCE T. Reilly for G. Montgomery

1115 KCF

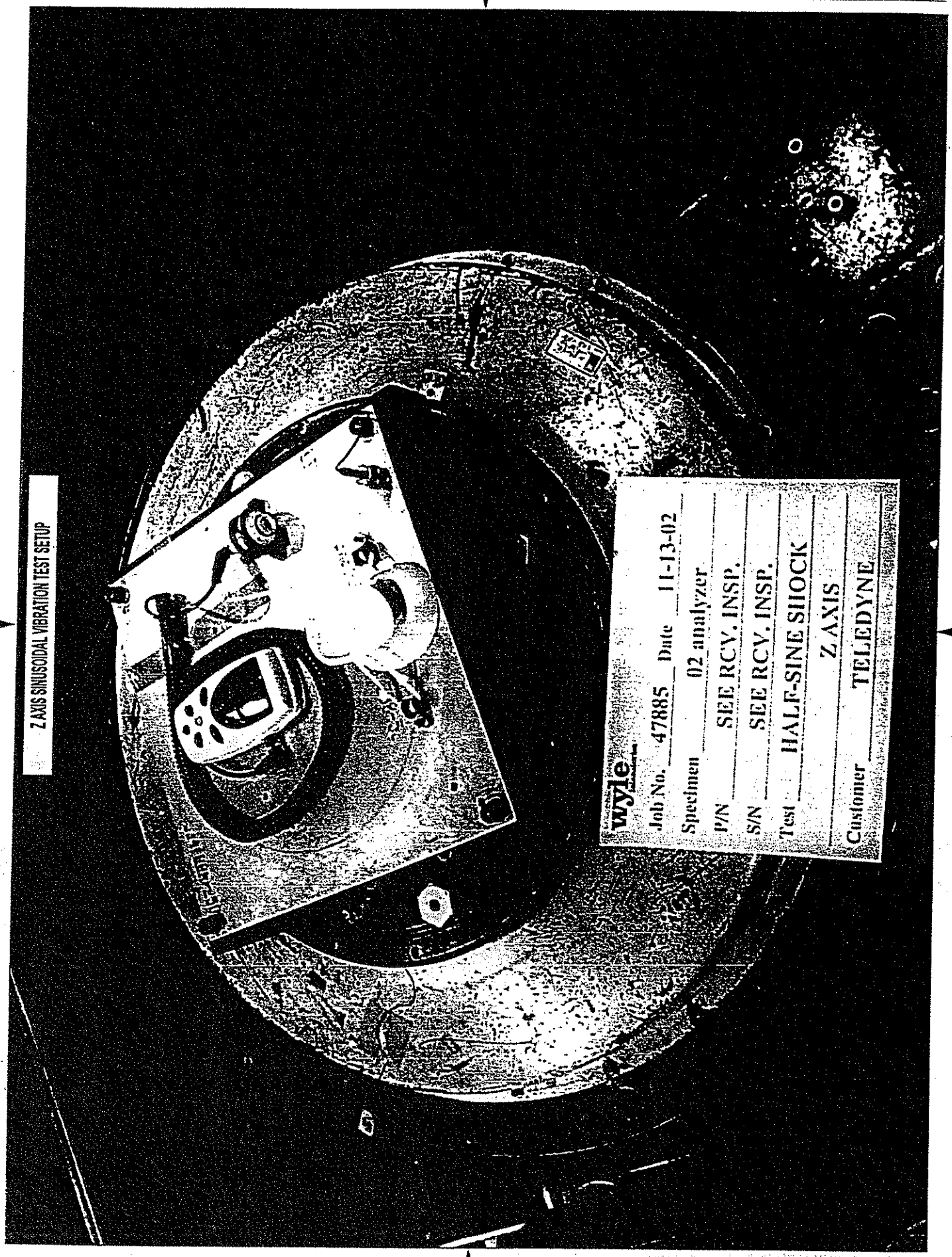
PHOTOGRAPH 1

INSTALLATION ON SHOCK TEST PLATE



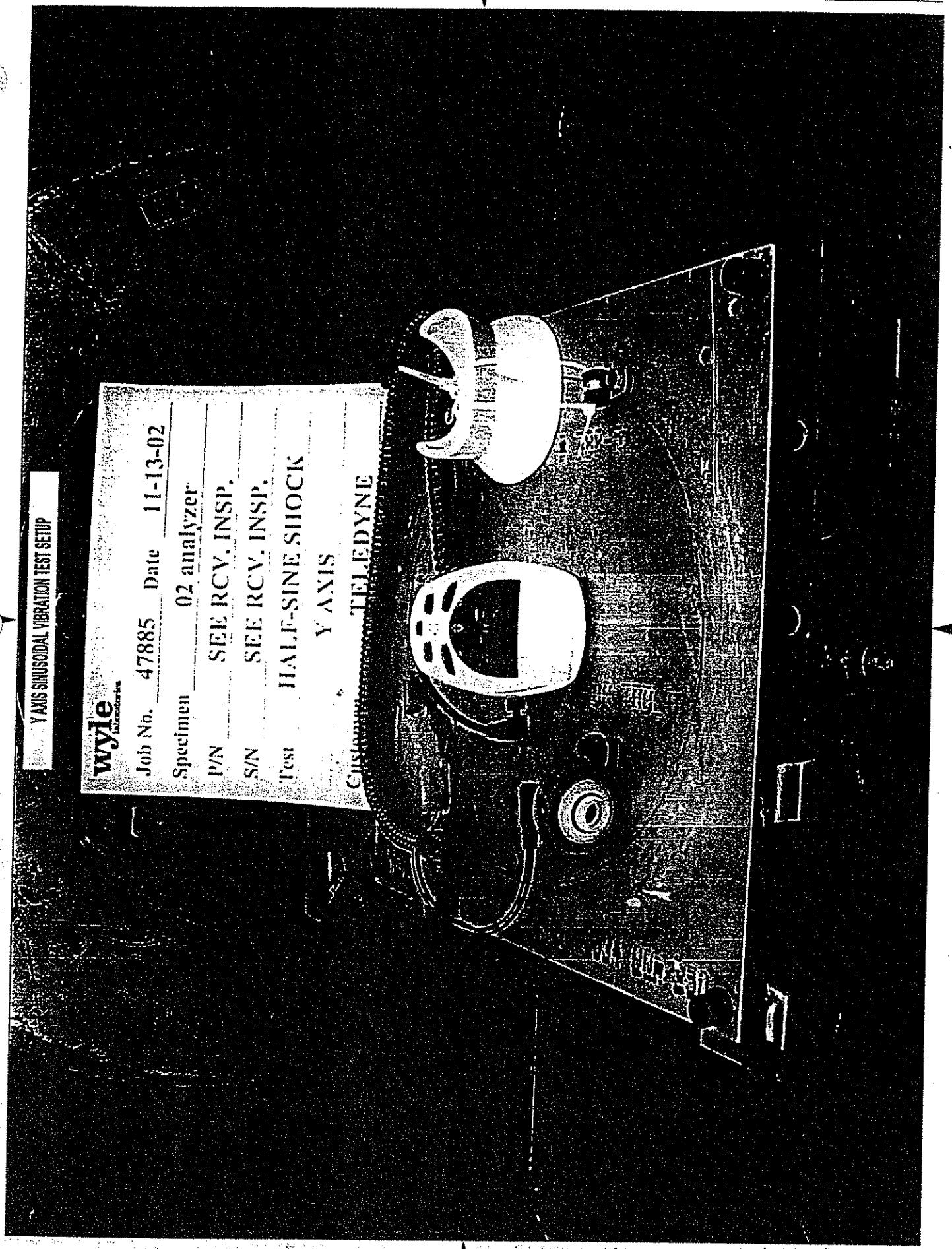
PHOTOGRAPH 2

Z AXIS SINUSOIDAL VIBRATION TEST SETUP



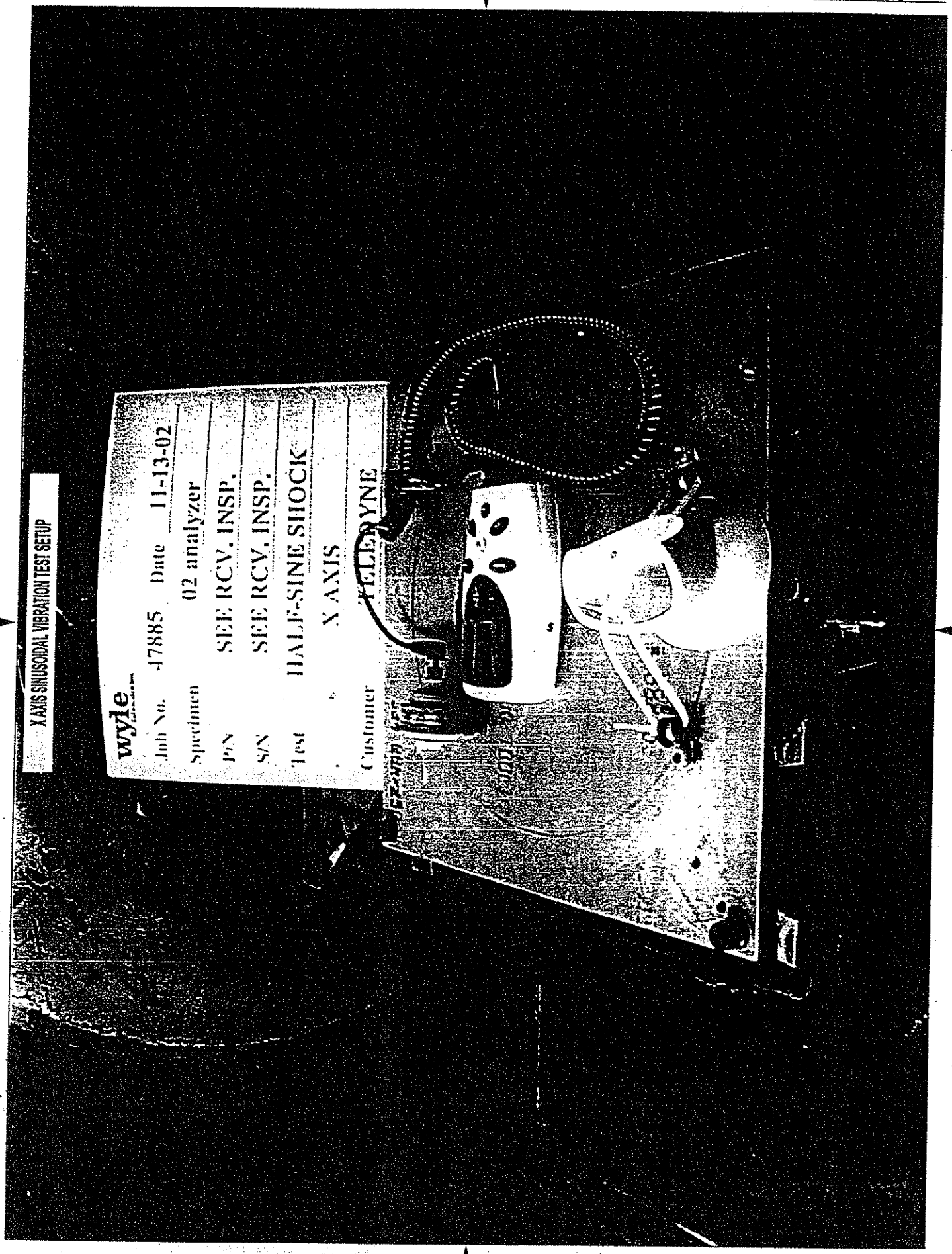
PHOTOGRAPH 3

Y AXIS SINUSOIDAL VIBRATION TEST SETUP



PHOTOGRAPH 4

X AXIS SINUSOIDAL VIBRATION TEST SETUP



DYN-A

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RECEIVING INSPECTION DATA SHEET

Customer	**Teledyne Analytical Instruments**	**Date**	10/31/02
Specimen	O2 Analyzer	**Job No.**	47885
		Page No.	1 of 1

No. of Specimens Received: 1(One)

Record identification information exactly as it appears on the tag or specimen:

Manufacturer: Teledyne Analytical Instruments

P/N's	S/N's
NA	NA

How does identification information appear? (e.g., name plate, tag, painted, imprinted, etc.) NA

Examination:

Inspection Results: Was there any visible evidence of damage to the specimen(s)? Yes ____ No X

Describe any observed damage:

Inspected By Stafford L. Orong

Sheet Number 1 of 1

Approved [signature] Date 10-31-2002

wyle laboratories

Test **SHOCK**

Customer **Teledyne Analytical Instrument** Specimen 02 ANALYZER Date 11-3-02

Part No. NA S/N NA Job No 47885

Test By RITHY SEY Witness

EQUIPMENT	MANUFACTURER	MODEL NO.	RANGE	WYLE NO.	CALIBRATION		ACCURACY
					LAST	DUE	
Vibration Exciter	Ling	335	16 K Force Lbs	14013	NA	NA	NA
Power Amplifier	Unholtz Dickie	2XSA120 1/2	120/240 KVA	13756	NA	NA	NA
Automatic Shock Control System	Data Physics Corp.	DP540	1 Hz to 20 KHz	30779	02-25-02	02-25-03	NA
LaserJet Printer	Hewlett-Packard	6P	NA	13326	NA	NA	NA
Oscilloscope	BK Precision	5105	100 MHz	14169	06-11-02	12-11-02	± 3%
Accelerometer	Endevco	7702-50	1Hz to 8 KHz 1 K G Peak	9181	09-18-02	03-18-03	± 5%
Charge Amplifier	Endevco	133	200 kHz BW 0 to 1k Gain	14112	06-28-02	12-28-02	± .5%

W614C

REPORT NO. 47885
PAGE NO. DYN.A.3

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TEST RECORD DATA SHEET

TEST TITLE SHOCK Page No. 1 of 1

Customer	TELEDYNE ANALYTICAL INSTRUMENTS			Job No.	47885
Specimen	02 ANALYZER			Date Started.	11-13-02
Part No.	NA	Serial No.	NA	Date Comp.	11-13-02
Spec.	Per SOW	Par.	— Photo YES	Amb. Temp.	75° ±15°F

REQUIREMENTS

No of Specimens	1	No. of Axis	3
No. of Impacts	18	No. of Directions	2
Impacts Each Direction	3	Wave Shape	HALF-SINE
Shock Magnitude (G)	30	Shock Duration (ms)	11

Examination: Visual, at conclusion of test.

Other

TEST METHOD

The specimen was assembled to a suitable test fixture and mounted on a vibration exciter, or a Wyle Shock Test Machine, pre-set to provide shock impacts in accordance with above requirements. The following data was obtained:

Axis	Z	Z	Y	Y	X	X
Direction	NEG.	POS.	POS.	NEG.	NEG.	POS.
Magnitude (G)	30	30	30	30	30	30
Duration (ms)	11	11	11	11	11	11
Total Impacts	3	3	3	3	3	3
Ref. Shock Plot No.	1-3	4-6	7-9	10-12	13-15	15-18

At the conclusion of the test, the specimen was removed from the test fixture and visually examined for evidence of damage.

TEST RESULT:

NO APPARENT DAMAGE.

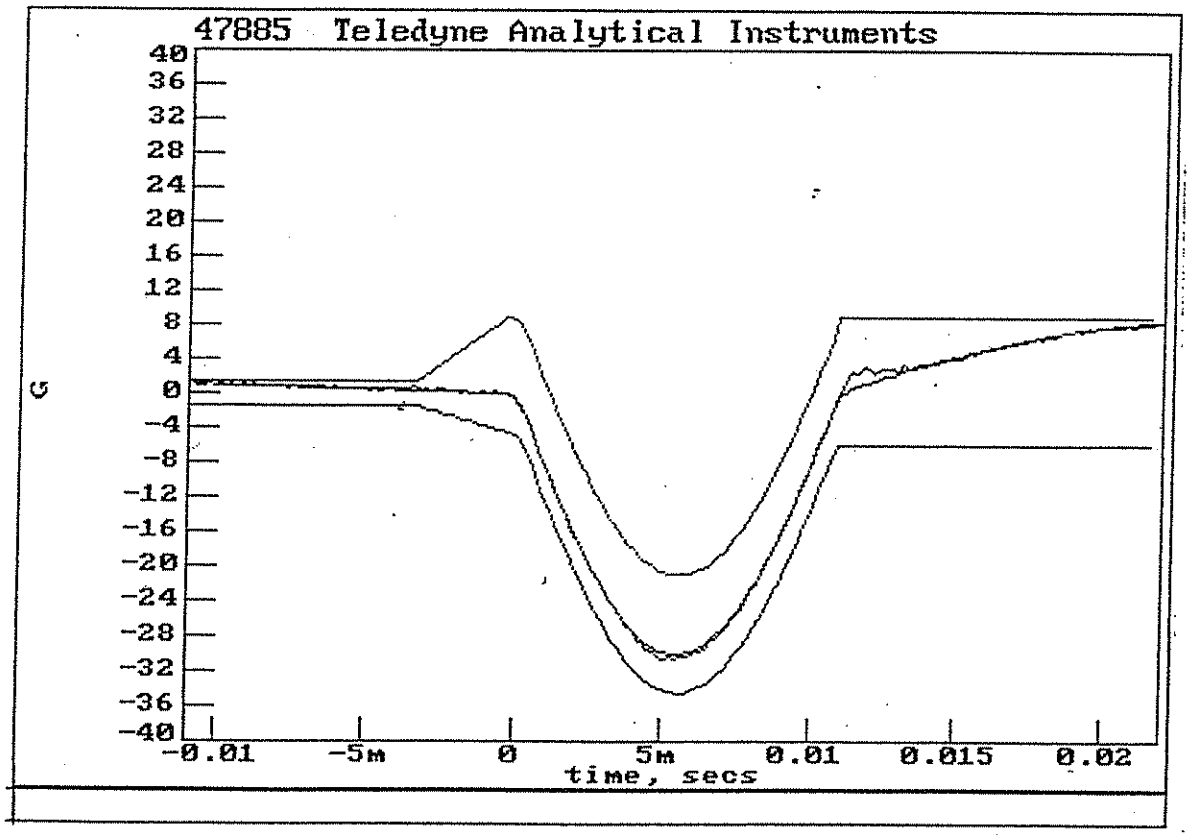
Tested by Rithy Sey

Engineer

wyle laboratories

SHOCK PLOT NO. 1

Customer	TELEDYNE ANALYTICAL INSTRUMENTS					Date	11-13-02
Specimen	02 ANALYZER					Job No.	47885
Part No	NA		Serial No.	NA		Operator	RITHY SEY
Test Axis	Z	Accel.	C1	& Axis	Z	Control (X)	Response ( )
Shock No.	1 of 3		Positive	( )	Negative	(X)	



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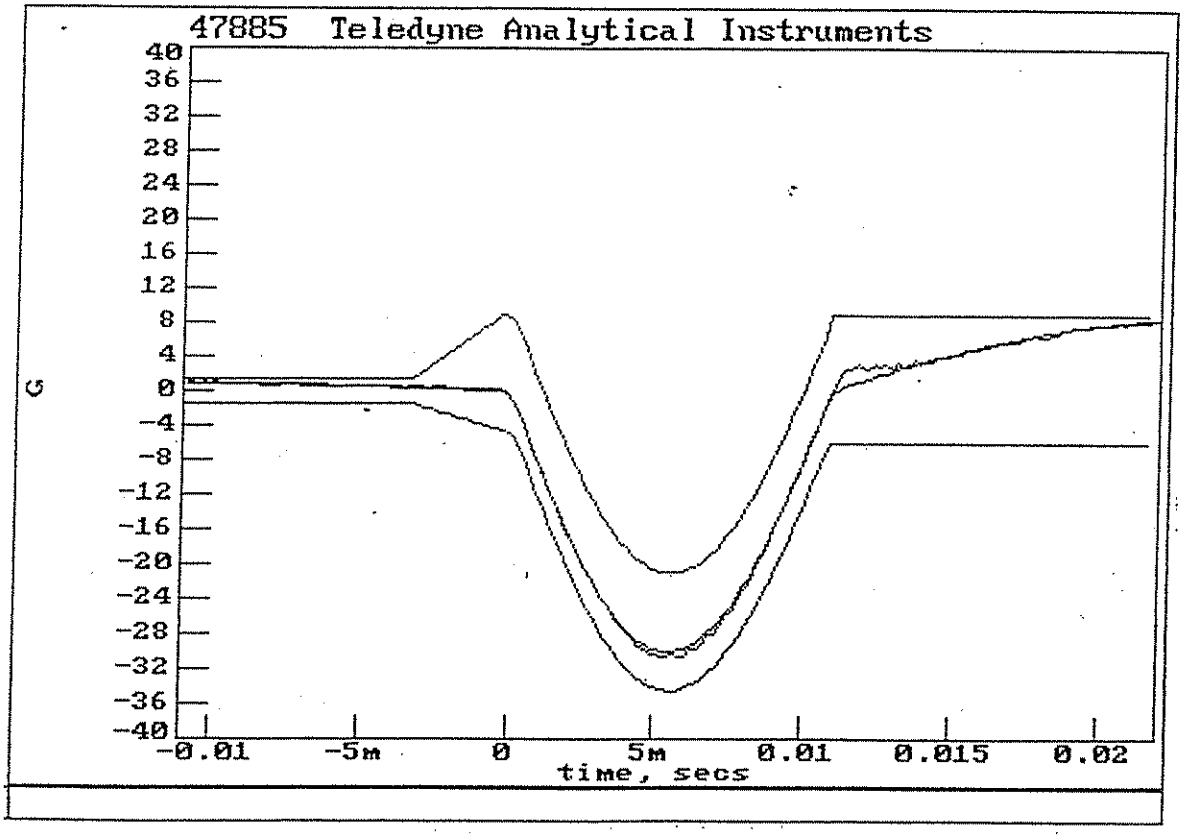
SHOCK PLOT NO. 2

Customer	TELEDYNE ANALYTICAL INSTRUMENTS					Date	11-13-02
Specimen	02 ANALYZER					Job No.	47885
Part No	NA		Serial No.	NA		Operator	RITHY SEY
Test Axis	Z	Accel.	C1	& Axis	Z	Control (X)	Response ( )
Shock No.	2	of	3	Positive	( )	Negative	(X)



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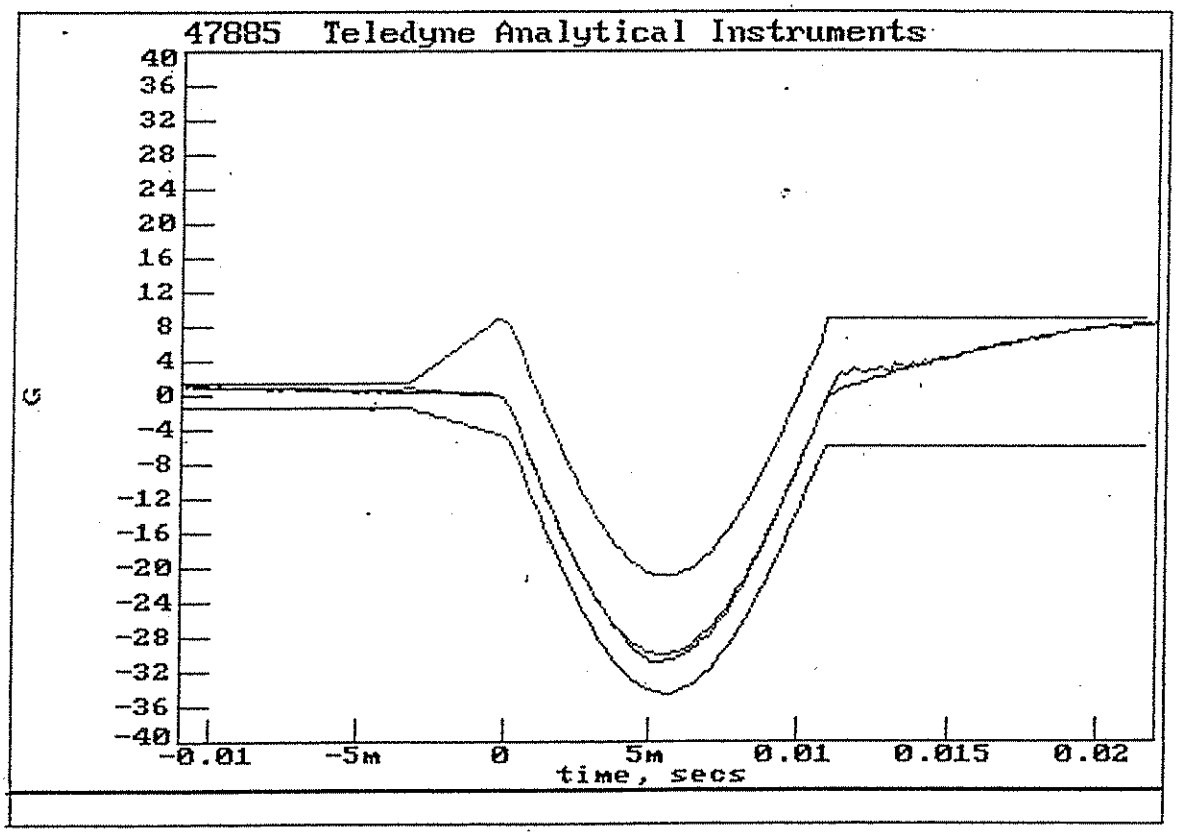
SHOCK PLOT NO. 3

Customer	TELEDYNE ANALYTICAL INSTRUMENTS					Date	11-13-02
Specimen	02 ANALYZER					Job No.	47885
Part No	NA		Serial No.	NA		Operator	RITHY SEY
Test Axis	Z	Accel.	C1	& Axis	Z	Control (X)	Response ( )
Shock No.	3	of	3	Positive	( )	Negative	(X)



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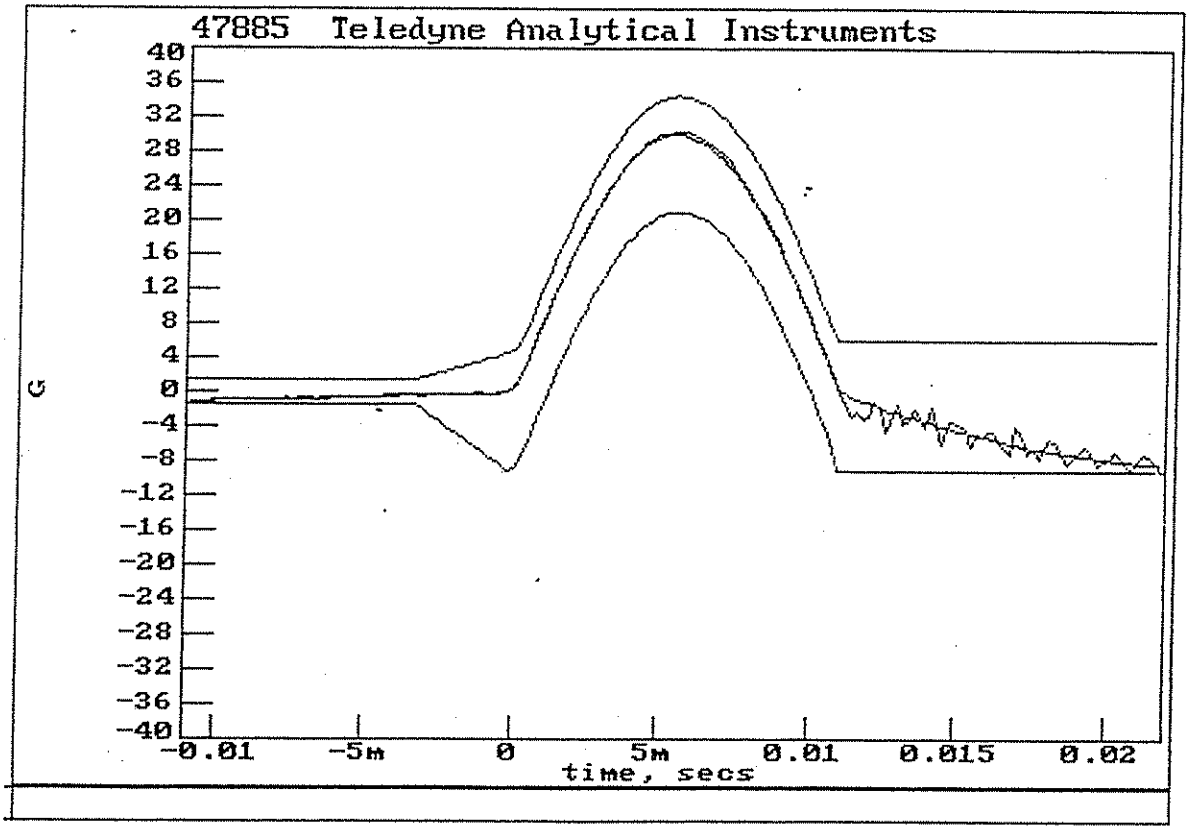
SHOCK PLOT NO. 4

Customer	TELEDYNE ANALYTICAL INSTRUMENTS					Date	11-13-02
Specimen	02 ANALYZER					Job No.	47885
Part No	NA		Serial No.	NA		Operator	RITHY SEY
Test Axis	Z	Accel.	C1	& Axis	Z	Control (X)	Response ( )
Shock No.	1	of	3	Positive	(X)	Negative	( )



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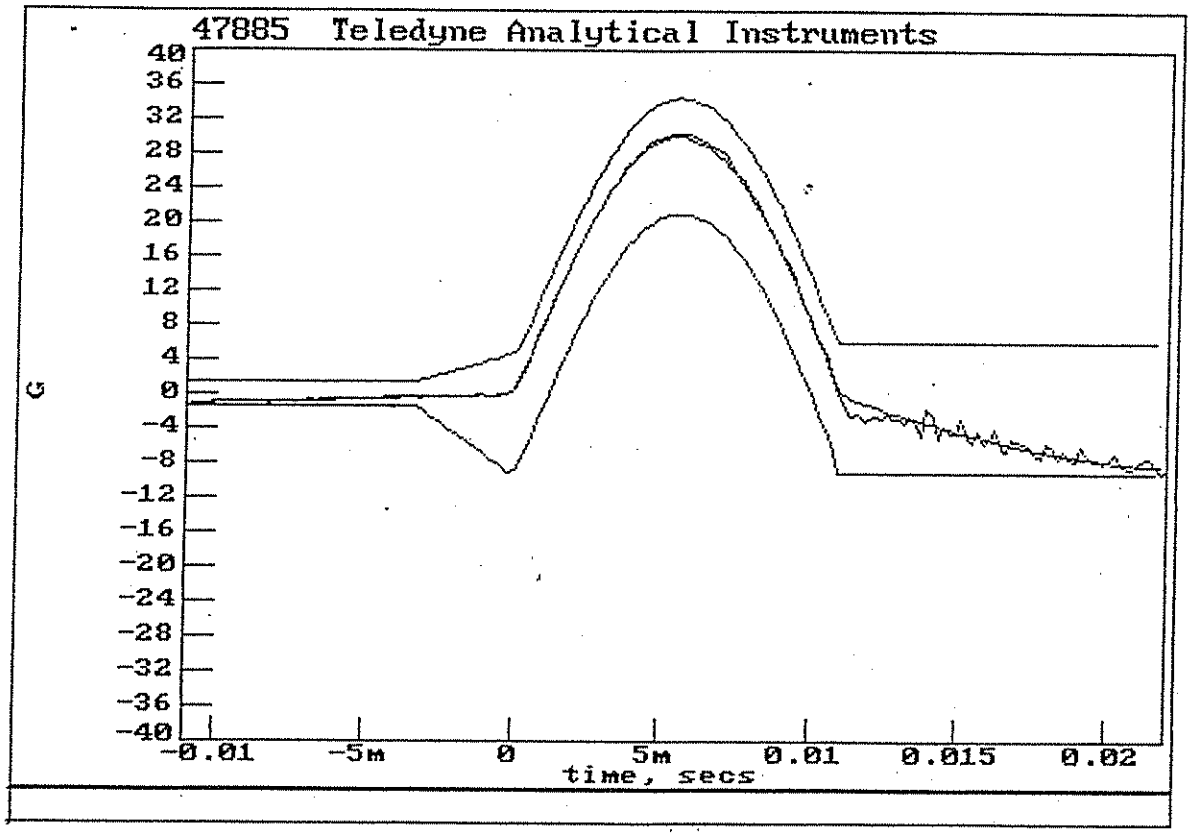
SHOCK PLOT NO. 5

Customer	TELEDYNE ANALYTICAL INSTRUMENTS					Date	11-13-02
Specimen	02 ANALYZER					Job No.	47885
Part No	NA		Serial No.	NA		Operator	RITHY SEY
Test Axis	Z	Accel.	C1	& Axis	Z	Control (X)	Response ( )
Shock No.	2	of	3	Positive	(X)	Negative	( )



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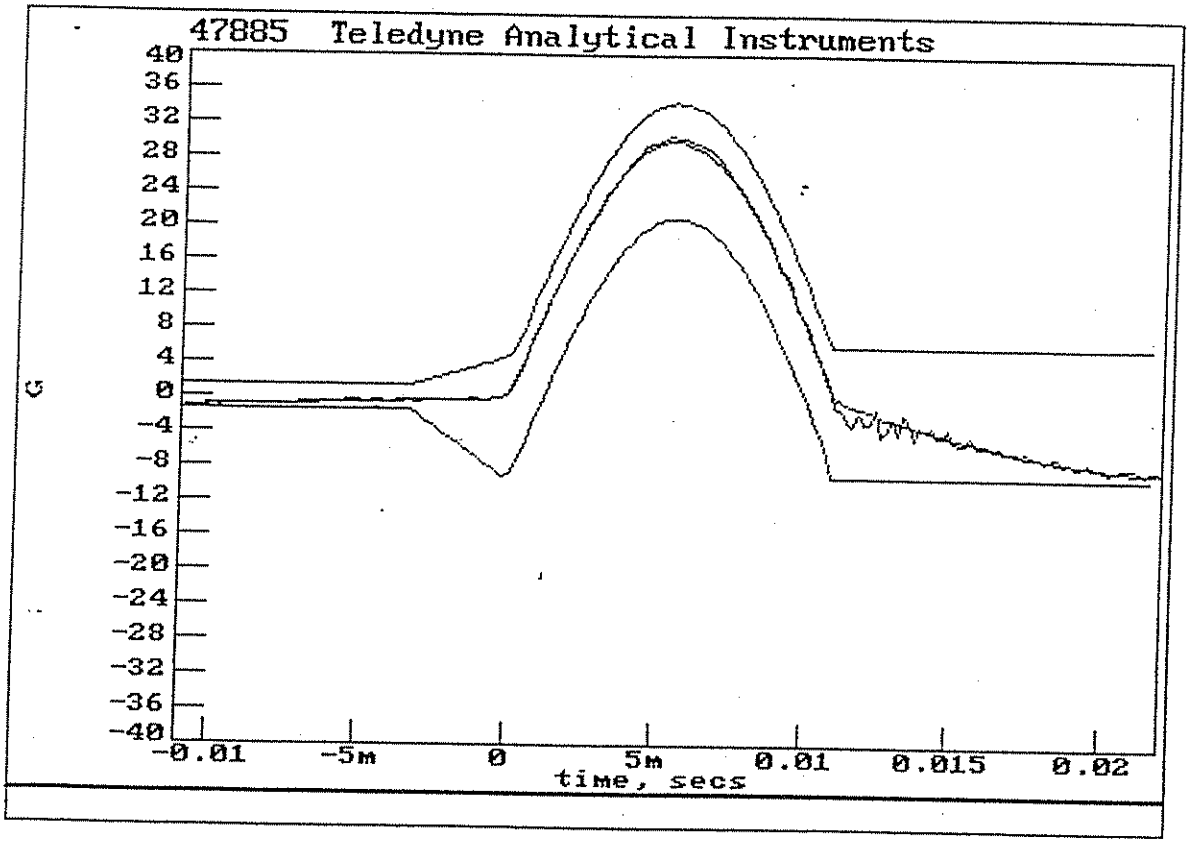
SHOCK PLOT NO. 6

Customer	TELEDYNE ANALYTICAL INSTRUMENTS					Date	11-13-02
Specimen	02 ANALYZER					Job No.	47885
Part No	NA		Serial No.	NA		Operator	RITHY SEY
Test Axis	Z	Accel.	C1	& Axis	Z	Control (X)	Response ( )
Shock No.	3	of	3	Positive	(X)	Negative	( )



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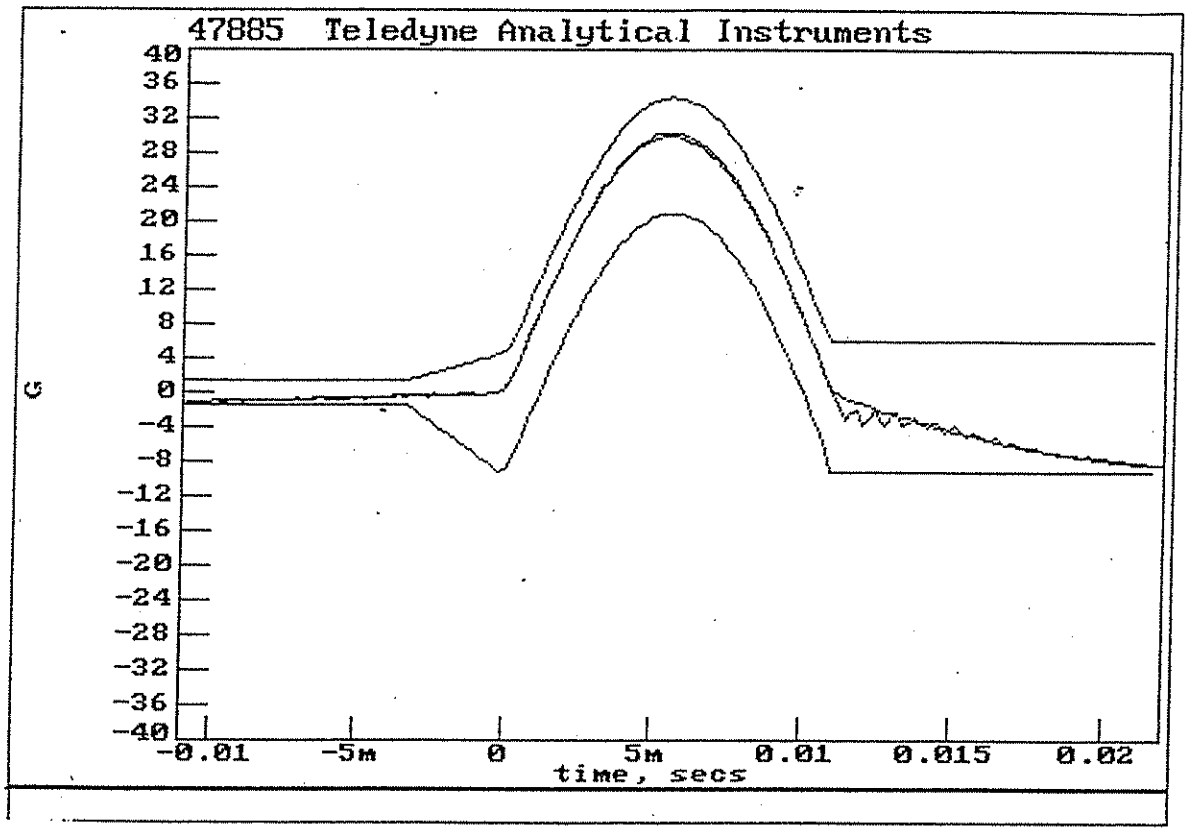
SHOCK PLOT NO. 7

Customer	TELEDYNE ANALYTICAL INSTRUMENTS					Date	11-13-02
Specimen	02 ANALYZER					Job No.	47885
Part No	NA		Serial No.	NA		Operator	RITHY SEY
Test Axis	Y	Accel.	C1	& Axis	Y	Control (X)	Response ( )
Shock No.	1	of	3	Positive	(X)	Negative	( )



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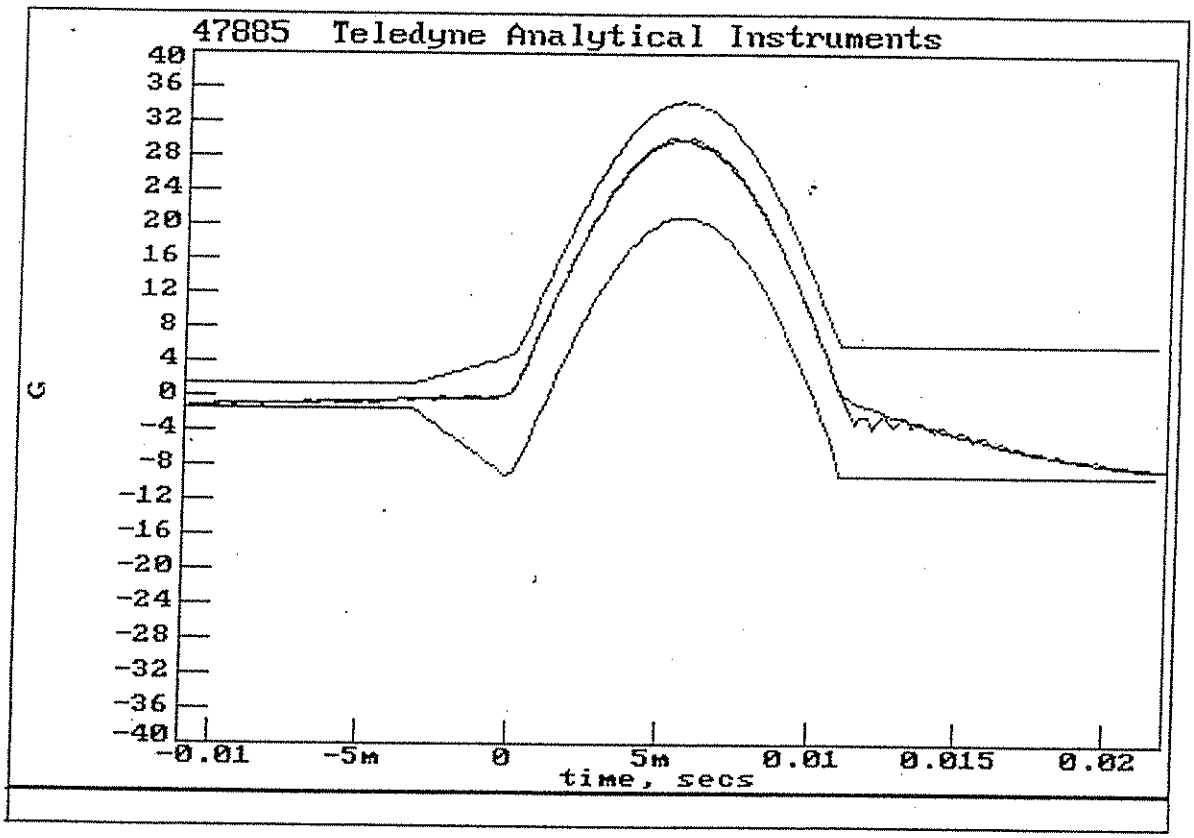
SHOCK PLOT NO. 8

Customer	TELEDYNE ANALYTICAL INSTRUMENTS					Date	11-13-02
Specimen	02 ANALYZER					Job No.	47885
Part No	NA		Serial No.	NA		Operator	RITHY SEY
Test Axis	Y	Accel.	C1	& Axis	Y	Control (X)	Response ( )
Shock No.	2 of 3		Positive	(X)	Negative	( )	



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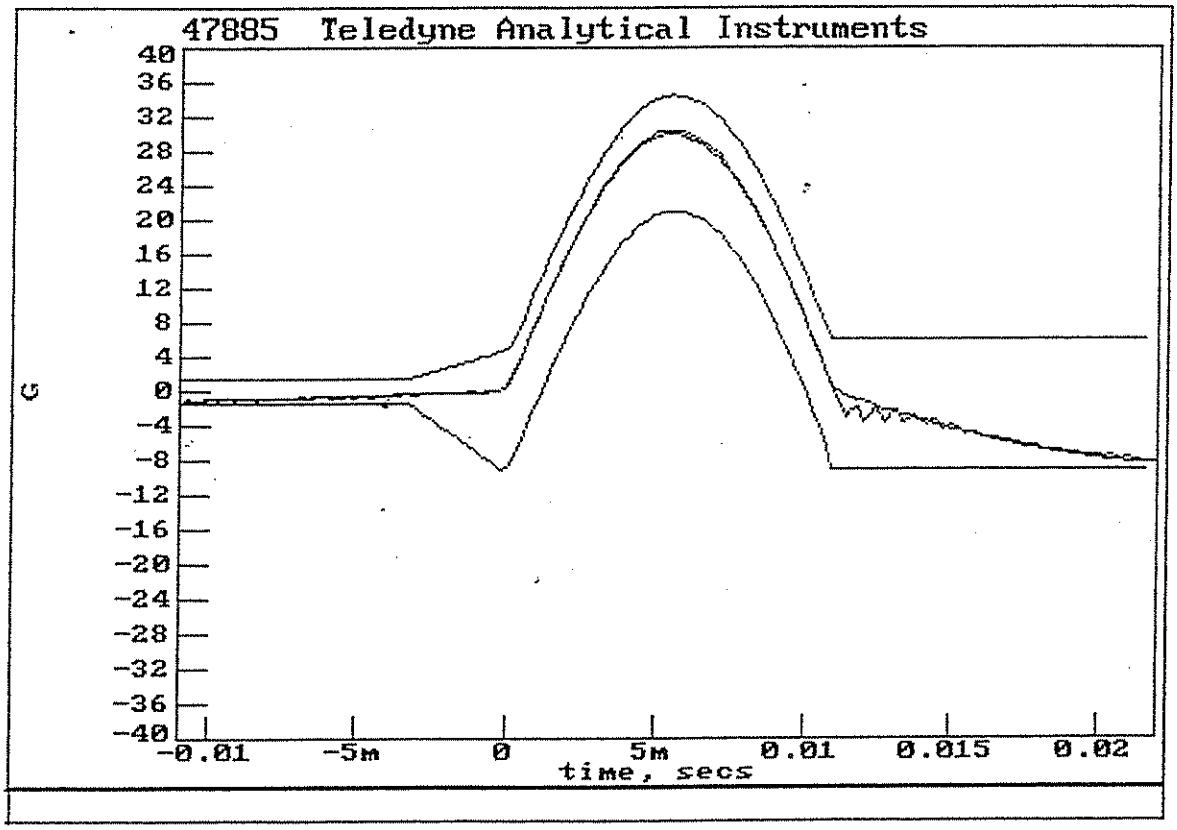
SHOCK PLOT NO. 9

Customer	TELEDYNE ANALYTICAL INSTRUMENTS					Date	11-13-02
Specimen	02 ANALYZER					Job No.	47885
Part No	NA		Serial No.	NA		Operator	RITHY SEY
Test Axis	Y	Accel.	C1	& Axis	Y	Control (X)	Response ( )
Shock No.	3	of	3	Positive	(X)	Negative	( )



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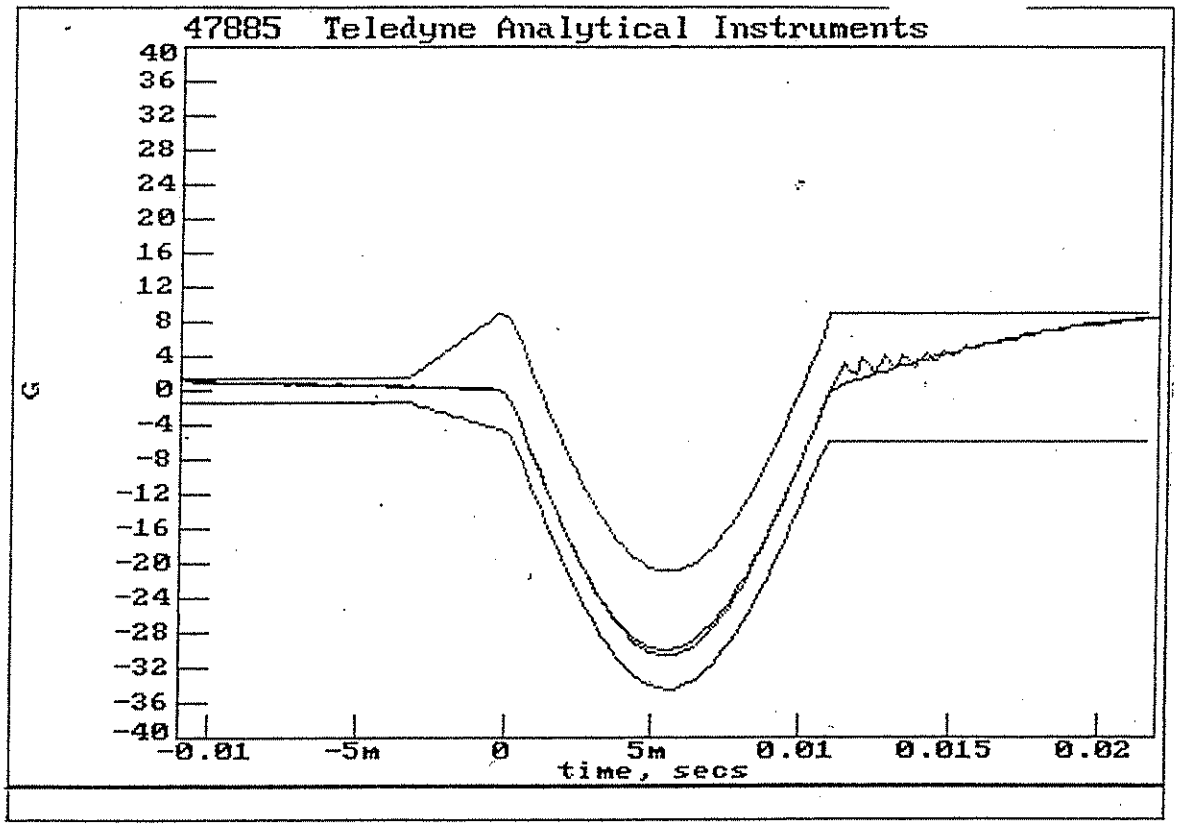
SHOCK PLOT NO. 10

Customer	TELEDYNE ANALYTICAL INSTRUMENTS					Date	11-13-02
Specimen	02 ANALYZER					Job No.	47885
Part No	NA		Serial No.	NA		Operator	RITHY SEY
Test Axis	Y	Accel.	C1	& Axis	Y	Control (X)	Response ( )
Shock No.	1	of	3	Positive	( )	Negative	(X)



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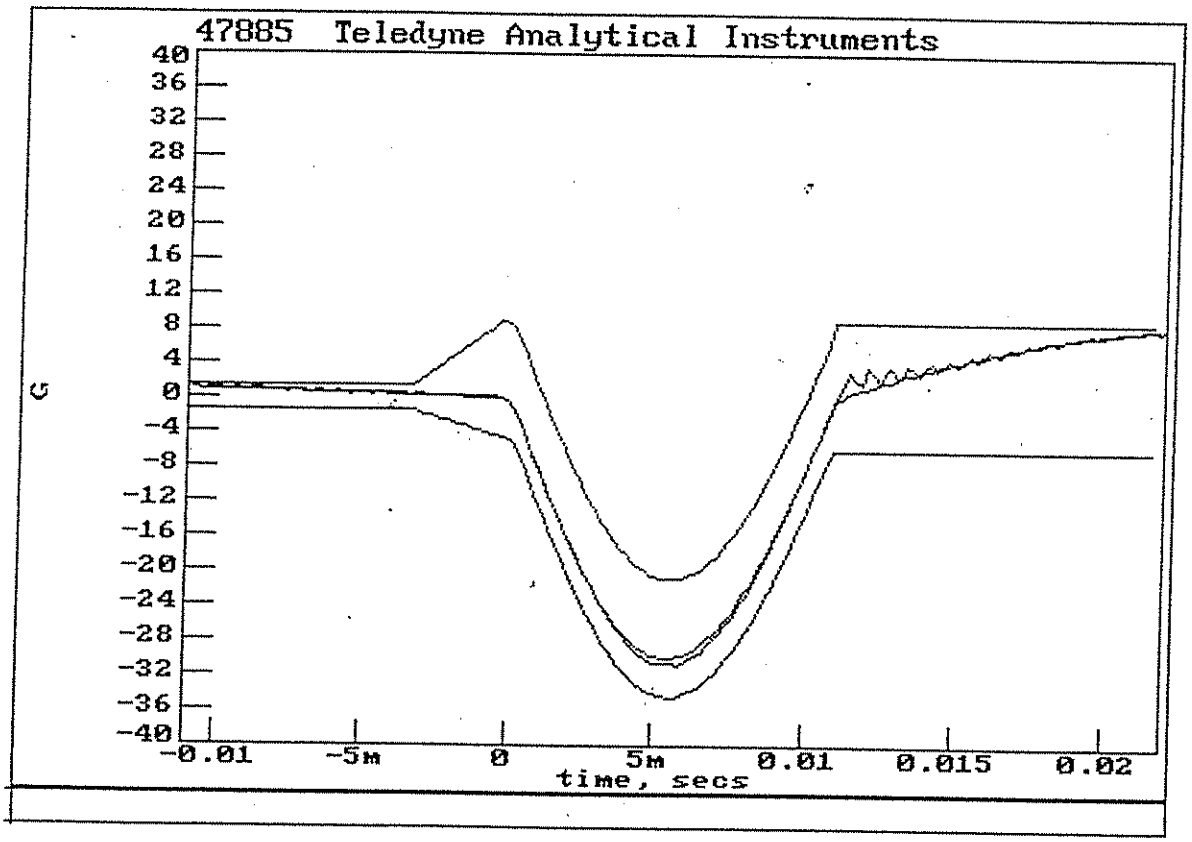
SHOCK PLOT NO. 11

Customer	TELEDYNE ANALYTICAL INSTRUMENTS					Date	11-13-02
Specimen	02 ANALYZER					Job No.	47885
Part No	NA		Serial No.	NA		Operator	RITHY SEY
Test Axis	Y	Accel.	C1	& Axis	Y	Control (X)	Response ( )
Shock No.	2 of	3	Positive	( )	Negative	(X)	



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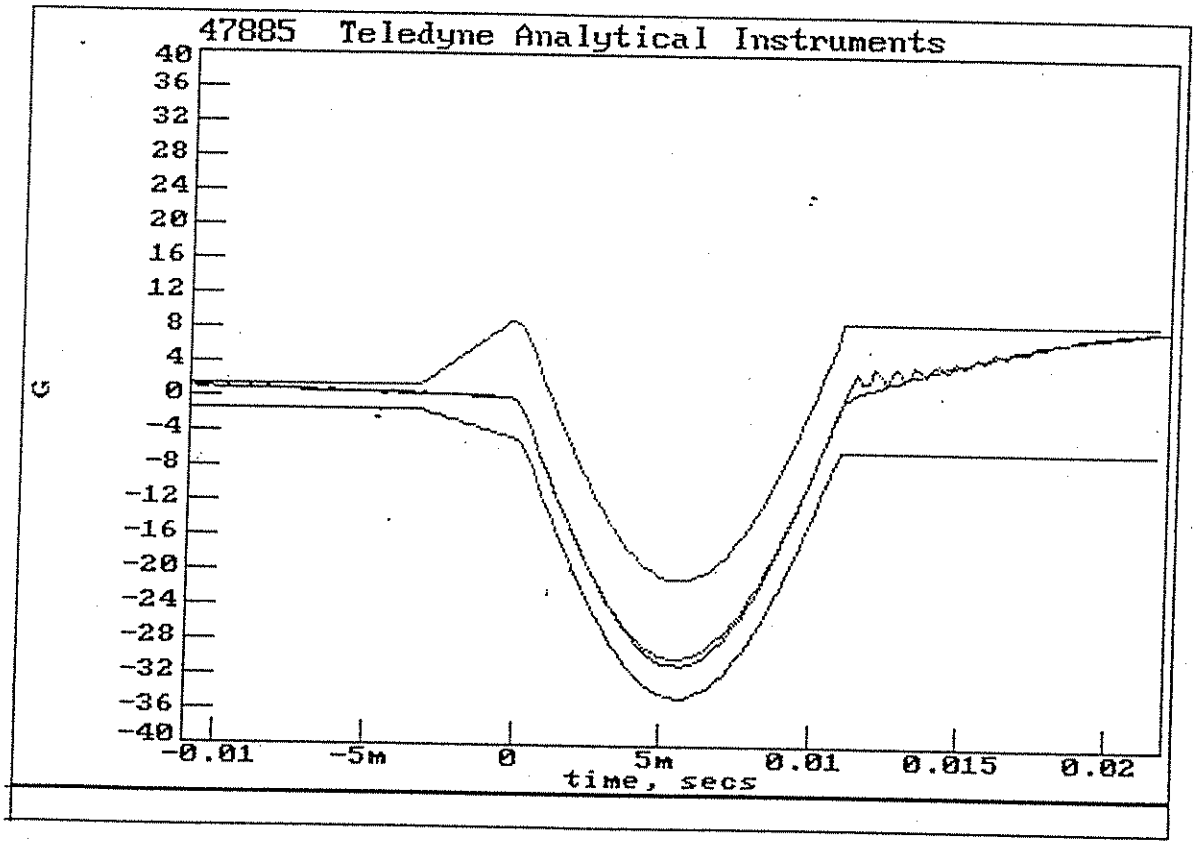
SHOCK PLOT NO. 12

Customer	TELEDYNE ANALYTICAL INSTRUMENTS					Date	11-13-02
Specimen	02 ANALYZER					Job No.	47885
Part No	NA		Serial No.	NA		Operator	RITHY SEY
Test Axis	Y	Accel.	C1	& Axis	Y	Control (X)	Response ( )
Shock No.	3	of	3	Positive	( )	Negative	(X)



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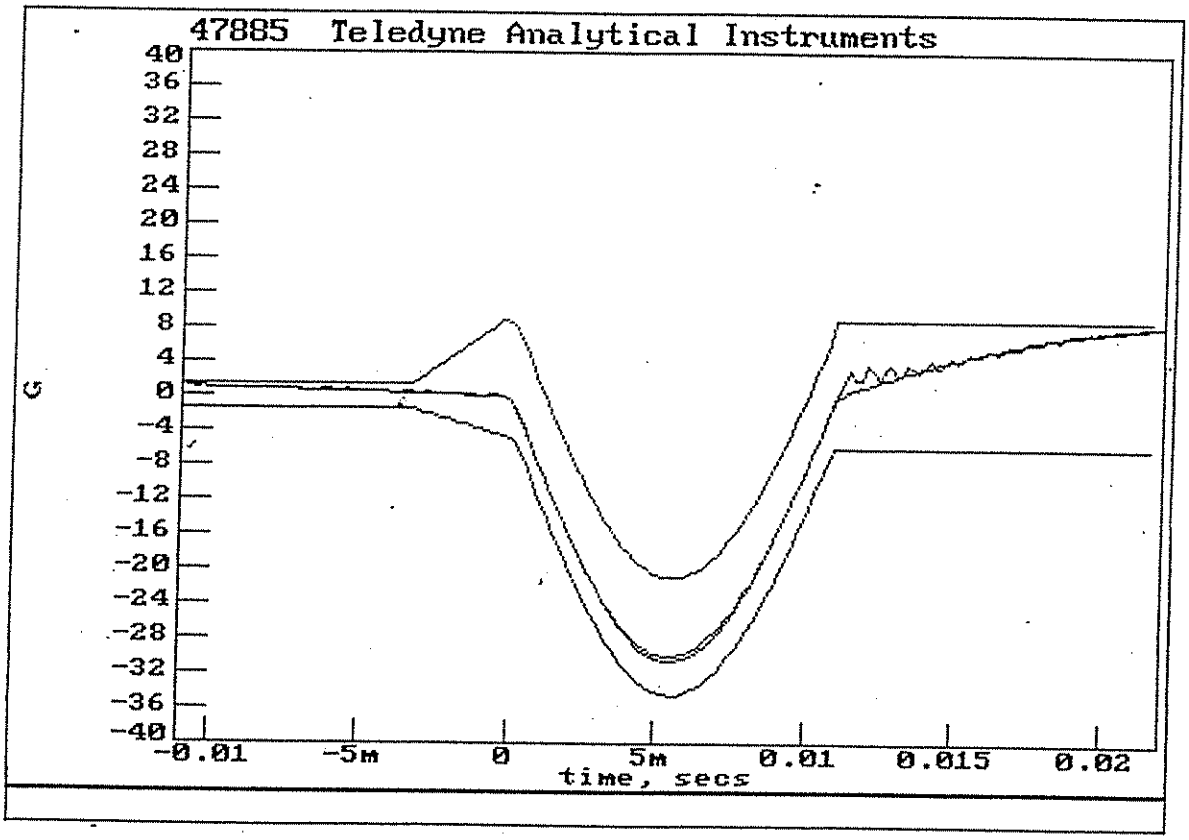
SHOCK PLOT NO. 13

Customer	TELEDYNE ANALYTICAL INSTRUMENTS					Date	11-13-02
Specimen	02 ANALYZER					Job No.	47885
Part No	NA		Serial No.	NA		Operator	RITHY SEY
Test Axis	X	Accel.	C1	& Axis	X	Control (X)	Response ( )
Shock No.	1	of	3	Positive	( )	Negative	(X)



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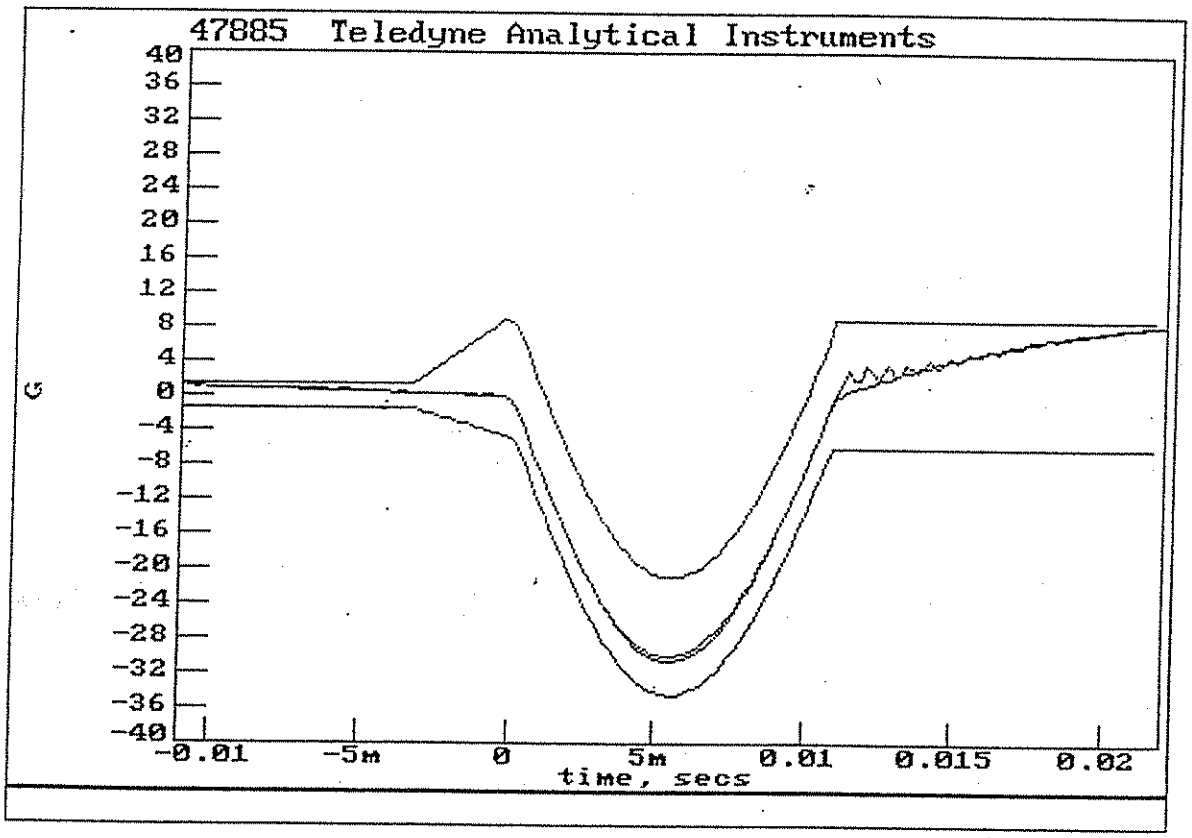
SHOCK PLOT NO. 14

Customer	TELEDYNE ANALYTICAL INSTRUMENTS					Date	11-13-02
Specimen	02 ANALYZER					Job No.	47885
Part No	NA		Serial No.	NA		Operator	RITHY SEY
Test Axis	X	Accel.	C1	& Axis	X	Control (X)	Response ( )
Shock No.	2	of	3	Positive	( )	Negative	(X)



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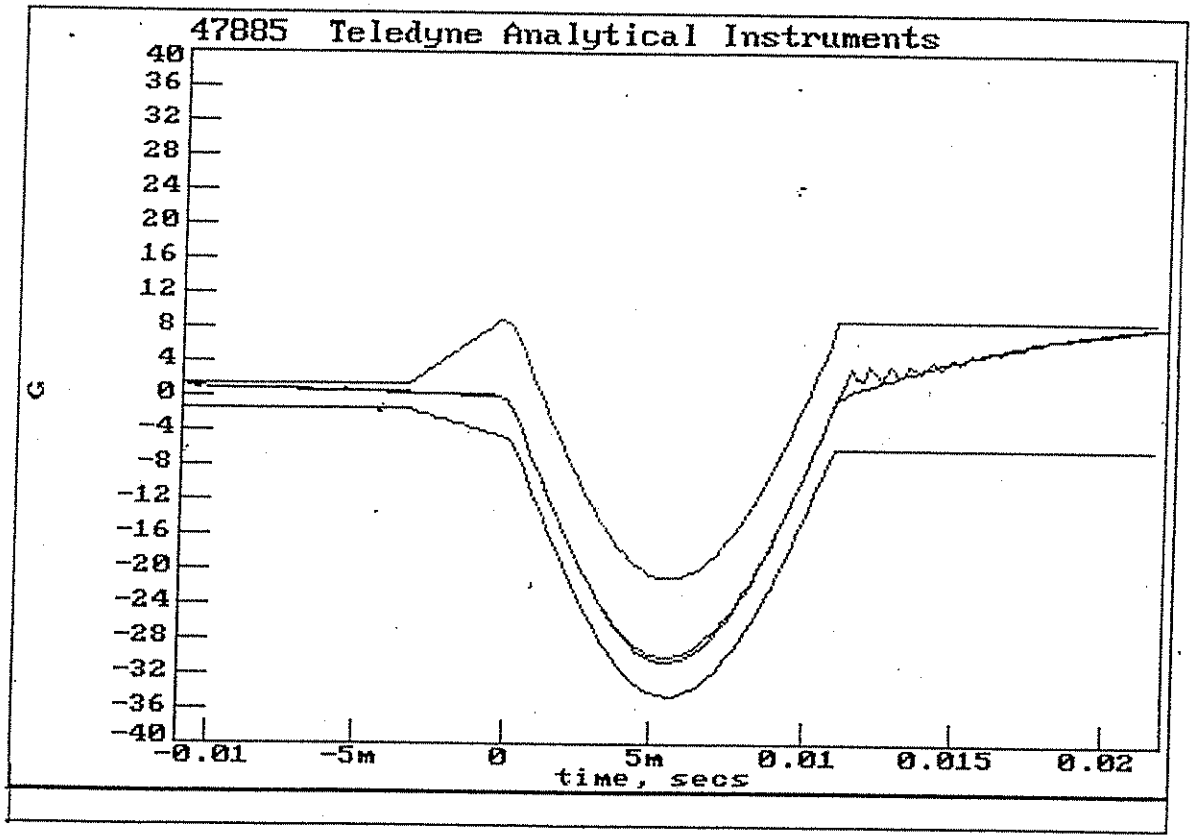
SHOCK PLOT NO. 15

Customer	TELEDYNE ANALYTICAL INSTRUMENTS					Date	11-13-02
Specimen	02 ANALYZER					Job No.	47885
Part No	NA		Serial No.	NA		Operator	RITHY SEY
Test Axis	X	Accel.	C1	& Axis	X	- Control (X)	Response ( )
Shock No.	3	of	3	Positive	( )	Negative	(X)



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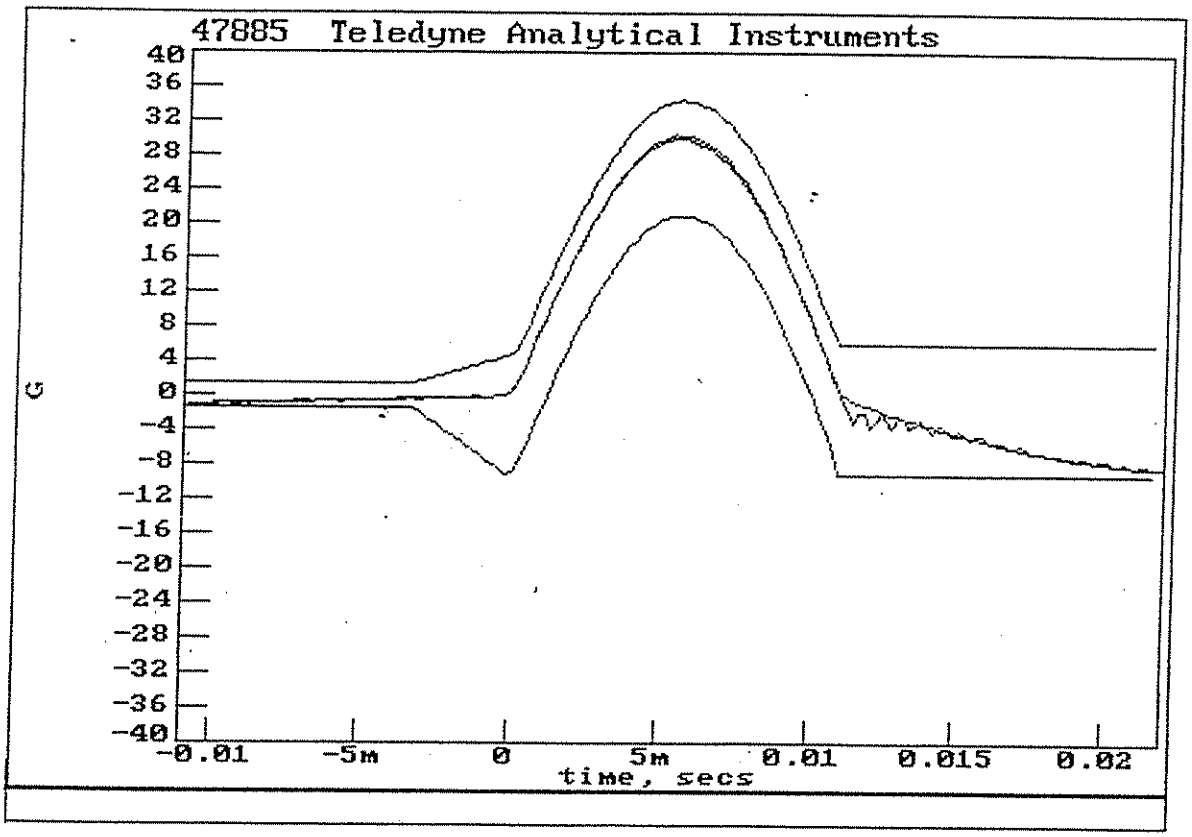
SHOCK PLOT NO. 16

Customer	TELEDYNE ANALYTICAL INSTRUMENTS					Date	11-13-02
Specimen	02 ANALYZER					Job No.	47885
Part No	NA		Serial No.	NA		Operator	RITHY SEY
Test Axis	X	Accel.	C1	& Axis	X	Control (X)	Response ( )
Shock No.	1	of	3	Positive	(X)	Negative	( )



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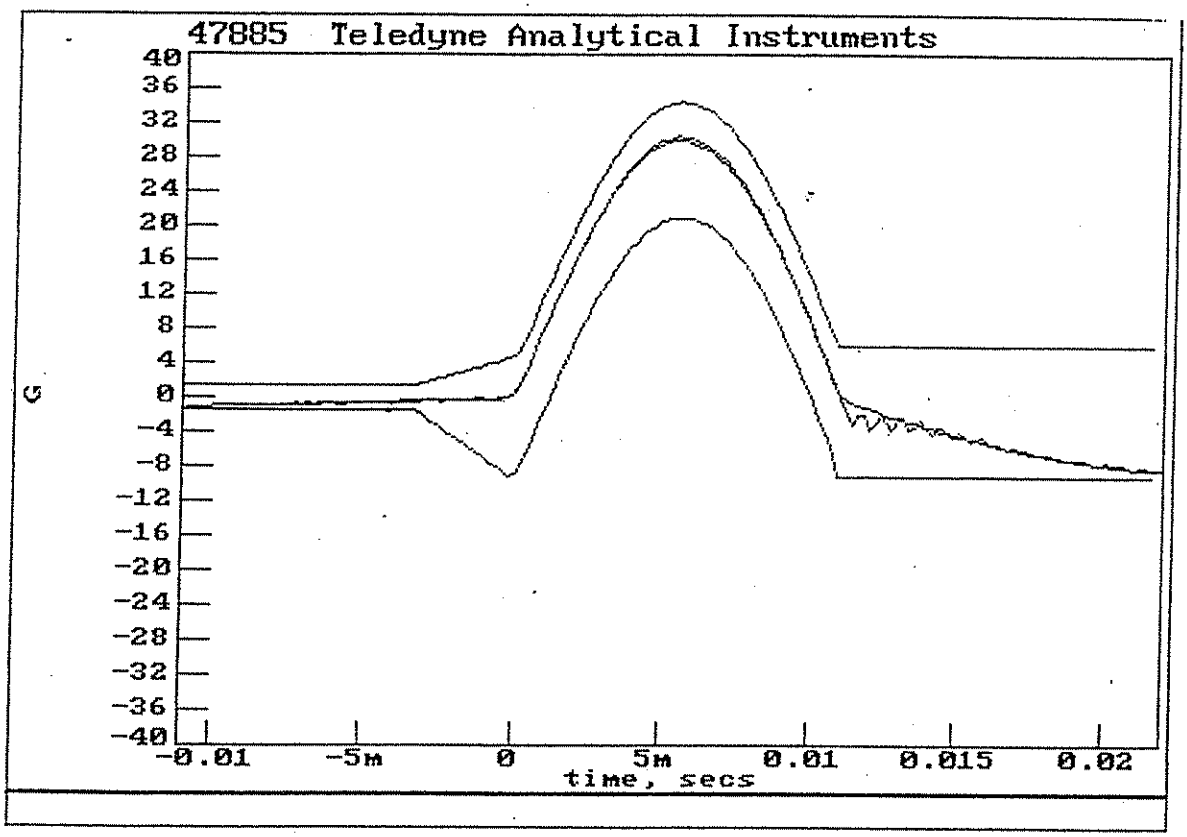
SHOCK PLOT NO. 17

Customer	TELEDYNE ANALYTICAL INSTRUMENTS					Date	11-13-02
Specimen	02 ANALYZER					Job No.	47885
Part No	NA		Serial No.	NA		Operator	RITHY SEY
Test Axis	X	Accel.	C1	& Axis	X	Control (X)	Response ( )
Shock No.	2 of	3	Positive	(X)	Negative	( )	



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SHOCK PLOT NO. 18

Customer	TELEDYNE ANALYTICAL INSTRUMENTS					Date	11-13-02
Specimen	02 ANALYZER					Job No.	47885
Part No	NA		Serial No.	NA		Operator	RITHY SEY
Test Axis	X	Accel.	C1	& Axis	X	Control (X)	Response ( )
Shock No.	3	of	3	Positive	(X)	Negative	( )