TEST REPORT
IEC 60601 -1

Medical electrical equipment
Part 1: General requirements for safety

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Date of issue ..... :	June 17, 2002
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Testing location ..... :	UL International Demko A/S, Lyskaer 8, DK-2730 Herlev, Denmark
Applicant ..... :	GN Otometrics A/S
Address ..... :	Dybendalsvænget 2, DK-2630Taastrup
Standard ..... :	IEC 60601-1:1988 + A1:1991 + A2:1995 and EN60601-1: 1990 +A1: 1993 +A2: 1995 +A13: 1996 (excluding CL. 36(EMC), CL. 48 (Biocompatibility) and CL. 52.1 (60601-1-4)
Test Report Form No. ..... :	I601-1_C/97-04
TRF Originator ..... :	Underwriters Laboratories Inc.
Master TRF ..... :	dated 97-04

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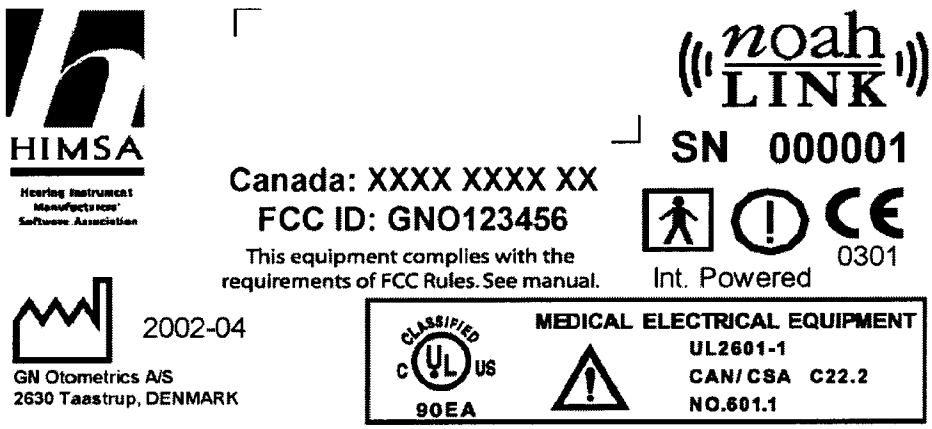
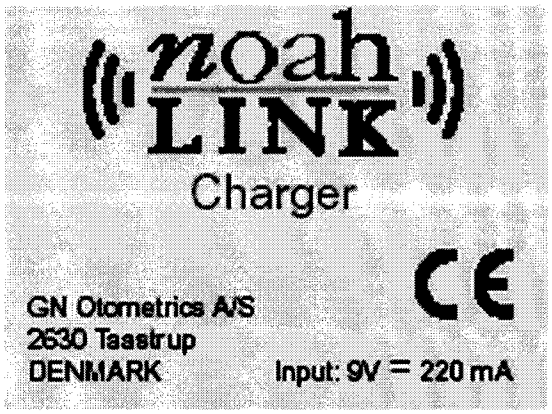
Test procedure ..... :	CB Scheme
Procedure deviation ..... :	N/A
Non-standard test method ..... :	N/A
Type of test object ..... :	Hearing Instrument Programmer
Trademark ..... :	-
Model/type reference ..... :	NOAH LINK
Manufacturer ..... :	Same as applicant
Rating ..... :	Internal Powered, 1.5Vdc

Copy of marking plate and summary of test results (information/comments):

Marking plate on NOAH link Programmer



Marking plate on NOAH Link Charger



GENERAL INFORMATION	
Test item particulars (see also clause 5):	
Classification of installation and use ..... :	portable, Type BF applied part
Supply connection ..... :	internally powered
Accessories and detachables parts included in the evaluation ..... :	NOAH LINK charger, rated 9VDC, 220mA
Options included ..... :	
Possible test case verdicts:	
- test case does not apply to the test object .....:N / A	
- test object does meet the requirement.....:Pass	
- test object does not meet the requirement.....:Fail	

Abbreviations used in the report:

- normal condition	:N.C.	- single fault condition	:S.F.C.
- operational insulation	:OP	- basic insulation	:BI
- basic insulation between parts of opposite polarity	:BOP	- supplementary insulation	:SI
- double insulation	:DI	- reinforced insulation	:RI

General remarks:

"(see Attachment #)" refers to additional information appended to the report.
"(see appended table)" refers to a table appended to the report.
Throughout this report a point is used as the decimal separator.
The tests results presented in this report relate only to the object tested.
This report is not valid as a CB Test Report unless appended to a CB Test Certificate issued by a NCB, in accordance with IECEE 02.
This report shall not be reproduced except in full without the written approval of the testing laboratory.
List of test equipment must be kept on file and available for review.
Summary of contents provided on the last page of this report.

General product information and considerations:

General - The product covered by this Report is Medical Electrical Equipment, Intended for Use in Health Care Facilities.

The NOAH LINK is intended to program Hearing Instruments, via Blue tooth communication.

The NOAH LINK charger is evaluated together with the Hearing Instrument Programmer NOAH LINK.

Accompanying documents indicates that the NOAH LINK shall be located outside the patient vicinity, when connected to the NOAH LINK charger. In the charging state the NOAH LINK is not considered Medical Electrical Equipment, why the Mains adaptor can be any IEC 60950 Certified Mains adaptor with rated output voltage of 9VDC and available power output less than 15W. In addition, the use of the NOAH LINK programmer is prevented during the charging state, by the electrical construction.

Attachments:

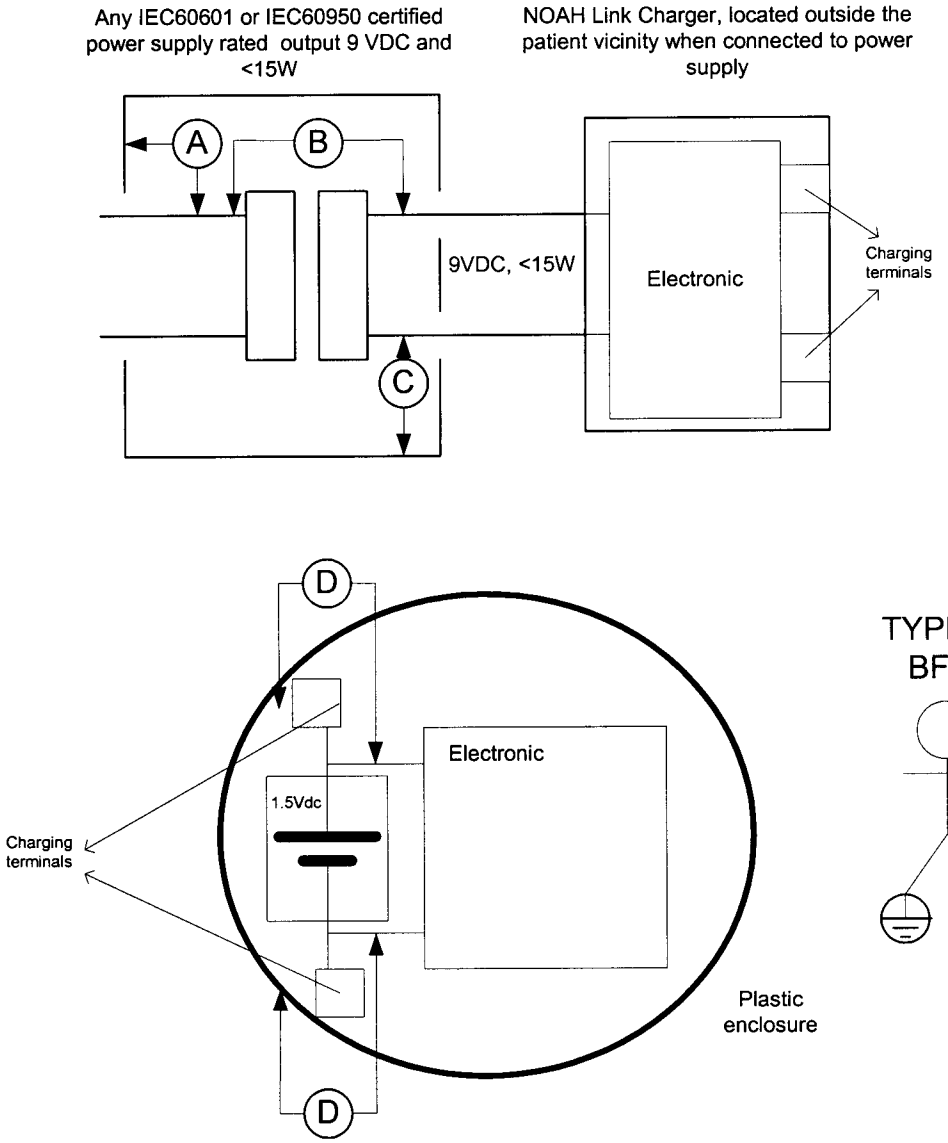
1 Pictures, total 3 pages

IEC 601 + Am. 1 and 2			
Clause	Requirement + Test	Result - Remark	Verdict
3	**GENERAL REQUIREMENTS**		Pass
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.)		Pass
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		N/A
5	**CLASSIFICATION**		Pass
5.1	Type of protection against electric shock		Pass
	Class I equipment		N/A
	Class II equipment		N/A
	Internally powered equipment		Pass
5.2	Degree of protection against electric shock		Pass
	Type B applied part		N/A
	Type BF applied part		Pass
	Type CF applied part		N/A
	Not classified - no applied parts		N/A
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	N/A
5.4	Methods of sterilization or desinfection		N/A
5.5	Equipment not suitable for use in the presence of flammable mixtures	Statement included in the User Manual	Pass
	Category AP equipment		N/A
	Category APG equipment		N/A
5.6	Mode of operation:		Pass
	-continuous operation		Pass
	-short-time operation, specified operation; period... :		—
	-intermittent operation, specified operation; rest period ..... :		—

IEC 601 + Am. 1 and 2			
Clause	Requirement + Test	Result - Remark	Verdict
	-continuous operation with short-time, stated permissible loading time ..... :		—
	-continuous operation with intermittent, stated permissible loading/rest time ..... :		—

INSULATION DIAGRAM

GN Otometrics, Model NOAH Link
Insulation diagram



Accissible part on the NOAH Link programmer is considered the applied part

	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	Double / reinforced	-	-	-	-	-	Covered in power supply evaluation
B	Double/ Reinforced	-	-	-	-	-	Covered in power supply evaluation
C	Operational	-	-	-	-	-	Covered in power supply evaluation
D	BI/SI	1.5Vdc	1.7mm	0.8mm	2.7mm	2.7mm	Distance of 2.7 mm measured between charge terminal and accessible enclosure. Since both terminals need to be touched at the same time BI is provided at one terminal and SI at other terminal.

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 the requirements of clauses 17, 20 and 57.

IEC 601 + Am. 1 and 2			
Clause	Requirement + Test	Result - Remark	Verdict

6	**IDENTIFICATION, MARKING AND DOCUMENTS**		Pass
6.1	Marking on the outside of equipment or equipment parts		Pass
6.1 c	Markings of the specific power supply affixed	Not required since the Equipment is not Medical Electrical Equpment when connected to the Charger	N/A
6.1 d	If marking is not practicable due to size or nature of enclosure, information is included in accompanying documents		N/A
6.1 e	Name and/or trademark of the manufacturer or supplier .....:	Both on charger and on NOAH LINK	Pass
6.1 f	Model or type reference .....:	model; NOAH charger and model; NOAK LINK	Pass
6.1 g	Rated supply voltages or voltage range(s)	Charger rated; 9VDC, 220mA	Pass
	Number of phases.....:		N/A
	Type of current .....:	Symbol no 4 located on charger	Pass
6.1 h	Rated frequency or rated frequency range(s) (Hz) :		N/A
6.1 j	Rated power input (VA, W or A) .....:	220mA marked on Charger	Pass
6.1 k	Power output of auxiliary mains socket-outlets		N/A
6.1 l	Class II symbol		N/A
	Symbol for degree of protection against ingress of water provided.....:	IPX0 rated, no requirement for marking	N/A
	Symbol for protection against electric shock .....:	Type BF marking located on NOAH LINK	Pass
	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	Only one type of applied parts	N/A
	Symbol for protection of defibrillation-proof applied parts		N/A
	Symbol 14 from Table DI for defibrillation-proof with protection partly in patient cable		N/A
6.1 m	Mode of operation (if no marking, suitable for continuous operation)	Continuos operation, no marking required	Pass
6.1 n	Types and rating of external accessible fuses .....:	No external accessible fuses	N/A
6.1 p	Ratings of external output.....:		N/A

IEC 601 + Am. 1 and 2			
Clause	Requirement + Test	Result - Remark	Verdict
6.1 q	Symbol for physiological effect(s):		Pass
	- attention, consult accompanying documents	Located on Charger, NOAH LINK Marking plate and in battery compartment	Pass
	- non-ionizing radiation, or symbols as adopted by ISO or IEC 417		N/A
6.1 r	Anaesthetic-proof symbol: AP or APG .....:		N/A
6.1 s	Dangerous voltage symbol		N/A
6.1 t	Special cooling requirements		N/A
6.1 u	Limited mechanical stability		N/A
6.1 v	Protective packing requirement(s)		N/A
	- Marking(s) for unpacking safety hazard(s)		N/A
	- Equipment or accessories supplied sterile, marked as sterile		N/A
6.1 y	Potential equalization terminal		N/A
	- Functional earth terminal		N/A
6.1 z	Removable protective means		N/A
	Durability of marking test	(see appended table 6.1)	Pass
6.2	Marking on the inside of equipment or equipment parts		Pass
6.2 a	Nominal voltage of permanently installed equipment		N/A
6.2 b	Maximum power loading for heating elements or holders for heating lamps		N/A
6.2 c	Dangerous voltage symbol		N/A
6.2 d	Type of battery and mode of insertion	Marked with exclamation mark and referenced in User manual	Pass
	- Marking referring to accompanying documents used for battery not intended to be changed by the operator		N/A
6.2 e	Fuses accessible with a tool identified either by type and rating or by a reference to diagram	Fuse F1 marked on PWB and referenced in Electrical schematics by fuse type and rating	Pass
6.2 f	Protective earth terminal	Internal Powered equipment	N/A
6.2 g	Functional earth terminal		N/A
6.2 h	Supply neutral conductor in permanently installed equipment (N)		N/A

IEC 601 + Am. 1 and 2			
Clause	Requirement + Test	Result - Remark	Verdict
6.2 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		N/A
	- Markings comply with IEC 445		N/A
6.2 k	For permanently connected devices the supply connections are clearly marked adjacent to the terminals (or in accompanying documents for small equipment)		N/A
6.2 l	Statement for suitable wiring materials at temperatures over 75 °C		N/A
6.2 n	Capacitors and/or circuit parts marked as required in Sub-clause 15c		N/A
6.3	Marking of controls and instruments		Pass
6.3 a	Mains switch clearly identified	When connected to Noah Charger and Mains adaptor the equipment is not considered Medical Electrical Equipment. Therefore no requirement.	N/A
	- ON and OFF positions marked according to Symbols 15 and 16 of table D1 or indicated by an adjacent indicator light	When connected to Noah Charger and Mains adaptor the equipment is not considered Medical Electrical Equipment. Therefore no requirement.	N/A
6.3 b	Indication of different positions of control devices and switches	Selector Switch located on the charger is provided with Green and yellow indicator LED's. Exclamation mark is located next to switch and referenced in User manual. On /OFF switch is located on the NOAH LINK, Marked with combination of symbol 15 and 16 table DI. Exclamation mark is also located on Noah link marking plate.	Pass
6.3 c	Indication of the direction in which the magnitude of the function changes, or an indicating device		N/A
6.3 f	The functions of operator controls and indicators are identified	On/off switch identy fied by symbols 15/16 of table DI, and Charge/ discharge switch is marked with exclamation mark and referenced in user manual	Pass
6.3 g	Numeric indications of parameters are in SI units except for units listed in Am. 2		N/A

IEC 601 + Am. 1 and 2			
Clause	Requirement + Test	Result - Remark	Verdict
6.4	Symbols		Pass
	Used symbols comply with Appendix D or IEC 417 and/or IEC 878 or ISO publications (if applicable)	Charger: table DI, Symbols 4, 14 NOAH LINK: table DI, Symbols15/16 table DII, symbol 2	Pass
6.5	Colors of the insulation of conductors		N/A
6.5 a	Protective earth conductor has green/yellow insulation		N/A
6.5 b	All insulations of internal protective earth conductors are green/yellow at least at their terminations		N/A
6.5 c	Only protective or functional earthing, or potential equalization conductors are green/yellow		N/A
6.5 d	Color of neutral conductor.....:		N/A
6.5 e	Colors of phase conductor(s) .....:		N/A
	- Compliance with IEC 227 and IEC 245		N/A
6.5 f	Additional protective earthing in multi-conductor, cords are marked green/yellow at the ends of the additional conductors		N/A
6.6	Medical gas cylinders and connections		N/A
6.6 a	In accordance with ISO ISO/R 32		N/A
6.6 b	Identification of connection point		N/A
6.7	Indicator lights and push-buttons		Pass
6.7 a	Red indicator lights used exclusively to indicate a warning of danger and/or a need for urgent action	No Red indicators provided on the NOAH LINK	N/A
	- Yellow used to indicate caution or attention required		N/A
	- Green used to indicate ready for action	Green indicator located on on the NOAH LINK to indicate ready for action and when communication is active to Hearing Aid. The Charger is provided with Red LED indicating discharge and Green LED indicating Charging state, The Red LED is accepted due to the fact, when Charger and NOAH LINK is connected it is not considered a Medical Electrical Equipment	Pass

IEC 601 + Am. 1 and 2			
Clause	Requirement + Test	Result - Remark	Verdict
6.7 b	Color red used only for push-buttons by which a function is interrupted in case of emergency	No red push bottom provided	N/A

IEC 601 + Am. 1 and 2			
Clause	Requirement + Test	Result - Remark	Verdict
6.8	ACCOMPANYING DOCUMENTS		Pass
6.8.1	Equipment accompanied by documents containing at least instructions for use, a technical description and an address to which the user can refer	User manual version GNO 7-26-66400/U1	Pass
	Classifications specified in Clause 5 included in both the instructions for use and the technical description	Int. Powered Type BF applied part Located in section "Technical specifications"	Pass
	Markings specified in Sub-clause 6.1 included in the accompanying documents if they have not been permanently affixed to equipment	Located in section 2.2 "Symbols"	Pass
	Warning statements and the explanation of warning symbols provided in the accompanying documents	Exclamation mark referenced in the user manual	Pass
6.8.2	Instructions for use		Pass
6.8.2 a	General information provided in instructions for use		Pass
	- state the function and intended application of the equipment	Section 1	Pass
	- include an explanation of: the function of controls, displays and signals	Section 6	Pass
	- the sequence of operation	Section 5-Section 7	Pass
	- the connection and disconnection of detachable parts and accessories	Section 3	Pass
	- the replacement of material which is consumed during operation	Section 3: Batteries	Pass
	- information regarding potential electromagnetic or other interference and advice regarding avoidance	Noah LINK warning note 4	Pass
	- include: indications of recognized accessories, detachable parts and materials, if the use of other parts or materials can degrade minimum safety	Section 3	Pass
	- instructions concerning cleaning, preventive inspection and maintenance to be performed including the frequency of such maintenance	Section 4	Pass
	General information provided in instructions:		Pass
	- information for the safe performance or routine maintenance		Pass

IEC 601 + Am. 1 and 2			
Clause	Requirement + Test	Result - Remark	Verdict
	- parts on which preventive inspection and maintenance shall be performed by other persons including the periods to be applied	Section 4.4	Pass
	- explanation of figures, symbols, warning statements and abbreviations on the equipment		Pass
6.8.2 c	Signal output or signal input parts intended only for connection to specified equipment described		N/A
6.8.2 d	Details about acceptable cleaning, disinfection or sterilization methods included	Section 4.4	Pass
6.8.2 e	Warning statement for mains operated equipment with additional power source		N/A
6.8.2 f	A warning to remove primary batteries if equipment is not likely to be used for some time	Section 4.2	Pass
6.8.2 g	Instructions to ensure safe use and adequate maintenance of rechargeable batteries	Section 5.1.2 and 6	Pass
6.8.2 h	Identification of specified external power supplies or battery chargers necessary to ensure compliance with the requirements of IEC 601-1	Specification of Mains adaptor not necessary due to the use of the charger is outside the patient vicinity	N/A
6.8.2 j	Identification of any risks associated with the disposal of waste products, residues, etc.	Disposal of Electronic and Batteries described in section 2.3 "Warnings"	Pass
	- Advice in minimizing these risks		Pass
6.8.3	Technical description		Pass
6.8.3 a	All characteristics essential for safe operation provided		Pass
6.8.3 b	Required type and rating of fuses utilized in the mains supply circuit external to permanently installed equipment		N/A
	- Instructions for replacement of interchangeable and/or detachable parts which are subject to deterioration during normal use	Batteries	Pass
6.8.3 c	Instructions or reference information for repair of equipment parts designated by the manufacturer as repairable provided	No user repairable parts inside the equipment	N/A
6.8.3 d	Environmental conditions for transport and storage specified in accompanying documents and marked on packaging	-25 deg C to +70deg C, <90%, non condensing,500hPa to 1060hPa	Pass

IEC 601 + Am. 1 and 2			
Clause	Requirement + Test	Result - Remark	Verdict
7	**POWER INPUT**		Pass
	Power Input Measurements	(see appended table 7)	Pass
10	**ENVIRONMENTAL CONDITIONS**		Pass
10.1	Equipment is capable while packed for transport or storage of being exposed to the conditions stated by the manufacturer	-25 deg C to +70deg C, <90%, non condensing,500hPa to 1060hPa	Pass
10.2.2 a	Rated voltage not exceeding 250 V for hand-held equipment		Pass
	Rated voltage not exceeding 250 V d.c. or single-phase a.c. or 500 V polyphase a.c. for equipment up to 4kVA		Pass
	Rated voltage not exceeding 500 V for all other equipment		N/A
	Rated input frequency not more than 1kHz		N/A
10.2.2 b	Internal replaceable electrical power source specified	Rechargeable (Ni-MH type), size AA(R6), rated 1.2V Alcaline batteries Type Alcaline size AA(R6) rated 1.5V	Pass

IEC 601 + Am. 1 and 2			
Clause	Requirement + Test	Result - Remark	Verdict

14	REQUIREMENTS RELATED TO CLASSIFICATION		Pass
14.4 a	Class I and Class II equipment in addition to basic insulation provided with an additional protection		N/A
14.4 b	Equipment supplied from external dc source of reverse polarity results in no safety hazard	Charger and Noah LINK connectors coded to avoid reverse connection	Pass
14.5 a	Dual classification for internally powered equipment with a means of connection to supply mains	When NOAH LINK programmer is connected to the Charger and connected to Mains adaptor the equipment is placed outside the patient vicinity. In addition the NOAH LINK is not able to function when connected to charger	N/A
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		N/A
14.6 c	Applied parts intended for direct cardiac application are of type CF		N/A

15	LIMITATION OF VOLTAGE AND/OR ENERGY		N/A
15 b	Voltage measured one sec after disconnection of the mains plug does not exceed 60V		N/A
15 c	For live parts accessible after equipment has been de-energized the residual voltage does not exceed 60 V nor residual energy exceed 2 mJ		N/A
	Marking provided for manual discharging		N/A

IEC 601 + Am. 1 and 2			
Clause	Requirement + Test	Result - Remark	Verdict
16	**ENCLOSURES AND PROTECTIVE COVERS**		Pass
16 a	Equipment enclosed to protect against contact with live parts, and with parts which can become live (finger, pin, hook test)		Pass
	Insertion or removal of lamps - protection against contact with live parts provided		N/A
16 b	Opening in a top cover positioned that accessibility of live parts by a test rod is prevented	No openings in enclosure	N/A
16 c	Conductive parts accessible after the removal of handles, knobs, levers		N/A
	- have a resistance of not more than 0.2 Ω		N/A
	- separated from live parts by one of the means described in Sub-clause 17g		N/A
16 d	Parts with voltage exceeding 25V a.c. or 60V d.c. which cannot be disconnected by external mains switch or plug protected against contact		N/A
16 e	Removable enclosures protecting against contact with live parts		Pass
	- Removal possible only with the aid of a tool		Pass
	- Use of automatic device making parts not live when the enclosure is opened or removed		N/A
	- Exception 16e applied to the following parts .....:	Battery compartment	Pass
16 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/A

IEC 601 + Am. 1 and 2			
Clause	Requirement + Test	Result - Remark	Verdict
17	**SEPARATION**		Pass
17 a	Separation method of the applied part from live parts:		Pass
	1) basic insulation: applied part earthed		N/A
	2) by protectively earthed conductive part (e.g. screen)		N/A
	3) by separate earthed intermediate circuit limiting leakage current to applied part in event of insulation failure		N/A
	4) by double or reinforced insulation	The user manual indicate that Hearing aids connected to the NOAH LINK must not have accessible conductive parts and the Patient cable shall be provided with Double insulation. Double/Reinforced insulation between internal power source and accessible parts on the NOAH LINK	Pass
	5) by protective impedances limiting current to applied part		N/A
	- Additional leakage current test in single fault conditions		N/A
17 c	There is no conductive connection between applied parts and accessible conductive parts which are not protectively earthed		Pass
17 d	Supplementary insulation between hand-held flexible shafts and motor shafts (Class I)		N/A
17 g	Separation method of accessible parts other than applied parts from live parts:		N/A
	1) basic insulation: accessible part earthed		N/A
	2) by protectively earthed conductive part (e.g. screen)		N/A
	3) by separate earthed intermediate circuit limiting leakage current to enclosure in event of insulation failure		N/A
	4) by double or reinforced insulation		N/A
	5) by protective impedances limiting current to accessible part		N/A
	- Additional leakage current test in single fault conditions		N/A
17 h	Arrangements used to isolate defibrillation-proof applied parts so designed that:		N/A

IEC 601 + Am. 1 and 2			
Clause	Requirement + Test	Result - Remark	Verdict
	- no hazardous electrical energies appear during a discharge of a cardiac defibrillator		N/A
	- after exposure to the defibrillation voltage, the equipment continues to perform its intended function		N/A