

МИНИСТЕРСТВО ЗДРАВООХРАНЕНИЯ РЕСПУБЛИКИ БЕЛАРУСЬ
РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ

№ ИМ-7.105922/2304

Настоящее удостоверение выдано

Interacoustics A/S, ДАНИЯ

и является подтверждением того, что Министерством здравоохранения Республики Беларусь зарегистрированы

**Аудиометры: аудиометр клинический: модель АС40;
см. приложение, всего номеров регистрации - 5**

Тип: **медицинская техника**

Производитель:

Interacoustics A/S, ДАНИЯ. Адрес: 5500 Middelfart, Audiometer Alle 1

Производственная площадка:

Interacoustics A/S, ДАНИЯ. Адрес: 5500 Middelfart, Audiometer Alle 1

и разрешены к производству, реализации и медицинскому применению на территории Республики Беларусь

В соответствии с руководством по эксплуатации

Регистрационный номер: **Мг-7.119296/7.006-2211**

Регистрационное удостоверение не является обязательством к закупке данных изделий медицинской техники.

Дата государственной регистрации:
03.04.2023 г.

Действительно до:
бессрочно

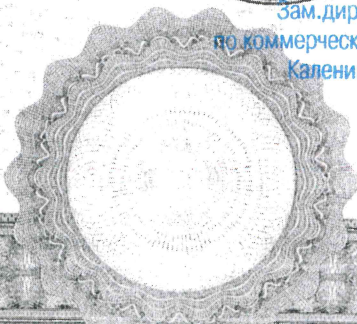
Заместитель Министра



Б. Н. Андросюк

Ильюк ОО

КОП



Зам. директора
по коммерческим вопросам
Каленик Е.В.



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ПРИЛОЖЕНИЕ К РЕГИСТРАЦИОННОМУ УДОСТОВЕРЕНИЮ № ИМ-7.105922/2304

Всего наименований:

5

Страница: 2

Страниц: 2

Изготовитель: Interacoustics A/S, ДАНИЯ

№	Номер регистрации	Наименование, нормативный документ, код:
1	Мт-7.119296/7.006-2211	Аудиометры: аудиометр клинический: модель AC40
2	Мт-7.119296/7.007-2211	Аудиометры: аудиометр импедансный: модель MT10
3	Мт-7.119296/7.008-2211	Аудиометры: аудиометр импедансный: модель AT235
4	Мт-7.119296/7.009-2211	Аудиометры: аудиометр диагностический: модель AD226
5	Мт-7.119296/7.010-2211	Аудиометры: аудиометр диагностический: модель AD629

Всего наименований: 5

КОПИЯ

Зам. директора
по коммерческим
делам
Каленик Е.



Заместитель Министра

Б. П. Андросюк

Final Inspection Report: **FI-187533**

ID no.: FI-187533	Inspector Initials: AAOZ	Date: 2024-10-28
Device Name: AC40 Clinical Audiometer	Item no.: 8526639	Tracking no.: SN1062515

1) Product to be inspected according to generic labelling instruction:

A: B: C: D: E:
 F: G: H: I: J:
 K: L:

2) Documentation and items according to packing list and/or order confirmation, to be present:

3) Test performance according to Test and Calibration Reports:

All tests are performed and approved:

All test certificates are signed:

4) Product to be intact (no scratches, bulges, missing buttons etc.):

5) Product to be inspected according to product related inspection instruction:

A: <input type="text" value="A"/>	B: <input type="text" value="A"/>
C: <input type="text" value="A"/>	D: <input type="text" value="A"/>
E: <input type="text" value="N/A"/>	F: <input type="text" value="N/A"/>
G: <input type="text" value="A"/>	H: <input type="text" value="A"/>
I: <input type="text" value="A"/>	J: <input type="text" value="A"/>
K: <input type="text" value="A"/>	L: <input type="text" value="N/A"/>
M: <input type="text" value="A"/>	N: <input type="text" value="N/A"/>
O: <input type="text" value="N/A"/>	P: <input type="text" value="A"/>
Q: <input type="text" value="A"/>	R: <input type="text" value="A"/>
S: <input type="text" value="N/A"/>	T: <input type="text" value="N/A"/>

Description ENG:

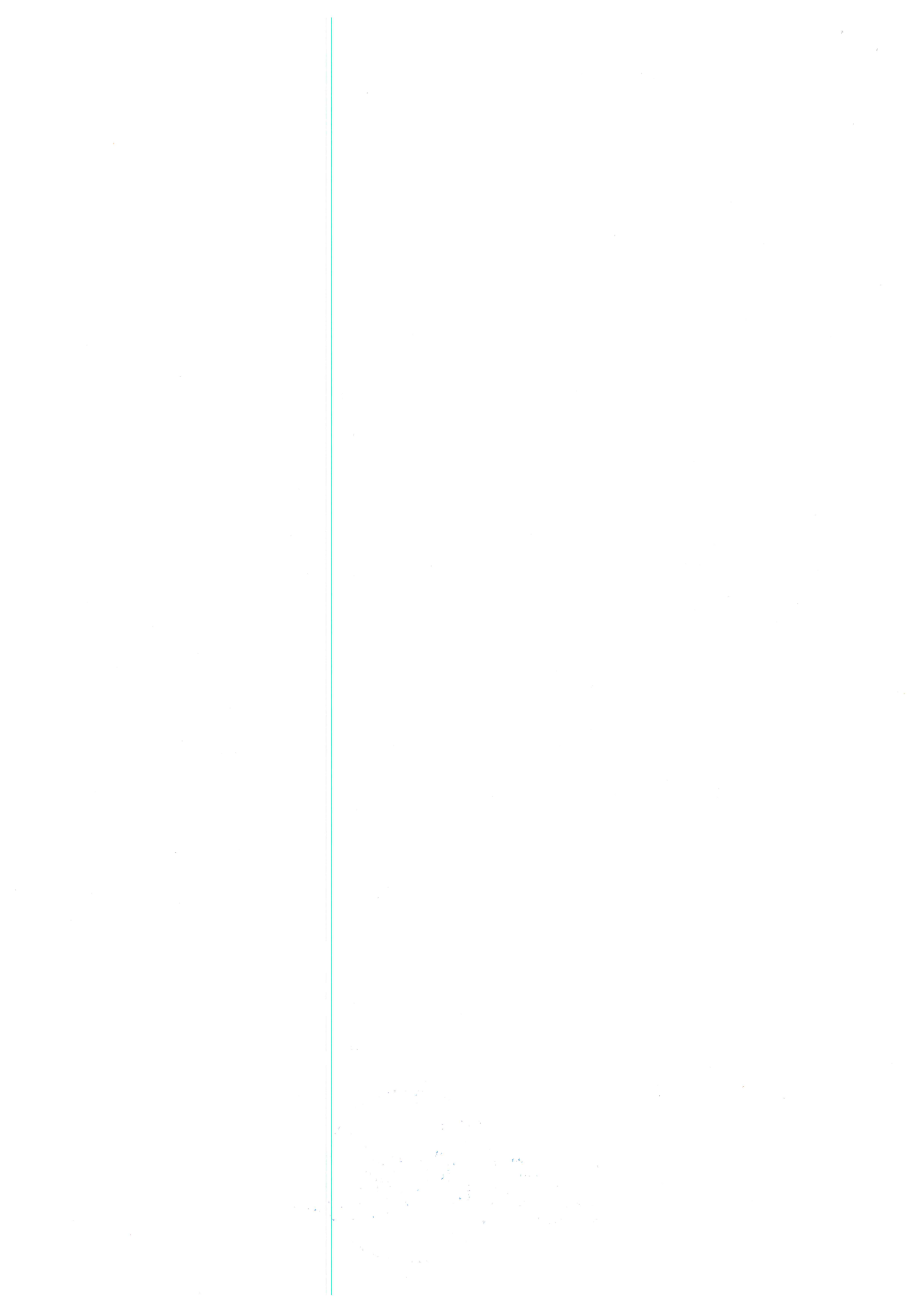
КОПИЯ

Decision: Approved

Зам.директора
по коммерческим вопросам
Каленик Е.В.



Om
(signature)



Safety Test Report



Result: pass
 Manufacturer: Interacoustics
 Device Type: AC40 (Model 1060)
 Model: AC40 (Model 1060)
 Serial No.: SN1062515
 Test Instruction: AC40 (Model 1060)
 Test Date: 25.03.2025
 Tested by: Jakub Jakimiak
 Test Location: Test Department
 High Voltage Tester: GPT-9804, SN:GEU220503, Due Date:2025-07-24

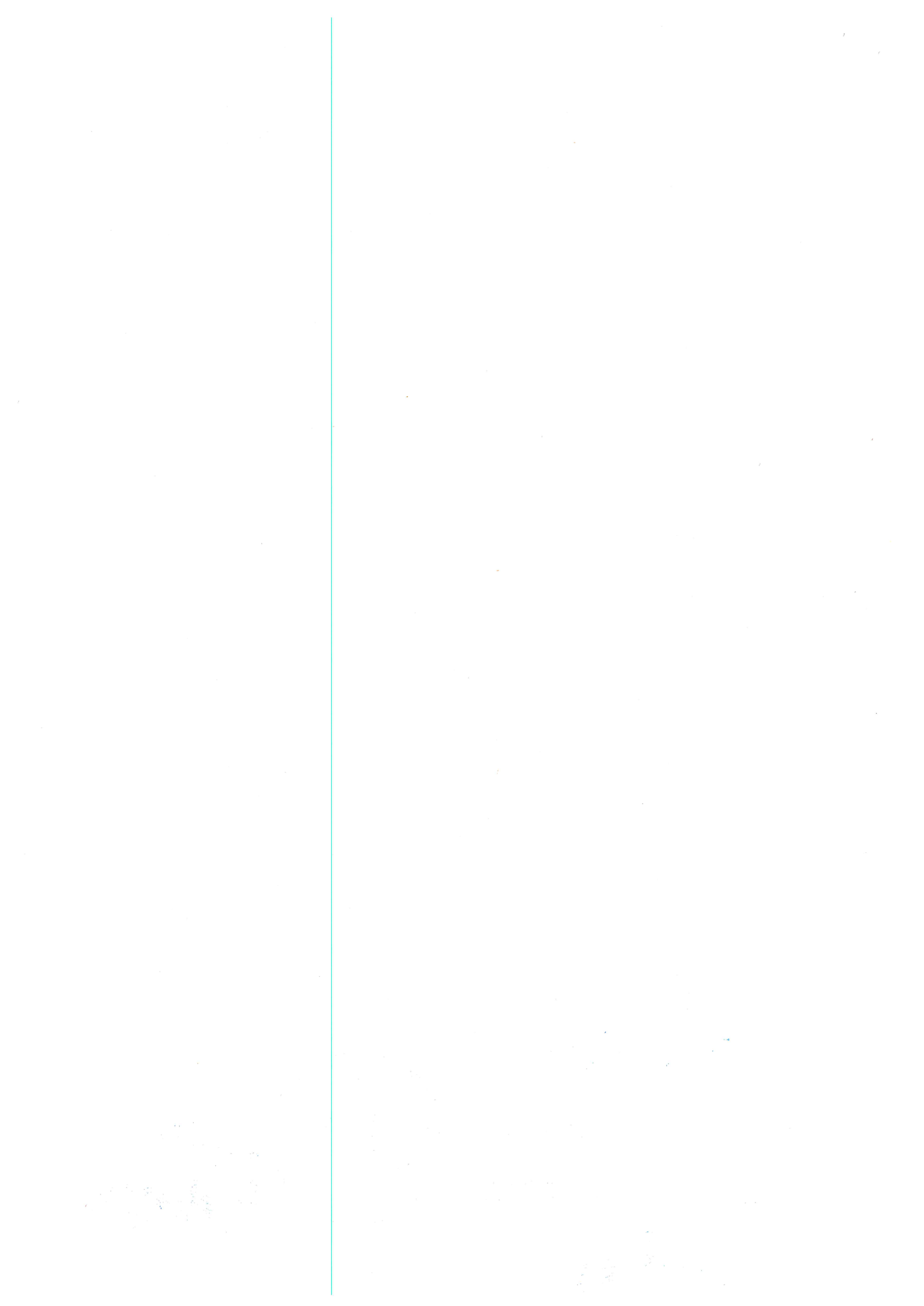
Step	Function	Work Step	Unit	Lower Limit	Upper Limit	Measured Value	Success
1	Test Equipment	Verification of test equipment: PASS					
2	high voltage	Input to Ground, 1sec. 1800VAC. Expected current < 6mA	1-Y/0-N/2-NA	1	1	1,00	Pass
3	SPL01	Line voltage	1-Y/0-N/2-NA	1	1	1,00	Pass
4	SPL19	general Power	V	100	240	237,20	Pass
5	SPL05 Z	IEC 60601 Protective 6Vac resistance 6Vac, Curr<25A, 5-10 s	VA	2	40	39,00	Pass
6	SPL46	IEC 62353 Equipment Insulation resistance	Ohm	0,01	0,2	0,09	Pass
7	SPL01 N	Nomierung	MOhm	20	100	100,00	Pass
8	SPL06	IEC 60601 Earth leakage current NC	V	264	264	264,00	Pass
9	SPL08	IEC 60601 Touch current NC	µA	10	1000	431,00	Pass
10	SPL09	IEC 60601 Touch current SFC PE open	µA	0	10	3,10	Pass
11	SPL07	IEC 60601 Earth leakage current SFC line open	µA	5	500	432,80	Pass
12	SPL10	IEC 60601 Touch current SFC line open	µA	20	2000	839,20	Pass
13	SPL06P	IEC 60601 Earth leakage current NC, P	µA	0	10	2,20	Pass
14	SPL08P	IEC 60601 Touch current NC, P	µA	10	1000	429,60	Pass
15	SPL09P	IEC 60601 Touch current SFC PE open, P	µA	1	75	4,30	Pass
16	SPL07P	IEC 60601 Earth leakage current SFC line open, (P)	µA	5	500	430,80	Pass
17	SPL10P	IEC 60601 Touch current SFC line open, (P)	µA	20	2000	841,10	Pass
18	SPL50	Line off	µA	0	10	3,60	Pass
19	SPL51	Read detailed informations off testing device	V	0	0	0,00	Pass
19	SPL51	Read detailed informations off testing device	-	0	0	2025,09	Pass
19	SPL51	Read detailed informations off testing device	-	0	0	10280410,65	Pass
			-	0	0	19022405,86	Pass

Comment on result:

Sign:

Зам.директора
 по коммерческим вопросам
 Каленик Е.В.





Audiometer Calibration Certificate

Audiometer Information		Page 1 of 4
Model: Interacoustics AC40		
Serial Number: SN1062515		
Firmware: 1.12.2		
Transducer	Model	S/N
Headphones	DD45	WT687721
HF Phones	Radioear DD450	WTA23625
Bone Oscillator	Radioear B81	043797



Calibration Information	
ACS Hardware Platform: EM-1-600, Serial Number: 600-0413-1	
ACS Hardware Cal Date: April 30, 2024, ACS Software Version: 5.1.0.22	
Audiometer Calibration Date: March 25, 2025 10:38:12 AM	
Next Calibration Due: March 25, 2026	
Calibrated by: DGS-IA-210	
Technician: JAJI	
Signature:	

Reference Standards	
Audiometer: IEC 60645-1 (2017)	
Headphones: ISO 389-1 (2017)	
Bone Oscillator: ISO 389-3 (2016)	
HF Phones: ISO 389-5, 389-8 (2006)	
Narrowband Noise: ISO 389-4 (1994)	
Speech: IEC 60645-2	

Headphone Level			
Test Level	Target Level	Osc 1 Left	Osc 1 Right
125 40	87.5	125.1	125.1
160 50	90.5	160.1	160.1
200 55	88.5	200.1	200.1
250 65	92.0	250.0	250.0
315 70	92.5	315.1	315.1
400 70	87.5	400.0	400.0
500 75	88.0	500.1	500.1
630 80	89.0	630.1	630.1
750 80	86.5	750.0	750.0
800 80	86.5	800.0	800.0
1000 80	86.0	1000.0	1000.0
1250 80	87.0	1250.1	1250.1
1500 80	88.0	1500.0	1500.0
1600 80	88.0	1600.1	1600.1
2000 80	88.0	2000.0	2000.0
2500 80	88.0	2499.9	2499.9
3000 80	88.0	2999.9	2999.9
3150 80	88.0	3149.9	3149.9
4000 80	89.0	3999.8	3999.8
5000 80	93.0	4999.8	4999.8
6000 75	95.5	5999.7	5999.7
6300 75	94.0	6299.7	6299.7
8000 75	87.0	7999.6	7999.6

Headphone THD			
Test Level	Test Freq	Osc 1 Left	Osc 1 Right
75	125	0.123	0.118
90	250	0.039	0.037
110	500	0.114	0.097
110	750	0.068	0.063
110	1000	0.094	0.088
110	1500	0.207	0.190
110	2000	0.256	0.263
110	3000	0.270	0.282
110	4000	0.473	0.548
90	6000	0.015	0.019
90	8000	0.005	0.007

Headphone Narrow			
Test Level	Test Freq	Osc 1 Left	Osc 1 Right
40	125	-0.0	0.1
45	160	-0.4	0.8
50	200	-0.3	0.1
60	250	-0.1	-0.1
65	315	-0.3	0.2
70	400	0.1	-0.0
70	500	-0.2	0.2
75	630	-0.3	-0.3
75	750	-0.0	-0.3
75	800	-0.2	-0.0
75	1000	0.1	0.2
75	1250	-0.0	-0.0
75	1500	0.0	0.2
75	1600	0.1	0.0
75	2000	-0.2	-0.3
75	2500	0.2	-0.1
75	3000	-0.2	-0.0
75	3150	-0.1	0.1
75	4000	0.3	0.2
70	6000	-0.2	0.2
70	8000	0.2	-0.0

Headphone White Noise			
Test Level	Test Freq	Osc 1 Left	Osc 1 Right
90	Total	0.1	0.1

Headphone Sensor			
Test Level	Test Freq	Osc 1 Left	Osc 1 Right
161681	125	0.123	0.118
102283	250	0.039	0.037
495037	500	0.114	0.097
155710	750	0.068	0.063
2838060	1000	0.094	0.088
2688662	1500	0.207	0.190

Headphone Coupler			
Test Level	Test Freq	Osc 1 Left	Osc 1 Right
155559	125	0.123	0.118
169773	250	0.039	0.037
171390	500	0.114	0.097
171393	750	0.068	0.063



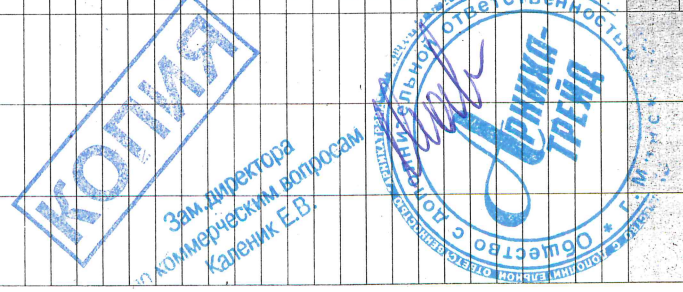
Зам. директора
по коммерческим вопросам
Каленик Е.В.



Audiometer Calibration Certificate

S/N: SN1062515

Interacoustics AC40				Headphone Speech Noise				Headphone Speech LM				HF Phones Level				HF Phones THD			
Test	Test Level	Osc 1 Left	Osc 1 Right	Test	Test Level	Osc 1 Left	Osc 1 Right	Test	Test Level	Osc 1 Left	Osc 1 Right	Test	Test Level	Osc 1 Left	Osc 1 Right	Test	Test Level	Osc 1 Left	Osc 1 Right
Speech	70	-0.0	0.1	EXT 1	1000	-0.0	-0.0	125	55	85.5	125.1	0.0	125.1	0.0	125.1	125	65	0.384	0.278
Equiv FF	70	-0.2	-0.2	EXT 2	1000	-0.0	-0.0	160	55	81.0	160.1	0.0	160.1	0.0	160.1	250	80	0.140	0.085
Non Lin	85	-0.2	0.1	MIC	1000	-0.0	0.0	200	60	82.0	200.1	-0.0	200.1	0.0	200.1	500	100	0.366	0.363
TENoise	65	0.0	0.0	EXT 1	Equiv FF	-0.0	0.0	250	60	78.0	250.0	-0.0	250.0	0.0	250.0	750	100	0.342	0.294
				EXT 2	Equiv FF	-0.0	0.0	315	65	80.5	315.1	-0.1	315.1	-0.1	315.1	1000	100	0.280	0.290
				MIC	Equiv FF	-0.0	0.0	400	70	83.5	400.0	0.0	400.0	-0.0	400.0	1500	100	1.578	1.278
				EXT 1	Non Lin	-0.0	0.0	500	70	81.0	500.1	0.0	500.1	0.0	500.1	2000	100	1.832	1.599
				EXT 2	Non Lin	-0.0	0.0	630	75	93.0	630.1	0.0	630.1	-0.0	630.1	3000	100	0.318	0.409
				MIC	Non Lin	-0.0	0.0	750	75	81.0	750.0	-0.0	750.0	-0.0	750.0	4000	100	0.327	0.190
								800	75	84.0	800.0	-0.0	800.0	-0.0	800.0	6000	80	0.012	0.016
								1000	80	85.5	1000.0	0.0	1000.0	-0.0	1000.0	8000	80	0.009	0.012
								1250	80	86.0	1250.1	0.0	1250.1	-0.0	1250.1	9000	80	0.010	0.007
								1500	75	86.0	1500.0	0.0	1500.0	-0.0	1500.0	10000	80	0.006	0.006
								1600	80	85.5	1600.1	-0.0	1600.1	-0.0	1600.1	11200	80	0.000	0.000
								2000	80	84.5	2000.0	-0.0	2000.0	-0.0	2000.0	12500	80	0.000	0.000
								2500	80	83.0	2499.9	-0.0	2499.9	0.0	14000	75	0.000	0.000	
								3000	85	87.5	2999.9	0.0	2999.9	0.0	16000	55	0.000	0.000	
								3150	80	84.0	3149.9	-0.0	3149.9	-0.0	18000	30	0.000	0.000	
								4000	80	89.5	3999.8	-0.0	3999.8	-0.0	20000	10	0.000	0.000	
								5000	70	84.0	4999.8	0.0	4999.8	0.0					
								6000	60	77.0	5999.7	-0.0	5999.7	-0.0					
								6300	60	77.5	6299.7	-0.0	6299.7	0.0					
								8000	55	72.5	7999.6	-0.0	7999.6	-0.0					
								9000	50	69.0	8999.5	-0.0	8999.5	-0.0					
								10000	60	82.0	9999.4	0.0	9999.4	0.0					
								11200	60	83.0	11199.4	0.0	11199.4	-0.0					
								12500	55	82.5	12499.3	-0.0	12499.3	-0.0					
								14000	45	80.0	13999.2	-0.0	13999.2	-0.0					
								16000	35	91.0	15999.0	-0.0	15999.0	0.0					
								18000	-5	78.0	17998.9	0.0	17998.9	-0.0					
								20000	-10	95.0	19998.8	-0.0	19998.8	-0.0					



Зам. директора
 Коммерческого вопроса
 Кареник Е.В.

Audiometer Calibration Certificate

S/N: SN1062515

Interacoustics AC40				Bone Narrow				Bone White Noise				Bone Speech Noise				Bone Speech Lvl			
Test Freq	Test Level	Target Level	Osc 1	Test Freq	Test Level	Osc 1	Test Signal	Test Level	Osc 1	Test Input	Test Signal	Osc 1	Test Input	Test Signal	Osc 1	Test Input	Test Signal	Osc 1	
250	10	81.0	-0.3	250	250		250			EXT 1	1000	-0.0							
315	10	78.0	-0.2	500	500		500			EXT 2	1000								
400	15	80.0	-0.2	750	750		750			MIC	1000								
500	20	82.0	0.2	1000	1000		1000												
630	20	77.5	-0.0	1500	1500		1500												
750	25	78.5	0.1	2000	2000		2000												
800	30	82.0	-0.2	3000	3000		3000												
1000	30	78.5	0.2	4000	4000		4000												
1250	35	80.0	0.3	6000	6000		6000												
1500	40	82.5	-0.1	Total	40	-0.1	Total	25	0.2										
1600	40	81.5	-0.1																
2000	45	82.0	-0.0																
2500	45	80.5	0.1																
3000	45	81.0	-0.2																
3150	45	82.0	0.1																
4000	40	80.5	-0.2																
5000	35	80.0	0.1																
6000	35	80.0	-0.1																
6300	35	80.0	-0.0																
8000	35	80.0	-0.1																

Electrical

Test Freq	Test Level	THD	Off	Oscillator 1, Left	Oscillator 1, Right	Over	Cross L	Cross R	Freq	THD	Off	Fall	Rise	Over	Cross L	Cross R	
1000	110	999.1	0.007	-122.4	34.9	34.9	0.13	-99.0	-95.2	999.1	0.009	-123.4	33.8	33.8	0.08	-99.1	-95.9

Linearity (EL)

Test Level	Osc 1 Left	Osc 1 Right	Test Level	Osc 1 Left	Osc 1 Right	Test Level	Osc 1 Left	Osc 1 Right	Test Freq	Osc 1 Left	Osc 1 Right	Test Level	Osc 1 Left	Osc 1 Right	Test Freq	Osc 1 Left	Osc 1 Right
110	0.18	0.15	70	-0.00	-0.00	30	-0.09	-0.05	125	5.02	5.02	464.5					
105	0.18	0.16	65	-0.02	-0.03	25	-0.13	-0.05	250	5.02	5.00						
100	0.17	0.15	60	-0.03	-0.03	20	-0.14	-0.05	500	5.04	5.00						
95	0.03	0.01	55	-0.03	-0.03	15	-0.16	-0.04	750	5.03	5.00						
90	0.02	0.01	50	-0.04	-0.03	10	-0.14	-0.02	1000	5.01	4.99						
85	0.02	0.01	45	-0.04	-0.03		+/-1.00	+/-1.00	1500	5.01	5.01						
80	0.01	0.00	40	-0.06	-0.04				2000	5.01	5.03						
75	0.01	0.00	35	-0.07	-0.04				3000	5.01	5.02						
									4000	5.02	5.02						
									6000	5.02	5.01						
									8000	5.02	5.01						

Warble Rate

Test Level	Osc 1 Left	Osc 1 Right	Test Level	Osc 1 Left	Osc 1 Right	Test Level	Osc 1 Left	Osc 1 Right
110	5.02	5.02	70	5.02	5.02	30	5.02	5.02
105	5.02	5.00	65	5.02	5.00	25	5.02	5.00
100	5.04	5.00	60	5.03	5.00	20	5.03	5.00
95	5.03	5.00	55	5.01	4.99	15	5.01	4.99
90	5.01	5.01	50	5.01	5.01	10	5.01	5.01
85	5.01	5.03	45	5.01	5.03			
80	5.01	5.02	40	5.01	5.02			
75	5.02	5.01	35	5.02	5.01			

Pulse Width

Test Level	Osc 1 Left	Osc 1 Right	Test Level	Osc 1 Left	Osc 1 Right
110	464.5	464.5	70	464.5	464.5
105	464.5	464.5	65	464.5	464.5
100	464.5	464.5	60	464.5	464.5
95	464.5	464.5	55	464.5	464.5
90	464.5	464.5	50	464.5	464.5
85	464.5	464.5	45	464.5	464.5
80	464.5	464.5	40	464.5	464.5
75	464.5	464.5	35	464.5	464.5

Notes

T: 23.3°C
H: 34.8%
P: 1013.4hPa

