### **%**TELEDYNE ANALYTICAL **INSTRUMENTS**

FORM 003 REV. 5

## ENGINEERING CHANGE ORDER

ECO No. 07-0162

(ECO)

ECR No. 07-0169

FILE; FM003-5.DOC

FAMILY:	MOS	TEI :	-	DDE	PARED B	\/.	T DCOB	P110111		
1	11100	AX300,	300-l					. ENGINE		CHANGE CATEGORY
AX300, MX300		MX300,	300-1		cent Fig 10/2/0	7	A	, /ഗ - ಆ ngel Aleg	gria '	MI M2 (M3) REC
REASON FOR CHANG	E:Rev	ised soft	vare so th	at when t	he only th	ne HI alar	m is disa	ble by pu	shing	CAUSE CODE
the HI alarm setting over	100.7	he low a	larm is stil	l function	al at LO s	set point.	Second e	change w	as to	12345678910
add a time out to "unlocke	ed ke	ys mode.	Keys are	returned	to "locke	d" mode a	after 6 se	conds if r	10	SUB-CONTRACT
buttons are pressed. The procedure TP-MX300/AX	ኃብብ /ር	10 Th 11 Th	DF 1/ALID	ATTICALLY	DP124 PA					YES OR (NO)
software change and per	custo.	mer ream	est X car	MILON)	VEA 1 Ki	evised m	anuais to	correspo	ng Wilh	RE-TRAINING REQ.
software change and per		····	/ <u>الــالــِالــِا</u>	- KE-1/	6.6K11	11)-KG	બલ <del>ાઇડ</del>	176765-	51156/5	YES OR NO
AFFECTED			ISION	M	ATER	IAL D	ISPO	SITIC	N	NOTIFIED BODY
	NCORP		<del></del>	N=N/	<u>'A U=U</u>	SE R≕	REWOR	K S=S	CRAP	NOTIFICATION []
DOCUMENTS	Į Ж	INIAR	l le	ON	STOCK	ASSY	TECT	FIN.	F1F1 5	MANUFACTURING
	ס"	yyas	1/22/08	ORDER	STOCK	ASSI	TEST	GOODS	FIELD	EFFECTIVITY
A75012	Χ	48	5,A	R	S	S	S	Ų	U	3/28/08
TPMX300/AX300 (SOFTWARE VALADATION)	Х	0	1	N	N	N	N	N	N	3/25/68
M75708	Χ	0	10/2/07	N	∛N	N	N	N	N	4/21/09
M75389	Х	0	9/27/07	N	*N	N	N	N	N	4/21/09
AX/MX300QS	Χ	0	9/27/07	N	N	N	N	N	N	4/2/108
M75387	X	0	9/27/07	N	メN N	Ν	N	N	N	4/2/09
M75707	Х	0	10/1/07	N	*N	N	N	N	N	4/2/160
FORM A 8 1351	X	<u>.</u>	0	$\mathcal{N}$	N	N	N	N	U	4/11/08
FULM A 81355	X		Ü	$\nu$	N	N	W	N	N	4/11/08
DESCRIPTION OF C	HANG	3E:		ر	11/5/10	REV	11.1216	入// アノつ	< 0.11	D REOKVER
A75012 PROGRAMA	<b>ING</b>	INSTRU	ICTIONS	•	3 )	~		1407C.	) 11116	, redicter
-Change pictorial of la	abel re	evision			1141	ORMA	WOH !	on 577	EE 7 .	5 0/5.
ls: 1.4 was: 1.										, ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
-Change software ver	sion i	n note 2								
is:A75012_4.HEX				Х						
-Add note 5						4	Tele			
PROGRAMMER "CO	NFIG	URATIC	N BITS"				Ana	lytical In:	strumen	ts
OSCILLATOR: OFF			1/22/	a s				ECO F	RELEASE	:
WATCH TIMER; ON POOLINGENT CONTROL CORV										
POWER OF TIMER: OFF										
BROWN OUT DETECT: DISABLED										
BROWN OUT VOLTAGE: 2 5V										
CODE PROTECT: OFF										
$i \neq i$										
3/12/18										
Updated Technical file	e Nar	ne;_ <del>/</del> /			<u> </u>	<del></del>	Date	-//	100	<del></del>
(	HAI	NGE C	ONTRO	OL BO	ARD	(CCB)	(SIG	SNATURE	& DATE)	1 <del>000   1</del>
ENGINEERING:		QUALJT			عبر و مساور و بير بسب	ES:	1010			DAL MARIA OFFI
1014	107		i falla	3-13-0	50 L.	こうえ	ملما بد	3/0 3	GENE	RAL MANAGER:
TEST: (0-10	07	PROD. C	ONTROL:	011		VFIGURA		110/	E. H. S	
Maytaltin	_ '	Patti	mont	, 7/1/0	8 7	7 ~ JL	77.7.	3/12/	E. n. S	**

### 76 TELEDYNE ANALYTICAL INSTRUMENTS

## ENGINEERING CHANGE ORDER (ECO)

ECO No.

07-0162

ECR No

07-0169

sH. 2 of 5

### **DESCRIPTION OF CHANGE:**

### AX/MX300QS MANUAL QUICK START AX300/MX300

-Revised note under "HI ALARM" section page 2 of 2

is: The HI alarm may be defeated by setting the HI alarm limit one step above 100%. The HI alarm setting will display - - to show that it is disabled. The LO alarm is still functional.

was: The HI and LO alarms may be defeated by setting the HI alarm limit one step above 100%. The display will blink ALARM OFF continually in this mode.

### M75708 MANUAL AX300-I M75389 MANUAL AX300

-Add to end of sect 2.1 before note.

is: . If the keys are unlocked but no button pressing action is taken for six seconds, the unit will revert to locked keys mode.

-Revised sect 3.7

is: D) Try calibrating with a known good sensor, if this fails, contact Customer Support.

was: E) Try calibrating with a known good sensor; if this falls, see symptom "Reading drifts over 2-3%..."

-Revised sentence in 2.4 sect ("DO")

is: Always use the plastic flow diverter only when using the tee adapter.

was: Removed the plastic flow diverter only when using the tee adapter

-Add note to section 2.1.1 pg 16 for AX300 manual and pg 15 for AX300-1 manual under step 2 IS: NOTE: THE SENSOR CABLE COMES IN MULTIPLE CONFIGURATIONS. AS SUCH, ANY REFERENCES TO CABLE CONTAINING COILS OR A LOCKING NUT ON THE PLUG MAY NOT REFLECT THE CABLE SUPPLIED WITH A SPECIFIC ANALYZER.

-Add note to section 2.1.5 pg 24 for AX300 manual and pg 22 for AX300-1 manual under figure 2-8

RS232 has been tested with window Hyperterminal. The setup changes with different windows version. If other software than window hyperterminal is used, consult with factory.

### Windows 95 version

Baud:

2400

Data:

Parity:

ODD

Stop bit:

Flow control:

NONE

Windows 98, Windows 2000 and Window XP version:

Baud:

2400

Data:

Parity:

ODD

Stop bit:

Flow control:

NONE

-Revised spare part list on page 48 for AX300 manual and page 44 for AX300-I is: C74721 Cable Assembly was: B69934 Cable Assembly

### TELEDYNE ANALYTICAL **INSTRUMENTS**

### ENGINEERING CHANGE ORDER (ECO)

ECO No

07-0162

ECR No

07-0169

of 5

### **DESCRIPTION OF CHANGE:**

M75387 MANUAL MX300 M75707 MANUAL MX300-I

-Revised note under "HI ALARM" sect 2.1.4

is: The HI alarm may be defeated by setting the HI alarm limit one step above 100%. The HI alarm setting will display - - to show that it is disabled The LO alarm is still functional

was: The HI and LO alarms may be defeated by setting the HI alarm limit one step above 100%. The display will blink ALARM OFF continually in this mode.

-Revised 4TH note under "HI ALARM" sect 2 1 4

is; When HI alarm is disabled (set point above 100%) the set point is shown as two dashes "--". The LO alarm setting is not affected

was: When the alarm is in the OFF condition (set point above 100%) the ALARM OFF status message blinks slowly on the LCD below the oxygen readout

-Revised 2 4 sect "DO"

is: Always use the plastic flow diverter when using the tee adapter.

Was: Remove the plastic flow diverter when using the tee adapter.

is:D) Try calibrating with a known good sensor, if this fails, contact Customer Support.

was: E) Try calibrating with a known good sensor; if this falls, see symptom "Reading drifts over 2-3%."

-Add note to section 2.1.1 pg 16

IS: NOTE: THE SENSOR CABLE COMES IN MULTIPLE CONFIGURATIONS. AS SUCH, ANY REFERENCES TO THE CABLE CONTAINING COILS OR A LOCKING NUT ON THE PLUG MAY NOT REFLECT THE CABLE SUPPLIED WITH A SPE **ANALYZER** 

-Add note to section 2 1 5 pg 24 for AX300 manual and pg 22 for AX300-1 manual under figure 2-8

RS232 has been tested with window Hyperterminal. The setup changes with different windows version. If other software than window hyperterminal is used, consult with factory

### Windows 95 version

Baud:

2400

Data:

Parity: Stop bit: ODD

Flow control:

NONE

Windows 98, Windows 2000 and Window XP version:

Baud:

2400

Data:

Parity:

ODD

Stop bit:

Flow control:

NONE

-Revised spare part list on page 46 for MX300 manual and page 44 for MX300-I

is: Ø74721 Cable Assembly

was: B69934 Cable Assembly

V: 1/21/08

### %TELEDYNE ANALYTICAL **INSTRUMENTS**

## ENGINEERING CHANGE ORDER (ECO)

ECO No

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### **DESCRIPTION OF CHANGE:**

### TPMX300/AX300 SOFTWARE VALIDATION

-Add steps 57, 58 and 59 wuth 4 new steps. Renumber steps that follow as required.

IS:

57	Adjust the High O2 Alarm to above 100%	High Alarm displays	្	Pass
	Verify that the High O2 Alarm set point displayes 2 dashes, and the Low O2 Alarm set point is displayed normally	dashes, Low Alarm displays normally	כ	fail
58	Adjust the High O2 Alarm to above 100%	No alarm sounds	<del>-</del>	Pass
	Set a voltage to obtain a reading of 100%, verify that no alarm is actuated		a	Fail
59	Adjust the High O2 Alarm to above 100%	Alarm sounds	ņ	Pass
	Set the low O2 Alarm to 25%, then set a voltage to obtain a reading of 21%, verify that alarm sounds		ت	Fail
60	Adjust the Sensor voltage to obtain an O2 reading of 21% Set the Low O2 Alarm to 20% Adjust the High O2 Alarm to above	Alarm activates below 20% and	Э	Pass
	100%	Check Sensor on below 18%	Ū	Fail
	Slowly adjust the Sensor voltage for readings from 21.0% down to 0%. Verify that the alarm activates below 20% and the "Check Sensor" icon is on when the reading is below 18%.	10/0W 18/0		

WAS:

57	Adjust the Sensor voltage to obtain an O2 reading of 21% Set the Low O2 Alarm to 20%	Alarm set points off	5	Pass
	Adjust the High O2 Alarm to above 100% Verify that the Low O2 Alarm set point and the High O2 Alarm set point are turned off and the Alarm Off display flashes slowly	flashes slowly	ວ	Fail
58	Adjust the Sensor voltage to obtain an O2 reading of 21% Set the Low O2 Alarm to 20% Adjust the High O2 Alarm to above 100% to turn off the planms	No alaims activate	Ð	Pass
	Adjust the Sensor voltage for readings up to 100% Verify that no alarms are activated		ū	Fail
59	Adjust the Sensor voltage to obtain an O2 reading of 21% Set the Low O2 Alarm to 20% Adjust the High O2 Alarm to above 100% to turn off the alarms	Alarm activates and Check Sensor on	0	Pass
	Slowly adjust the Sensor voltage for readings from 21 0% down to 0% Verify that the slarm activates and the "Check Sensor" icon is on when the reading is below 18%		9	Fail

PRTELEDYNE ANALYTICAL INSTRUMENTS

## ENGINEERING CHANGE ORDER (ECO)

ECO No.

07-0162

ECR No.

07-0169

### **DESCRIPTION OF CHANGE:**

### TP-MX300/AX300 (SOFTWARE VALIDATION) REV 0 (cont.)

5 Add last step to procedure

76	Press the LOCK/UNLOCK button to unlock the keys	Flashing stops around 3 to 9	ន	Pass
	Display should flash slowly. Do not press buttons. Display should stop flashing between 3 and 9 seconds after. Unit reverts to locked mode.	seconds, when not flashing, CAL button has no effect	Э	Fail
	Verify locked mode by pressing the CAL button, calibration should NOT start			

6 Add to instroduction section 1 0 of this procedure, page 2; was: "This document defines the conditions and provides for the recording of the results of the Software Validation Test of the TAI Medical Percent Oxygen Analyzer, Model MX300 and AX300"

is: 'This document defines the conditions and provides for the recording of the results of the Software Validation Test of the TAI Medical Percent Oxygen Analyzer, Model MX300 and AX300 (Including models MX300-I and AX300-I).

()-4/8/08

FORM A81355 REVISION UPDATE INSERT SHEET, A X 300/A X 300-1 FORM A81351 REVISION UPDATE INSERT SHEET, /1/ 300/ pix 300-/ -Initial release

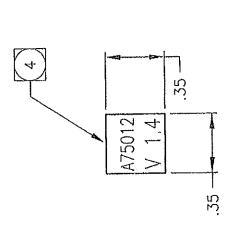
Manual rework instructions for AX300, AX300-I, MX300 and MX300-I Production to add insert Form A81355 for old stock manual for MX300 and MX300-I -Make copies of sheets and cut on dotted line into halves. Each half sheet is inserted inside front cover of

manual.

Production to add insert Form A81351 for old stock manual for AX300 and AX300-I -Make copies of sheets and cut on dotted line into halves. Each half sheet is inserted inside front cover of manual.

Form are located in j:\forms directory Purchasing to re-order manual with new revision level once existing stock | Inventory is used completely.

Z Z 7 Ϋ́F ₹ ₹ ₹ ₹ APP ₹ 12/28/06 10/1/03 10/2/07 6/14/04 DATE REVISIONS INC ECO 04-0042 INC. ECO 06-0193 INC ECO 07-0162 INC ECO 03-0233 DESCRIPTION REV ß 4 N



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3.	T 7 S 7
- •	

PROGRAMMER "CONFIGURATION BITS" WATCHDOG TIMER: ON OSCILLATOR: XT ഗ

BROWN OUT VOLTAGE: 2.5V

BROWN OUT DETECT: DISABLED

POWER UP TIMER: OFF

CODE PROTECT: OFF

	-	-	-		1 582	MICORPROCESSOR, PIC16LC774-1/PT, (MICROCHIP)
		TEM	άJ	PART	PART NO.	DESCRIPTION
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_						

SPECIFIED
OTHERWISE
UNLESS
NOTES:

OBSERVE ALL PROPER ANTI-STATIC PRACTICES	OPERATOR MUST BE PROPERLY GROUNDED.
<u>, '</u>	

PROGRAM P/N 1 582 USING THE FOLLOWING

SOFTWARE FILE: A75012\_4.HEX

ci

TELEDYNE ANALYTICAL INSTRUMENTS A business unit of Teledyne Instruments	TEST PROCEDURE	TEST AND CALIBRATION DEPARTMENT
MODEL NUMBER:	PROCEDURE NUMBER:	PAGE: 1 OF 14
##W000/AW000	TP-MX300/AX300	REV.: 1 REV. DATE: 9/27/07
MX300/AX300	(SOFTWARE VALIDATION)	ECO #: 07-0162

PRELIMINARY PRINT DATE 9/22/67 INIT

### WARNING

TESTING OF THIS INSTRUMENT MAY INVOLVE ELECTROSTATIC SENSITIVE DEVICES (ESD), HIGH VOLTAGE. PERSONNEL WHO ARE NOT FAMILIAR WITH PROCEDURES FOR THE ABOVE MUST CHECK WITH THEIR SUPERVISOR PRIOR TO BEGINNING THE TEST.

CONCURRENCE	DATE	CONCURRENCE	DATE
ORIGINATOR		SENSOR DEPARTMENT	
PRODUCTION ENGINEER		QUALITY ASSURANCE	
TEST DEPARTMENT		отнея	

## MODEL NUMBER: PROCEDURE NUMBER: PAGE: 2 OF 14 MX300 / AX300 TP-MX300/AX300 REV.: 1 REV. DATE: 9/27/07

TP-MX300/AX300 (SOFTWARE VALIDATION) ECO #: 07-0162

### 1.0 INTRODUCTION

This document defines the conditions and provides for the recording of the results of the Software Validation Test of the TAI Medical Percent Oxygen Analyzer, Model MX300 and AX300 (including models MX300-I and AX300-I).

### 2.0 APPLICABLE DOCUMENTS

FDA Guidance Document on Software Validation Statement of Work MX300/AX300

### 3.0 TEST OBJECTIVE

The objective of this test is to validate the software of the MX300 / AX300 oxygen monitor / analyzer.

### 4.0 TEST DESCRIPTION

The testing is performed at room temperature and includes testing of all functions of the MX/AX 300 Oxygen Analyzer to insure the software is functioning properly and is in compliance with design specification.

### 5.0 TEST EQUIPMENT

- 5.1 Power Requirement- The device is powered by 4.5V DC which should be provided by an adjustable DC power supply
- 5 2 Equipment Requirements As follows
  - (a) Keithley Voltage Source, Model 220 or equivalent
  - (b) DMM Fluke Model 8020A or equivalent
  - (c) RS232 cable
  - (d) PC computer with Window's Terminal or equivalent software installed
  - (e) DC Power Supply, HP 6237B or equivalent
  - (f) Stopwatch

# MODEL NUMBER: PROCEDURE NUMBER: PAGE: 3 OF 14 TP-MX300/AX300 (SOFTWARE VALIDATION) PAGE: 3 OF 14 REV.: 1 REV. DATE: 9/27/07 ECO #: 07-0162

### 6.0 TEST SETUP

Set up the unit to be tested per Figure 1

### 7.0 SETUP

Set the mode switches for 3 1/2 digit display, analog output and alarms enabled (i.e., JP3 only)

Calibration: Unless otherwise specified, calibrate the instrument as follows:

Use a Sensor Simulator with a series resistance of 100 Ohms

Set the sensor voltage to 50 mV, +/- 0.02 mV. Calibrate the instrument for 100.0% +/- 0.2% O2.

When the test calls for setting the sensor voltage, adjust the Sensor Simulator to the specified voltage +/- 0 05 mV

For battery supply, connect a variable supply capable of 2.0 to 6.0 volts at 10 mA minimum. Unless otherwise specified, set the battery voltage to 4.5 +/- 0.02 Volts.

When the test calls for setting the Battery Voltage, adjust the supply to the specified voltage +/- 0.02 Volts

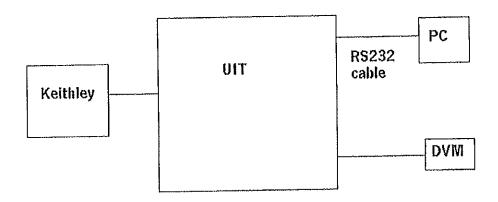


FIGURE 1

MODEL NUMBER:	PROCEDURE NUMBER:	PAGE: 4 OF 14
	TP-MX300/AX300	REV.: 1 REV. DATE: 9/27/07
MX300 / AX300	(SOFTWARE VALIDATION)	ECO#: 07-0162

171	X300 / AX300	(SOFTWARE VALIDATION)	ECO#: 07-0162	
STEP#	OPE	RATOR ACTION	RESULT	PASS / FAIL
1		est (POST) Verify the Alarm LED and	LED illuminates temporarily & audio tone temporarily	□ Pass □ Fall
2	Verify that all LCD segmen	nts are turned on temporarily during POS	T All segments on	Ø Pass □ Fail
3	Self-test. With an instrument the instrument passes the Powmode flashing 0 00	set up normally, apply power and verify that ver-On Self Test and enters the Pre-Calibratio	Unit powers on without errors	Pass    Pass
4	Turn off the unit and remove and install the batteries. Verit condition and does not start.	the batteries. Hold the calibration key pressed y that the instrument beeps, displays an error	d POST fails	E Pass  D Fail
5	that the error is show	wn the key shownapply power and verify n on the display. Repeat for each key	□ Batt Key Err = 61 □ Cal Key Err = 62 □ Up Key Err = 63 □ Dn Key Err = 64 □ Sil Key Err = 65 □ Hi Key Err = 66 □ Alm Key Err = 67 □ Lock Key Err = 68	Pass  Fail  Pass
6	I waste that the Angles output	ted during POST by using an oscilloscope to t pulses up to 1.0 v +/- 0 2 volts for 40 to 200 to 0 +/- 0 1 volt and no errors are shown on t	)   VOIIS	O Fall
7	Turn power off. Connect Install batteries Verify th	a 50 Ohm resistor across the analog outp at an error occurs	out. 50 Ohm resistor causes Err 7.1	@ Pass
8	Pre- Calibration Mode with	onck on. The unit should automatically enter the display flashing 0 00 Set the Sensor volt key. The unit should count down from 10 to test the Lock key and the unit should enter the 9%.	0 automatically	© Pass □ Fail

		PROCEDURE NUMBER:	PAGE: 5 OF 14	:		
MODEL NUMBER:			REV.: 1 REV. DATE: 9/27/07			
MX	300 / AX300	TP-MX300/AX300 (SOFTWARE VALIDATION)	ECO#: 07-0162			
			-	PASS / FAIL		
STEP#	OPE	RATOR ACTION	RESULT			
9	verify the O2 display flashes Alarm display flashes Using	n the normal mode, press the Lock key and Press the Hi Alarm key and verify that the Hitle Up/Down keys, verify that each time the ges in the proper direction Hold a key down rements automatically in the direction of the	activations Autokey	Pass  () Fail		
10	Adjust the Sensor voltage to that the Check Sensor icon is	display 21% Disconnect the sensor and veri	fy Sensor error	Pass  D Fail		
11	Set the voltage to 3.4 Volts a activate	nd verify that the battery alarm does not	No Alarms	Pass    Fail		
12	Set the voltage to 3.2 Volts a with no segments activated	nd verify that the Battery Icon outline apper	Low Buttery Icon Active	P Pass		
13	Set the voltage to 3 2 Volts a with no segments activated that the battery icon turns of	and verify that the Battery Icon outline appea Then raise the voltage up to 3 4 Volts and ve f.	Low Battery Icon turns off.	Pass  G Fail		
14	voltage slowly and observe t	and hold down the Battery Test key. Lower the battery status on the display. Verify that the bases to zero as the voltage is lowered to 3.4 erify that the battery status icon turns off.	tto   decicase na outroi)	& Poss		
15	Set the voltage to 3 6 Volts the backlight is off Measure that it is below 1.4 mA	Set the instrument so all alarms are inactive at the current drain with a milliamp meter. Ve	and rify (Less than 1 4 mA)	D Pass		
16	Set the voltage to 4 0 Volts verify that the instrument sh	Gradually lower the voltage to 3 0 volts and uts down.	Shuts down	Pass		
17	Circuit accuracy test. Set the voltage to 5 0 mV. Record to 0.5%	e Battery Voltage to 3.3 Volts. Set the sensor the reading. Verify the O2 reading is 10 0 +/-	/0.0 % O2 (9.5 to 10.5 %)	Pass  O Fail		
18	Circuit accuracy test. Set the voltage to 5 0 mV. Record to 5 %	e Battery Voltage to 5.0 Volts. Set the senso the reading. Verify the O2 reading is 10.0 +/-	/ / / / / % O2 (9.5 to 10.5 %)	@ Pass		
19	Circuit accuracy test. Set th voltage to 10 0 mV. Record 0 5%	e Battery Voltage to 3 3 Volts. Set the senso I the reading. Verify the O2 reading is 20 0 +	r /- <u>20./</u> % O2 (19.5 to 20.5 %)	D Pass		

#### PAGE: 6 OF 14 PROCEDURE NUMBER: MODEL NUMBER: REV. DATE: 9/27/07 REV.: 1 TP-MX300/AX300 MX300 / AX300 ECO#: 07-0162 (SOFTWARE VALIDATION) OPERATOR ACTION RESULT PASS / FAIL STEP# Pass Circuit accuracy test Set the Battery Voltage to 5.0 Volts Set the sensor 20.1 %02 20 voltage to 100 mV Record the reading. Verify the O2 reading is 20 0 +/-Fail (19.5 to 20.5 %) 0.5% Pass Circuit accuracy test Set the Battery Voltage to 3 3 Volts. Set the sensor 981 %02 21 voltage to 49 0 mV Record the reading Verify the O2 reading is 98.0 +/-Fail $\Box$ (97.5 to 98.5 %) 0.5% 4 Pass Circuit accuracy test Set the Battery Voltage to 5 0 Volts Set the sensor 95.1 %02 22 voltage to 490 mV Record the reading. Verify the O2 reading is 98.0 +/-Fail (97.5 to 98.5 %) 0.5% Pass Circuit Response time Set the Battery Voltage to 5.0 Volts Adjust the // U Seconds 23 sensor voltage for an O2 reading of 99 +/- 1%. Unplug the sensor and wait Fail 15 seconds. Verify that the O2 reading is less than 0.4% At the same time, (Less than 8 Sec) start a stopwatch and plug in the sensor. When the O2 reading exceeds 88.2 %, stop the stopwatch Verify that the time is less than 8 seconds Pass Circuit Response time. Set the Battery Voltage to 3 3 Volts Adjust the 1.3 \_ Seconds 24 sensor voltage for an O2 reading of 99 +/- 1%. Unplug the sensor and wait Fail O 15 seconds Verify that the O2 reading is less than 0.4% At the same time, (Less than 8 Sec) start a stopwatch and plug in the sensor When the O2 reading exceeds 88 2 %, stop the stopwatch Verify that the time is less than 8 seconds Pass Circuit Response time. Set the Battery Voltage to 5 0 Volts Adjust the Z./\_ Seconds 25 sensor voltage for an O2 reading of 99 +/- 1% and wait 15 seconds At the Fail same time, start a stopwatch and unplug in the sensor When the O2 reading (Less than 8 Sec) drops below 9 9%, stop the stopwatch Verify that the time is less than 8 seconds Pass Pass Circuit Response time. Set the Battery Voltage to 3 3 Volts Adjust the 1,62 Seconds 26 sensor voltage for an O2 reading of 99 +/- 1% and wait 15 seconds At the 0 Fail same time, start a stopwatch and unplug in the sensor When the O2 reading (Less than 8 Sec) drops below 9.9%, stop the stopwatch Verify that the time is less than 8 seconds. Pass DAC accuracy test. Connect a 10k resistive load to the Analog output. Set 51.3 m/Volts 27 the Battery Voltage to 5.0 Volts. Adjust the sensor voltage for an O2 □ Fail reading of 05% +/-05% Record the reading and verify that the Analog (0.04 to 0.06 Volts) output measures 0 05 +/- 0.01 Volts. 51.2mVolis Pass Without changing the setup for the previous test, adjust the battery voltage 28 to 3 3 Volts and wait 5 seconds. Record the voltage and verify that it did not Difference Fail change by more than 0 5% from the previous test. (Diff= -05 to 05%) DAC accuracy test Connect a 10k resistive load to the Analog output Set 2 Pass the Battery Voltage to 5 0 Volts Adjust the sensor voltage for an O2 2008 Volts 29 reading of 20% +/- 0 5%. Record the reading and verify that the Analog O Fail

(0 195 to 0 205 Volts)

output measures 0 2 +/- 0 01 Volts

### PAGE: 7 OF 14 PROCEDURE NUMBER: MODEL NUMBER: REV. DATE: 9/27/07 REV.: 1 TP-MX300/AX300 MX300 / AX300 (SOFTWARE VALIDATION) ECO #: 07-0162 PASS / FAIL RESULT OPERATOR ACTION STEP# Pass 200.7 Volts Without changing the setup for the previous test, adjust the battery voltage 30 to 3 3 Volts and wait 5 seconds Record the voltage and verify that it did not Difference Fail change by more than 0 5% from the previous test. (Diff = -05 to 05%) Pass DAC accuracy test. Connect a 10k resistive load to the Analog output Set 990,2- Volts 31 the Battery Voltage to 5 0 Volts Adjust the sensor voltage for an O2 Fail reading of 99% +/- 0.5%. Record the reading and verify that the Analog (0 985 to 0 995 Volts) output measures 0 99 +/- 0 005 Volts 990. | Volts Pass Without changing the setup for the previous test, adjust the battery voltage 32 to 3 3 Volts and wait 5 seconds. Record the voltage and verify that it did not osci\_\_Difference П Fail change by more than 0.5% from the previous test (Diff = -05 to 05%) Pass With no alarms no active, set the keyboard to the Locked mode. Press each 33 □ Low Alarm OK key listed on the right and verify that the backlight turns on immediately and Fail automatically turns off 2 +/- 1 seconds later. Also verify that no other □ Up OK activity occurs and the display does not change (other than the reading). □ High Alarm OK □ Battery Check OK Down OK ☐ Alarm Test OK Cal OK ☐ Silence OK Pass Set the High alarm to 40% Adjust the sensor simulator so that the reading is □ LowAlarm 34 45% and the alarm is active. Set the keyboard to the Locked mode. Press - no effect Fail U each key listed on the right and verify that the keys have not effect, except □ Up - no effect that the Silence key turns off the audio alarm and the BatteryChk key shows ☐ HiAlarm - no effect the battery status □ BatteryChk -active O Down - no effect [] AlarmTest - no effect ☐ Cal - no effect ☐ Silence - quiets alarm

### PAGE: 8 OF 14 PROCEDURE NUMBER: MODEL NUMBER: REV. DATE: 9/27/07 REV.: 1 TP-MX300/AX300 MX300 / AX300 07-0162 (SOFTWARE VALIDATION) ECO#: PASS / FAIL RESULT OPERATOR ACTION STEP# Pass Set the Sensor voltage to 13.0 mV Verify that the unit calibrates at 20 9% For each test shown below, set the sensor voltage and record the 35 corresponding O2 reading. Verify that the O2 reading is within 1 0% Fail 100 % 62 2 mV 99 0 to 101 0% 49.9% 49 0 to 51 0% 31.1 mV 208% 199 to 21.9% 13.0 mV 9.9 % 90 to 11.0% 6 22 mV Pass Set the Sensor voltage to 10.0 mV. Verify that the unit calibrates at 20 9% For each test shown below, set the sensor voltage and record the 36 corresponding O2 reading. Verify that the O2 reading is within 1 0% Fail O A 99.9% 99 0 to 101.0% 47 85 mV 50.0 % 49 0 to 51.0% 23 92 mV В 19.9 to 21.9% 100 mV C 9.0 to 11.0% 4 78 mV D. 00. J % 0.0 mV 0.0 to 1.0% Ē. Set the Sensor voltage to 5.2 mV. Verify that the unit calibrates at 20 9% Pass For each test shown below, set the sensor voltage and record the 37 corresponding O2 reading Verify that the O2 reading is within 1 0%. Fail 24.88 mV 99 0 to 101.0% A. 12.44 mV 49 0 to 51 0% В. 19.9 to 21.9% 5.2 mV 90 to 110% 2 49 mV n Pass Set the Sensor voltage to 62 20 mV. Verify that the unit calibrates at 100.0% For each test shown below, set the sensor voltage and record the 38 corresponding O2 reading Verify that the O2 reading is within I 0% Fail 0 99 0 to 101 0% 62 20 mV A 49.0 to 51 0% 31 10 mV B. 20.8% 13 00 mV 20.0 to 22.0% C 9.9 % 90 to 11.0% 6 22 mV D.

### 9 OF 14 PAGE: PROCEDURE NUMBER: MODEL NUMBER: REV. DATE: 9/27/07 **REV.: 1** TP-MX300/AX300 MX300 / AX300 ECO#: 07-0162 (SOFTWARE VALIDATION) OPERATOR ACTION RESULT PASS/FAIL STEP# Pass Set the Sensor voltage to 47.85 mV. Verify that the unit calibrates at 100.0%. For each test shown below, set the sensor voltage and record the 39 corresponding O2 reading Verify that the reading is within 10% of the Fail $\Box$ specified voltage. 100.0% 47 85 mV 99 0 to 101.0% 49 0 to 51.0% 23 92 mV 19.9 to 21 9% 10 00 mV C 10.0 % 90 to 11.0% 4 78 mV @ Pass Set the Sensor voltage to 28.35 mV. Verify that the unit calibrates at 100 0%. For each test shown below, set the sensor voltage and record the 40 corresponding O2 reading. Verify that the reading is within 1 0% of the Fall Ü specified voltage A /<u>UU.U</u>% 99.0 to 101.0% 28.35 mV 49 0 to 51 0% 14 00 mV B. 199 to 21.9% 5.85 mV Ç. 2.8 mV 9.0 to 11.0% Pass Set the Sensor voltage to the value in the table. Press the Cal key and verify Check Sensor that the Check Sensor indicator is activated and the calibration cannot be 41 indicator and Cal □ Fail fails at: completed No Sensor Fails 4.23 mV Fails 13.77 mV Fails 20.00 mV Fails 27.09 mV Fails 65.87 mV Fails 75.00 mV Fails \_

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MX300 / AX300

TP-MX300/AX300 (SOFTWARE VALIDATION)

**REV.: 1** 

MX300 / AX300		(SOFTWARE VALIDATION)	CO#: 07-0162		
STEP#	OPE	RATOR ACTION	RESULT	PASS / FAIL	
42	Set the Sensor voltage to the v	alue in the table. Press the Cal key and verify value indicated and the Check Sensor indicate k key and repeat for each value in the table	Check Sensor indicator does not activate and Calibration is successful  4.44mV 20 9% OK	2 Pass	
43	to obtain a reading of 50.0%.	nV. Calibrate at 20 9% Set the Sensor voltage. Turn off the instrument Wait 10 seconds or ment back on. Verify that the reading still	Retained calibration reading Ju. (49.0% to 51.0%)	@ Pass	
44	set the mode to High Alarm 20% and lock the keyboard	obtain an O2 reading of 100%. Set the Low C Verify that the set point can be adjusted to For High Alarm setpoints of 50% and 99%.	O2	Pass  () Fail	
45	Adjust the Sensor voltage to Alarm to 100%  Set the mode to Low Alarm and lock the keyboard.	obtain an O2 reading of 19%. Set the High C Verify that the set point can be adjusted to 2 for Low Alarm setpoints of 50% and 99%.	D Sets ok to 50%	15 Pass	
46	Adjust the Sensor voltage to Alarm to 20%  Set the mode to High O2 Alakeyboard  Set the mode to Low Alarm 49.9% Continue to adjust the	obtain an O2 reading of 49% Set Low O2  arm. Adjust the set point to 50% and lock the  Verify that the set point can be adjusted up to Low Alarm up to 98 0% and verify that the pushed above the Low Alarm.	pushing the High Alarm above it.	Pass  Fail	
47	Adjust the Sensor voltage to O2 Alarm to 90% and the Landt activate.	obtain an O2 reading of 21 0% Set the High ow O2 Alarm to 20 0% Verify that alarm do	h es No Alarms	D Pass	

### 11 OF 14 PROCEDURE NUMBER: PAGE: MODEL NUMBER: REV. DATE: 9/27/07 REV.: 1 TP-MX300/AX300 MX300 / AX300 (SOFTWARE VALIDATION) ECO#: 07-0162 PASS / FAIL STEP# OPERATOR ACTION RESULT O Pass Adjust the Sensor voltage to obtain an O2 reading of 21 0%. Set the High No Alarms O2 Alarm to 22.0% and the Low O2 Alarm to 19%. Verify that the alarm 48 Fail IJ does not activate Adjust the Sensor voltage to obtain an O2 reading of 21% Set the High O2 U Pass Low O2 visual Alarm to 90% and the Low O2 Alarm to 22%. Verify that the alarm 49 Alarm and audio Fail $\Box$ alarm both activates. activated. Pass Adjust the Sensor voltage to obtain an O2 reading of 21% Set the Low O2 No Alarms Alarm to 18% and the High O2 Alarm to 22% Verify that the alarm does 50 Fail not activate Adjust the Sensor voltage to obtain an O2 reading of 21% Set the Low O2 Pass High O2 visual Alarm to 18% and the High O2 Alarm to 20%. Verify that the alarm 51 Alarm and audio Fail П alarm both activates activated Adjust the Sensor voltage to obtain an O2 reading of 21%. Set the Low O2 Poss Audio alarm Alarm to 18% and the High O2 Alarm to 25% Adjust the Sensor voltage for 52 silences for 115 to an O2 reading of 28% and verify that both the visual High O2 and audio Fall 120 secs. alarms are activated. Press the Silence key and start a timer. Verify that the Secs audible alarm is silent for 115 to 120 seconds, after which the audible alarm silent sounds again. Record the silent time. Adjust the Sensor voltage to obtain an O2 reading of 21%. Set the Low O2 7 Pass Audio alarm Alarm to 20% and the High O2 Alarm to 25%. Adjust the Sensor voltage for 53 silences for 115 to an O2 reading of 18% and verify that both the visual Low O2 and audio Fall П 120 secs. alarms are activated. Press the Silence key and start a timer. Verify that the 116 \_ Secs audible plarm is silent for 115 to 120 seconds, after which the audible plarm silent sounds again. Record the silent time Adjust the Sensor voltage to obtain an O2 reading of 21% Set the Low O2 Pass Pass Audio alarm has Alarm to 20% and the High O2 Alarm to 25% Adjust the Sensor voltage for 54 bursts an O2 reading of 18% and listen to the audio alarm Adjust the Sensor Fail voltage for an O2 reading of 28% and listen to the audio alarm Verify that the alarm is not a continuous tone, but has bursts that identify it as a high priority alarm (3 beeps, short pause, 2 beeps, long pause) O Poss User interface test. Unlock the keyboard and verify that pressing the Alarm Visual and audio Test key starts the alarm test which activates the high and low alarms as well 55 alarms activated. as the audio alarms and that the test turns off automatically Fail П Adjust the Sensor voltage to obtain an O2 reading of 21% Set the Low O2 Poss

High Alarm adjusts

() Fail

above 100%

56

Alarm to 20%

Adjust the High O2 Alarm to above 100%

### MODEL NUMBER:

MX300 / AX300

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TP-MX300/AX300 (SOFTWARE VALIDATION) PAGE: 12 OF 14

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ECO#: 07-0162

	(SOFTWARE VALIDATION) E	CO#, 07-0102	و د انتخاب و این برین می می می این این برای برای برای برای برای برای برای برای
STEP#	OPERATOR ACTION	RESULT	PASS/FAIL
57	Adjust the High O2 Alarm to above 100%  Verify that the High O2 Alarm set point displayes 2 dashes, and the Low O2 Alarm set point is displayed normally.	High Alarm displays dashes, Low Alarm displays normally	C⊬ Pass □ Fail
58	Adjust the High O2 Alarm to above 100%  Set a voltage to obtain a reading of 100%, verify that no alarm is actuated	No alarm sounds.	Poss    Fail
59	Adjust the High O2 Alarm to above 100%.  Set the low O2 Alarm to 25%, then set a voltage to obtain a reading of 21%, verify that alarm sounds	Alarm sounds	Ø Pass □ Fail
60	Adjust the Sensor voltage to obtain an O2 reading of 21% Set the Low O2 Alarm to 20% Adjust the High O2 Alarm to above 100%.  Slowly adjust the Sensor voltage for readings from 21.0% down to 0%. Verify that the alarm activates below 20% and the "Check Sensor" icon is on when the reading is below 18%.	Alarm activates below 20% and Check Sensor on below 18%	O Pass
61	Adjust the Sensor voltage to obtain an O2 reading of 21% Set the Low O2 Alarm to 20% Adjust the High O2 Alarm to 25%. Turn the instrument off for 10 seconds and then turn it back on. Verify that the High and Low O2 alarm set points are still 20% and 25%	Alarm set points retained at 20% and 25% after power off	Pass
62	Setup the unit to run in the normal mode continuously displaying O2 Verify that the unit is operating normally and then connect a 50 Ohm resistor across the analog output Verify that Error 3 occurs	Unit powers on with E3 0	Pass    Fail
63	Setup the unit to run in the normal mode continuously displaying O2. Use a precision voltage source for the sensor. Monitor the reading over 1 hour and record the high and low readings. The difference should be less than +/- 20 %	Difference < 2 %  Max 20. 7  Min 20 4  Diff 0.0	(A Pass  () Fail
64	Remove batteries Attempt to install one or more of the batteries backwards. Verify that the unit does not turn on install the batteries properly and verify that the unit turns on normally	Reversed batteries — unit not on. Unit not damaged and functions normally	() Pass
65	Remove batteries and re-install When the audio alarm stops sounding, quickly press and hold down the + key Verify that the unit beeps 2 times with pauses between and the display is blank	Beeps error code 2	E Poss ☐ Fail
66	Calibrate the unit to 20 9% with a sensor connected. Observe that the reading does not change more than 2% O2 when brought within 3 feet of an operating computer for 10 seconds.	Reading stable within +/-2% O2 when near a computer  Min 20.4  Lo. 9	⊕ Pass ☐ Fail

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digital mode is

Digital output

odd parity

operational and uses

matches O2 reading

O2 resolution is

does not appear.

No alarms on

cannot be set

High O2 Audio

Alarm intensity

Low O2 Audio

Alarm intensity

<u>65</u> dBA (45.75)

135 dBA (45-75)

units % and tenths

display and alarms

0

Fail

Pass

Fail

Pass

D Fail

N Pass

☐ Fail

☑ Pass

CV Poss

O Fail

Fail

Ü

computer or data terminal to the digital output jack. Set the baud rate to

2400, 7 data bits and odd parity Verify that the data displayed matches the

With unit configured for Digital output (RS232). Calibrate the instrument at

100% O2 Attach a compatible, digital device to the digital serial connector

Configure the unit for low-resolution mode (IP6) and analog output Verify

that the low-resolution mode is operational and the tenths digit does not

Configure the unit for No-Alarms mode (JP5) and analog output. Verify

that the alarms do not show on the display and that the alarms cannot be set.

Adjust the Sensor voltage to obtain an O2 reading of 21% Set the High O2

Alarm to 90% and the Low O2 Alarm to 22% Verify that the audio alarm

Adjust the Sensor voltage to obtain an O2 reading of 24% Set the Low O2

Alarm to 18% and the High O2 Alarm to 22%. Verify that the audio alarm

sound pressure level is between 45 dBA and 75 dBA at one meter.

sound pressure level is between 45 dBA and 75 dBA at one meter

that displays the digital output. Change the Sensor voltage to produce O2

readings from 0 to 100% in 10% steps. Verify that the digital output

corresponds exactly to the reading on the display.

O2 reading. Change the terminal setting to even parity and verify that the

data on the terminal shows errors

69

70

71

72

73

74

appear.

MODEL NUMBER:		PROCEDURE NUMBER:	PAGE: 14 OF 14			
MX300 / AX300		TP-MX300/AX300	REV.: 1 REV. DA			
	15.5	(SOFTWARE VALIDATION)				
STEP#	OPE	RATOR ACTION	RESULT	PASS / FAIL		
75	Connect a compatible sensor sensor calibrates and then disp	Calibrate the sensor for 20.9%. Verify that the slays 20.9% +/- 1%	O2 = 20.9% $(19.9% to 21.9%)$	Pass  D Fail		
76	flashing between 3 and 9 seco	ntton to unlock the keys  Do not press buttons Display should stop  nds Unit reverts to locked mode.  ng the CAL button, calibration should NOT	Flashing stops around 3 to 9 seconds, when not flashing, CAL button has no effect	⊋ Pass □ Fail		
77	Hold down one of the MAXIMUM. If an er seconds, this is a FA If the error does occur	perform the following test:  k keys shown below for 15 seconds for (E60 to E68) does not occur before 15  IL.  then it is a PASS  move, then replace the battery at Step 1) for each key  key:  Err = 60 Err = 61 Err = 62 Err = 63 Err = 64 Err = 65 Err = 66 Err = 66 Err = 67	Error Code listed to the left is shown when is a key is simulated to be stuck	Pass  C Fail		
Softwal Operati Did the	re Version/. or Name <u>////////////////////////////////////</u>	Hardware Version <u>NA</u> Odi mussin Dale 3-12-0 s  Signature Mull				

		Date(s) of Test_/-2/-08
	TEST PROCE	EDURE DATA SHEET
Model Number <u>MX300</u> I		Serial Number <u>259469</u>
Test Personnel Andrew	RASINUSSIU (	QC Witness (if applicable)
TP-117 Test Proc. Number	X300/AX300 NARL VOLIDATION	Revision / Rev. Date 9-27-67
	QUIPMENT	
INSTRUMENT	MFG/MODEL	SERIAL NO. CAL.DUE DATE
SOUTCE MEASURE UNIT	Kelthley 230	CC 05705 6-1-08
STOP WATCH	Programmabi	CC 05697 2-12-08
Power Supply	HP 62371	3 E1000097 NOT Regulard
Multimeter	Pluke 45	CC09259 9-21-08
Pigita Oscope Sound Level meter	Tech Front x 24	32A TOO 517 Not Required
Sound Level meter	Padlo shock	NA NOT REQUIRED

		TEST	PROCEDU	RE DATA POI	NTS		
Step#	Data	Step#	Data	Step#	Data	Step#	Data
Otop ii			<u> </u>				
	<del>, , , , , , , , , , , , , , , , , , , </del>						
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