IEC 601 + Am. 1 and 2			
Clause	Requirement + Test	Result - Remark	Verdict
58	**PROTECTIVE EARTHING - TERMINALS AND CONNECTIONS**		N/A
58.1	Clamping means of the protective earth terminal		N/A
	Not be able to loosen without the aid of a tool		N/A
	Screws for internal earth connections are covered or protected against loosening from outside		N/A
58.7	Earth pin of the appliance inlet regarded as the protective earth terminal		N/A
58.8	The protective earth terminal not used for the mechanical connection or the fixing of any component not related to earthing		N/A
58.9	Where the protective earth connections are made via a plug or socket device the protective earth connection is made before and interrupted after the supply connections during connection and interrupting		N/A

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Clause	Requirement + Test	Result - Remark	Verdict

59	**CONSTRUCTION AND LAYOUT**		Pass
59.1	Internal wiring		Pass
59.1 a	Cables and wiring protected against contact with a moving part	No moving parts	N/A
	Wiring having basic insulation only protected by additional fixed sleeving		N/A
	Components are not likely to be damaged in the normal assembly or replacement of covers		Pass
59.1 b	Movable leads are not bent around a radius of less than five times the outer diameter of the lead		N/A
59.1 c	Insulating sleeving adequately secured		N/A
	If the sheath of a flexible cable or cord is used as supplementary insulation it complies with requirements of IEC 227 and IEC 245 and dielectric test		N/A
	Conductors subjected to temperatures exceeding 70°C have an insulation of heat-resistant material		N/A
59.1 d	Aluminum wires of less than 16 mm^2 cross-section not used		N/A
59.1 f	Connecting cords between equipment parts considered as belonging to the equipment	No connecting cords	N/A
59.2	Insulation		Pass
59.2 b	Mechanical strength and resistance to heat and fires retained by all types of insulation		Pass
59.2 c	Insulation not likely to be impaired by deposition of dirt or by dust resulting from wear of parts		Pass
	Parts of rubber resistant to ageing		N/A
59.3	Excessive current and voltage protection		Pass
	Internal electrical power source provided with device for protection against fire hazard	Provided with fuse rated F5A	Pass
	Fuse elements replaceable without opening the enclosure fully enclosed in a fuseholder		N/A
	Protective devices between an isolated applied part and the body of the equipment do not operate below 500 V r.m.s.		N/A
59.4	Oil containers		N/A
	Oil containers adequately sealed		N/A
	Container allow for the expansion of the oil		N/A

IEC 601 + Am. 1 and 2			
Clause	Requirement + Test	Result - Remark	Verdict
	Oil containers in mobile equipment sealed to prevent the loss of oil during transport		N/A
	Partially sealed oil-filled equipment or equipment parts provided with means for checking the oil level		N/A

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

6.1	TABLE: marking durability	Pass
Marking tested		Remarks
Charger label, Bayer 1010, with 3M 467 adhesive		Marking clearly legible, edges did not lift or curl
Noah link marking label, Zebra Technologies Corporation, type Poly-Trans 4G		Marking clearly legible, edges did not lift or curl
Silk screened Exclamation mark located on Charger		Marking clearly legible

7	TABLE: power input				Pass
Operating condition	Voltage	Frequency	Current	Power	Remarks
Noah Charger was connected to external DC power source of 9 Vdc. Battery in NOAH LINK was drained then charged by the Noah Charger. Maximum current was recorded	9Vdc	DC	173mA		Charger rated 220mA

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

15b	TABLE: residual voltage in attachment plug										N/A
Voltage measured between:	Measurements [V]										Remarks
	1	2	3	4	5	6	7	8	9	10	
pin 1 and earth pin											
line pin 1 and enclosure											
line pin 2 and enclosure											
pin 2 and earth pin											
supply pins (pin 1 & pin 2)											

15c	TABLE: residual voltage or energy in capacitors				N/A
Capacitor and its location	Residual voltage (V)	Time after disconnection (s)	Capacitance value (µF)	Residual energy (mJ)	Remarks
supplementary information:					

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

17h1	TABLE: defibrillation-proof applied parts				N/A
Test Condition: Fig. 50 or 51	Accessible part of measurement:	Applied part with test voltage	Test voltage polarity	Measured voltage between Y1 and Y2 (mV)	Remarks
supplementary information:					

17h2	TABLE: defibrillation-proof recovery time			N/A
Applied part with test voltage	Test voltage polarity	Recovery time from accompanying documents (s)	Measured recovery time (s)	Remarks
supplementary information:				

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

18	TABLE: protective earthing				N/A
Test location		Test current (A)	Measured voltage (V)	Resistance (ohms)	Remarks
supplementary information:					

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

19	TABLE: leakage current				Pass
Type of leakage current and test condition (including single faults)		Supply voltage	Supply frequency	Measured max. value	Remarks
P,B/A		Internal powered	DC	0uA/ 0uA	(Enclosure wrapped in foil)
PM,B/A		Internal powered	60Hz	18uA/ 16uA	(Mains on the applied part, enclosure wrapped in alu-foil and connected to ground)
(Record at least maximum measured value for each test required by Clause 19 and the specific conditions of the test circuit and equipment).					

Abbreviations used:

ER - Earth leakage current	A - After humidity conditioning
EN - Enclosure leakage current	B - Before humidity conditioning
P - Patient leakage current	1 - Switch closed or set to normal polarity
PM - Patient leakage current with mains on the applied parts	0 - Switch open or set to reversed polarity
PA -Patient auxiliary current	NC - Normal condition
Fig. 15 - refers to Fig. 15 in IEC601-1	SFC - Single fault condition
MD - Measuring device	

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

20	TABLE: dielectric strength				Pass
Insulation under test (area from insulation diagram)	Insulation type: (OP-operational / BI-basic / SI-supplementary / DI-double / RI-reinforced)	Reference voltage (V)	Test voltage (V)	Remarks	
A Mains to Enclosure	DI/RI	240Vac	-	Evaluated in Mains adaptor	
B Mains to sec electronic	DI/RI	240Vac	-	Evaluated in Mains adaptor	
C Secondary to Mains adaptor enclosure	Operational	9Vdc	-	Evaluated in Mains adaptor	
D Battery voltage to Applied part/ enclosure of NOAH LINK	BI/SI	1.5Vdc	500V	Passed test before and after hum. treatment	

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

21	TABLE: mechanical strength		Pass
Part under test		Test (impact, drop, force, handle, rough handling, mobile)	Remarks
Enclosure of NOAH LINK		CL21.a 45 N applied to enclosure over an area of 625 mm2	+
Enclosure of NOAH LINK		CL21.b Impact by 0.5J	+
NOAH LINK programmer		CL21.5 Drop test from 1 m onto hard wood board	+
Charger and NOAH LINK		CL21.6 Rough handling. Dropped from a high of 5 cm onto hard wood board	+
+ No cracking of the enclosure or access to live parts			

24	TABLE: - stability		N/A
Part under test		Test condition	Remarks
supplementary information:			

29	TABLE: X - radiation			N/A
Part under test		Test condition	Measured radiation (mR)	Remarks
supplementary information:				

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

42	TABLE: normal temperature	Pass
Supply voltage: 9.9Vdc(9Vdc+10%) Ambient temperature: see remarks	Test Condition: NOAH LINK installed with software simulating continuous programming of a Hearing Aid. To simulate the Hearing aid, the NOAH LINK was connected to external resistors simulating the load of 45 mA. Test continued until thermal stability was reached. When testing the charger, the Ni-MH battery was drained then charged until thermal stability was reached.	

Measuring location	Measured temperature [°C]	Remarks
Noak Link: PWB near T7	33°C	+
PWB near IC12	54°C	+
BT1	39°C	++
PWB near Fuse F1, rated F5A	39°C	+
Enclosure of NOAH Link (applied part)	54°C, (49°C)	++, Accepted since max temperature of 49°C was measured during normal programming of Hearing instrument. The 54°C was measured during charge of battery. Applied part is not intended to get in contact with patient skin, but only touching the clothes.
PWB near IC11	36°C	+
Charger: PWB near D5	59°C	+
PWB near VR1	74°C	+
PWB near R10	60°C	+
PWB near D1	47°C	+
+ Corrected to ambient temperature of 25C ++ Corrected to ambient temperature of 40C		
COR - indicates measurements taken using change-of-resistance method		

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

44	TABLE: overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, desinfection		Pass
Test type and condition		Part under test	Remarks
CL 44.5 Humidity treatment for 48 hours at 93% RH, 30C		Noah link	+
CL 44.7 Cleaning. Cleaned with a soft , slightly damped cloth with a small amount of detergent on it.		Enclosure Noah link	+
+ No dielectric breakdown, when CL 20 was repeated. No wetting of uninsulated live parts			

45	TABLE: hydrostatic pressure and pressure-relief device cycling test		N/A
Test type and condition	Part under test	Test pressure	Remarks
supplementary information:			

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

52	TABLE: abnormal operation		N/A
Test type, condition and clause reference		Observed results	Remarks
supplementary information:			

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

56.1	TABLE: lists of critical component parts				Pass
Object/part No	Manufacturer/ trademark	Type/model	Technical data	Standard	Mark(s) of conformity[1])
Noah Link Marking plate material	Zebra Techniologies Corporation	Poly-Trans 4G, printed with Zebra's 5095 ribbon	Top coated flexible vinyl permanent acrylic adhesive		Evaluated in this application
Enclosure material	BASF Corp	Terluran, type GD-22	HB, Not relied on as fire enclosure. P<15W	UL94	UL, evaluated in this application
Battery	Friwo	NiMH Accu	rated 1.2 V, 1800 mA, AA-size		Evaluated in this application
Fuse F1	Littelfuse		rated F5A, 32V. SMD component	IEC127 fast acting	UL, S
PWB			Rated 105°		UL, CSA
Noah Link Charger Marking plate material	Bayer	type 1010 with 3M 467 adhesive	Indicating: Noah Link Charger, GN Otometrics, Input 9Vdc, 220mA		Evaluated in this application
[1]) an asterisk indicates a mark which assures the agreed level of surveillance					

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Clause	Requirement + Test	Result - Remark	Verdict

56.10	TABLE: actuating parts and controls		N/A
Part under test		Torque applied	Remarks
supplementary information:			

56.11b	TABLE: foot operated control devices-loading		N/A
Part under test		Observed results	Remarks
supplementary information:			

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

57.4	TABLE: cord anchorages			N/A
Cord under test	Mass of equipment	Pull	Torque	Remarks
supplementary information:				

57.4b	TABLE: cord bending		N/A
Cord under test	Test mass	Measured curvature	Remarks
supplementary information:			

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

57.9.1a	TABLE: transformer short circuit					N/A
Winding under test	Protection	Measured temperatures (°C)			Test duration	Remarks
		Primary	Secondary	Ambient		
supplementary information:						

57.9.1b	TABLE: overload						N/A
Winding under test	Protection	Measured temperatures (°C)			Test duration	Test current or thermal cutout temp.	Remarks
		Primary	Secondary	Ambient			
supplementary information:							

57.9.2	TABLE: transformer dielectric strength				N/A
Transformer under test	Test voltage applied to	Test voltage	Test frequency	Remarks	
supplementary information:					

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

	TABLE: additional tests		
Clause	Test type and condition	Remarks and observed results	Verdict
20.3	Working voltage measurements: Voltage on Applied part connector	1.3Vdc	
20.3	Working voltage measurements: Voltage on Noah Charger pins	4.96Vdc	
49	Interruption of the power supply. Noah Link interrupted	New data has to be entered	No hazard
49	Interruption of the power supply. Noah Link Charger interrupted then reenergized	Battery charger stop Charge/discharge. When reenergized charger continue with charge / discharge	No hazard
52.1	Power availability test. Battery protected by Fast acting fuse rated F5A.	The fuse characteristics indicate that fuse will open within 5 sec. if 200% of rated current is drawn.	<15W after 1 min
56.7	Battery inserted in reverse position, then Noah link was connected to charger	No Temperature rise was detected on the battery, since no charging of battery is done	No hazard
59.2	Ball pressure test on enclosure parts	Maximum impression measured to 0.95mm in diameter	Pass