DANAK
Reg.nr. 225

Telelaboratoriet

TEST REPORT

An Accredited Technical Test Executed under the Danish Accreditation Scheme

Prøvningsrapport

for akkrediteret prøvning i henhold til Dansk Akkrediterings Ordning

No. of annexes 16
Antal bilag

Test-report No *Prøvningsrapport Nr.*	UPRR020009-01	**Our reference** *Vor reference*	Martin Arndt	**Copy No** *Eksemplar Nr.*	1
Equipment *Udstyr*	Medical Bluetooth device				
Manufacture *Fabrikat*	GN Otometrics A/S				
Type *Type*	NOAHlink				
Serial No *Serie Nr.*	-	**Equipment received** *Udstyr modtaget*			
Client *Rekvirent*	GN Otometrics A/S				
Address *Adresse*	Dybendalsvænget 2,				
Postal code *Post Nr.*	2630	**City** *By*	Tåstrup	**Country** *Land*	Danmark
The testing has been carried out in accordance with *Prøvningen er udført i henhold til*	EN 301 489-17(2000) and EN 60601-1-2 (1995)				
Remarks *Bemærkninger*	All the tested parameters fulfil the requirements				
Date and signature *Dato og underskrift*	17. June 2002		Martin Bülow Arndt		

Martin Bülow Arndt
B.Sc.(E.E.)

The test result is only valid for the equipment tested.
Prøvningsresultatet gælder kun for det afprøvede udstyr.

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DANAK (DANSK Akkreditering)

DANAK blev etableret i 1991 med hjemmel i lov nr. 394 om erhvervsfremme af 13. juni 1990.

Kravene til akkrediterede prøvningslaboratorier er fastlagt i Erhvervsfremme Styrelsens bekendtgørelse om akkreditering af laboratorier til teknisk prøvning m.v., samt til GLP-inspektion. Bekendtgørelsen henviser til andre dokumenter, hvor akkrediteringskriterierne er beskrevet yderligere.

Standarderne DS/EN ISO/IEC 17025 "Generelle krav til prøvnings- og kalibreringslaboratoriers kompetence" og DS/EN 45002 "Generelle kriterier for bedømmelse af prøvningslaboratorier" beskriver grundlæggende akkrediteringskriterier. DANAK anvender fortolkningsdokumenter til de enkelte krav i standarderne, hvor det skønnes nødvendigt. Disse vil hovedsageligt være udarbejdet af "European co-operation for Accreditation (EA)" eller "International Laboratory Accreditation Co-operation (ILAC)" med det formål at opnå ensartede kriterier for akkreditering på verdensplan. DANAK udarbejder desuden tekniske forskrifter vedr. specifikke krav til akkreditering, som ikke er indholdt i standarderne.

For at et laboratorium kan være akkrediteret kræves blandt andet:

- at laboratoriet og dets personale skal være fri for enhver kommerciel, økonomisk eller anden form for pression, som kan påvirke deres tekniske dømmekraft.
- at laboratoriet har et dokumenteret kvalitetsstyringssystem.
- at laboratoriet råder over prøveteknisk udstyr og lokaler af en tilstrækkelig standard til at kunne udføre den prøvning som laboratoriet er akkrediteret til.
- at laboratorieledelse og -personale har såvel faglig kompetence som praktisk erfaring i udførelsen af den prøvning som laboratoriet er akkrediteret til.
- at der er indarbejdet faste rutiner for sporbar kalibrering og usikkerhedsbestemmelse.
- at akkrediteret teknisk prøvning udføres efter fuldt validerede og dokumenterede metoder.
- at laboratoriet skal registrere forløbet af akkreditere prøvning således, at dette kan rekonstrueres.
- at laboratoriet er underkastet regelmæssigt tilsyn af DANAK.
- at et akkrediteret laboratorium skal have en forsikring, som kan dække laboratoriets ansvar i forbindelse med udførelsen af akkrediterede ydelser.

Prøvningsrapporter, der bærer DANAK's logo, anvendes ved rapportering af akkrediterede ydelser og viser, at disse er foretaget i henhold til akkrediteringsreglerne.

DANAK was established in 1991 in pursuance of the Danish Act No. 394 of 13 June 1990 on the promotion of Trade and Industry.

The requirements to be met by accredited laboratories are laid down in the "Danish Agency for Trade and Industry's" ("Erhvervsfremme Styrelsen´s") Statutory Order on accreditation of laboratories to perform testing etc., and GLP-inspection. The Statutory order refers to other documents where the criteria for accreditation are specified further.

The standards DS/EN ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories" and DS/EN 45002 "General criteria for the assessment of testing laboratories" describes fundamental criteria for accreditation. DANAK uses guidance documents to clarify the requirements in the standards, where this is considered to be necessary. These will mainly be drawn up by the "European co-operation for Accreditation (EA)" or the "International Laboratory Accreditation Co-operation (ILAC)" with a view to obtains uniform criteria for accreditation worldwide. In addition, DANAK draws up Technical Regulations with specific requirements for accreditation that are not contained in the standards.

In order for a laboratory to be accredited it is, among other things, required:

- that the laboratory and its personnel are not subject to any commercial, financial and other pressures, which might influence their technical judgement.
- that the laboratory operates a documented quality system.
- that the laboratory has at its disposal all items of equipment, facilities and premises required for correct performance of the service that it is accredited to perform.
- that the laboratory management and personnel have technical competence and practical experience in performing the service that they are accredited to perform.
- that the laboratory has procedures for traceability and uncertainty calculations.
- that accredited testing is performed in accordance with fully validated and documented methods.
- that the laboratory keeps records which contain sufficient information to permit repetition of the test.
- that the laboratory is subject to surveillance by DANAK on a regular basis.
- that the accredited laboratory shall take out an insurance, which covers liability in connection with the performance of accredited services.

Reports carrying DANAK´s logo are used when reporting accredited services and show that these have been performed in accordance with the rules of accreditation.

Title: Test on GN Otometrics NoahLink, to EN 60 601-1-2 (1995) and EN 301 489-17 (2000)

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Title: Test on GN Otometrics NoahLink, to EN 60 601-1-2 (1995) and EN 301 489-17 (2000)

1. Test Specification and Methods

Purpose of Test: The tests are performed in order to demonstrate compliance with the requirements of the EMC directive 89/336/EEC and article 3.1b of the R&TTE directive 99/5/EEC.

Test Specification(s):

[1] EN 301 489-17; 2000 Electromagnetic Compatibility and Radio spectrum Matters (ERM); Electromagnetic Compatibility (EMC) standard for 2,4 GHz wideband transmission systems and High Performance Radio Local Area Network (HIPERLAN)

[2] EN 301 489 -1; 2000 Information technology equipment – Immunity characteristics. Limits and methods of measurement.

[3] EN 60 601-1-2; 1995 Medical electrical equipment - Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility - Requirements and tests.

Normative references:

The Test methods and procedures are defined in the following basic standards (for undated references the latest edition applies):

[4] EN50081-1;1992 Electromagnetic Compatibility Generic Emission Standard, part1: Residential, commercial, and light industry

[5] EN 50082-1;1992 Electromagnetic Compatibility - Generic Immunity Standard, part 1: Residential, commercial, and light industry

[6] EN 55022; 1994 Limits and methods of measurement of radio frequency interference characteristics of information technology equipment.

Title: Test on GN Otometrics NoahLink, to EN 60 601-1-2 (1995) and EN 301 489-17 (2000)

[7]	CISPR 16-1; 1993	Specification for radio disturbance and immunity measuring apparatus and methods; Part 1: Radio disturbance and immunity measuring apparatus.
[8]	EN 61000-4-2	Part 4: Testing and measuring techniques Section 2: Electrostatic discharge immunity test (IEC 1000-4-2)
[9]	EN 61000-4-3	Part 4: Radiated, Radio Frequency Electromagnetic Field - Immunity Test (IEC1000-4-3)
[10]	EN 61000-4-4	Part 4: Testing and measuring techniques Section 4: Electrical fast transient burst immunity test (IEC 1000-4-4)
[11]	EN 61000-4-5	Part 4: Testing and measuring techniques Section 5: Surge immunity test (IEC 1000-4-5)
[12]	EN 61000-4-6	Part 4: Testing and measuring techniques Section 6: Immunity to conducted disturbances Induced by Radio-Frequency Fields (IEC 1000-4-6)
[13]	EN 61000-4-11	Part 4: Testing and measuring techniques. Section 11: Voltage dips, short interruptions and voltage variations immunity test (IEC 1000-4-11)
[14]	ISO 7637-1;1990	Road vehicles - Electrical disturbance by conducting and coupling - Part1: passenger cars and light commercial vehicles with nominal 12 V supply voltage - Electrical transient conduction along supply lines only.
[15]	ISO 7637-2;1990	Road vehicles - Electrical disturbance by conducting and coupling - Part2: Commercial vehicles with nominal 24 V supply voltage - Electrical transient conduction along supply lines only.

Title: Test on GN Otometrics NoahLink, to EN 60 601-1-2 (1995) and EN 301 489-17 (2000)

2. Deviations or Exclusions from the Test Specifications

2.1. Immunity

Immunity tests is performed in such a way that both the immunity in EN 301 489-17 and EN 60601-1-2 are covered. This is achieved by selecting the worst case criteria and most stringent performance requirement in each test.

2.2. Emission

Spurious emission is tested separately and these results can be found in test-report no. UPRR020008-01.

3. EUT description

3.1. EUT identification

The EUT is a medical device providing a wireless link to hearing aids to be used during their individual calibration. The EUT operates in the 2.4GHz band and the RF and protocols used are based on the Bluetooth technology.

Product:	Medical Bluetooth Device
Type No:	NOAHlink
Manufacture:	GN Otometrics A/S

3.2. EUT port(s)

Following port was examined during the tests:

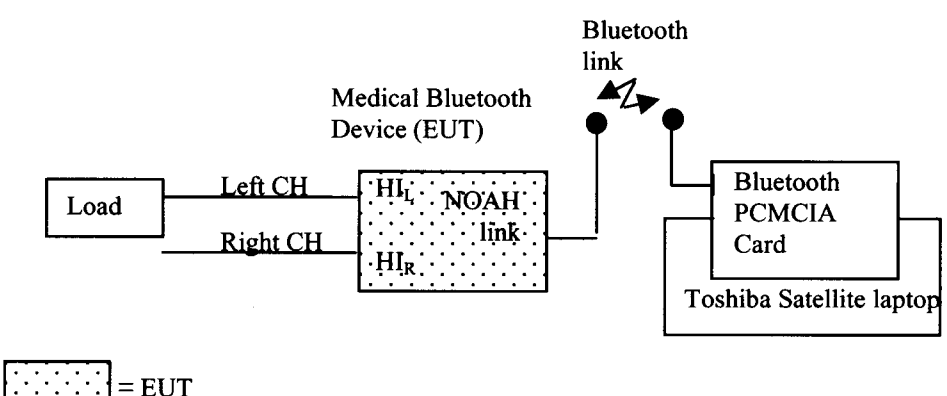
1. Enclosure port

The EUT is battery operated only.

Title: Test on GN Otometrics NoahLink, to EN 60 601-1-2 (1995) and EN 301 489-17 (2000)

3.3. Operation of the EUT

A continuos link between the EUT and a Bluetooth enabled laptop PC was established. The PC was running a programme, which were sending a MPEG3 file containing a 400Hz sin-wave signal. The signal was decoded in the EUT and send, as an analogue current, to the left and right HI connectors. From these terminals there would be a coax connection to the hearing aid, however for the testing the termination of the left line were made in resistive load. The signal current at the load was set to a level 20dB full-scale output of 30uA. During RF immunity testing audio quality were tested at this point (over resistive load)



Note: Left channel chosen for the testing due to more complex PCB layout and longer traces in the audio path.

4. Performance criteria

The maintenance of the radio links and the correct data transfer is used as indicators to evaluate the performance of the EUT.

At the conclusion of the test the EUT shall operate as intended with no loss of user control functions or stored data, and the data link shall have been maintained.

4.1. Criteria A Continuous phenomena

During the test: Shall operate as intended. May show degradation of performance. No loss of function is allowed. Link with 400Hz audio signal at 20dB below full-scale shall be maintained during exposure. The maximum 1kHz audio break trough signal should at all times be more than 45dB below the full-scale output current of 30uA RMS. This corresponds to a 55dB SPL audio signal when full scale is at 100dB SPL.

At the conclusion of the test: The EUT shall operate as intended. May show degradation of performance. No loss of function, stored data or user programmable functions are allowed.

4.2. Criteria B Transient phenomena

During the test: May show loss of function (one or more). May show degradation of performance.

At the conclusion of the test: Functions shall be self-recoverable. Shall operate as intended after recovering. Shall be no degradation of performance and no loss of stored data or user programmable functions.

Title: Test on GN Otometrics NoahLink, to EN 60 601-1-2 (1995) and EN 301 489-17 (2000)

5. Compliance with Specification

5.1. Immunity

PORT	ENVIRONMENTAL PHENOMENON	Reference subclause	RESULT
Enclosure	RF-electromagnetic field 26 - 80MHz 3V/m, 80%AM, 1kHz	[3]-36.202.2	Pass
	RF-electromagnetic field 80 - 1000MHz 3V/m, 80%AM, 1kHz	[3]-36.202.2 [2]- 9.2	Pass
	Electrostatic Discharge (ESD) 4kV Contact discharge/8kV Air discharge	[3]-36.202.1 [2]- 9.3	Pass

6. Measurements, Examinations and Derived Results

General Comments

The measurement uncertainties stated below are calculated according with the requirements of the Danish Institute of Fundamental Metrology.

Title: Test on GN Otometrics NoahLink, to EN 60 601-1-2 (1995) and EN 301 489-17 (2000)

6.1. Test results, Immunity

6.1.1. Electrostatic discharge.

Air discharges: Level: ±2kV, ±4kV and ±8kV

Contact discharges: Level: ±2kV and ±4kV

Measurement uncertainty:
Generator charging voltage: **±5%** (k=2)

Test points:

The following points were tested with direct or indirect contact discharges:

- On the shield of the L/R audio out connectors
- On the two charge terminal for the rechargeable battery
- Horizontal and vertical coupling planes

The following points were tested with air discharges:

- All cabinet seems
- Around all LED's
- All sides of the EUT

Measurement result:

EUT was operating as intended during and after the test. No loss of function or stored data.

Conclusion: The EUT comply with performance criteria B.

Test performed by: MBARDate: 2. April 2002

Title: Test on GN Otometrics NoahLink, to EN 60 601-1-2 (1995) and EN 301 489-17 (2000)

6.1.2. RF field (26- 80MHz and 80 - 1000MHz)

Test level:

RF-Field strength: 3 V/m, unmodulated carrier
Modulation: 80% AM at 1000Hz.

Measurement uncertainty:

Applied field strength: **-1.3dB/+1.1dB** (k=2)
Measured audio level: **±0,9 dB** (k=2)

Measurement results:

EUT was operating as intended during and after the test. No loss of function or stored data. The audio brake trough signal a 1000Hz was at all times during the test more than the 45dB below the full-scale output current of 30uA RMS.
During test with the Bluetooth link in idle mode no unintentional transmission was observed.

Conclusion: The EUT complied with performance criteria A, at all frequencies.

Test performed by: MBAR Date: 21. March and 2 April 2002

Title: Test on GN Otometrics NoahLink, to EN 60 601-1-2 (1995) and EN 301 489-17 (2000)

7. List of instruments

ESD:		
ESD Generator	Schaffner NSG 435	18360
Radiated RF-field immunity:		
RF generator	Marconi 2024	17649
Field sensor	Holaday HI 4400	17400
RF power amplifier	AR 500W1000M7	19011
RF power amplifier	Bonn BTA 0122-1000	16443
Log. per. antenna	EMCO 3142	NSL1228
Power meter	R&S NAP	16397
Power sensor	R&S NAP-Z6	16398
Monitoring equipment:		
Selective voltmeter	Wandel u. Goltermann, PMG13	7574
Selective voltmeter	Wandel u. Goltermann, PMG13	8147
AC-voltmeter	Hewlett Packard	18302
AC-voltmeter	Hewlett Packard	17651
Spectrum Analyser	Advantest R3361A	17652

Support equipment

Laptop PC
Toshiba Satellite
Digianswer Bluetooth Card