TEST REPORT
IEC/EN 60601-2-66
Medical electrical equipment

Part 2-66: Particular requirements for the basic safety and essential performance of hearing instruments and hearing instrument systems

Report Reference No. ..... : CHTSM19120019

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Date of issue ..... : 2019-12-04

Testing Laboratory ..... : Shenzhen Huatongwei International Inspection Co., Ltd.

Address ..... : 1/F, Bldg9, Hongfa Hi-tech Industrial Park, Genyu Road, Tianliao, Gongming, Shenzhen, Guangdong, China

Applicant's name ..... : **Huizhou Jinghao Medical Techology Co., Ltd.**

Address ..... : Floor 6, Huicheng Industry Building, No.9 Huifeng Dong'er Road, Zhongkai High-tech Zone, Huizhou City, Guangdong Province, China

Test specification:

Standard ..... : ☒ IEC 60601-2-66:2015 ☒ EN 60601-2-66:2015

Test procedure ..... : Test report only

Non-standard test method ..... : N/A

Test Report Form No ..... : IEC60601_2_66D

Test Report Form(s) Originator ..... : TÜV SÜD Product Service GmbH

Master TRF ..... : Dated 2017-06

Test item description ..... : hearing aid

Trade Mark ..... : N/A

Manufacturer ..... : Huizhou Jinghao Medical Techology Co., Ltd.

Model/Type reference ..... : JH-D26(HA70), JH-D31,JH-D36,JH-D37,JH-118,JH-119,JH-129

Ratings ..... : 1.5Vd.c.

IEC/EN 60601-2-66

Summary of testing:

Tests performed (name of test and test clause):

1) 201.7.1.1 & 201.12.2Usability according to IEC 60601-1-6 is not evaluated in this report.

2) 201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS according to IEC 60601-1-2 is not evaluated in this report.

Testing location:

Shenzhen Huatongwei International Inspection Co., Ltd.

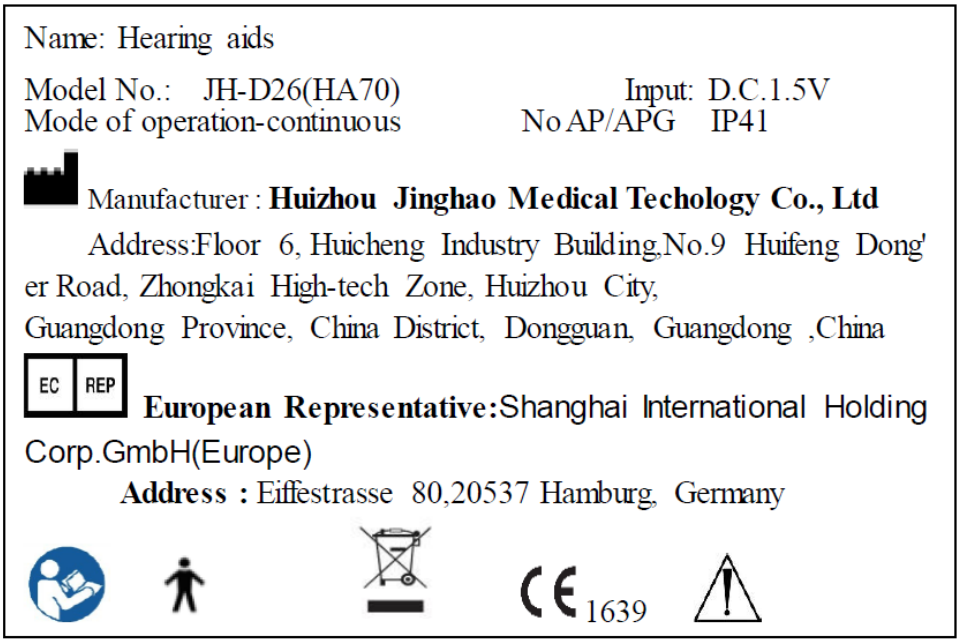
1/F, Bldg9, Hongfa Hi-tech Industrial Park, Genyu Road, Tianliao, Gongming, Shenzhen, Guangdong, China

Summary of compliance with National Differences

N/A

Copy of marking plate

(The artwork below may be only a draft)



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Test item particulars..... :	
Classification of installation and use ..... :	Body-worn
Supply connection ..... :	Internal Battery
Possible test case verdicts:	
- test case does not apply to the test object.....:	N/A
- test object does meet the requirement .....:	Pass (P)
- test object does not meet the requirement.....:	Fail (F)
Testing:	
Date of receipt of test items .....:	2019-11-05
Date(s) of performance of tests.....:	2019-11-05 to 2019-11-27

General remarks:

The test results presented in this report relate only to the object tested.
This report shall not be reproduced, except in full, without the written approval of the Issuing testing laboratory.
"(see Enclosure #)" refers to additional information appended to the report.
"(see appended table)" refers to a table appended to the report.

Throughout this report a ☐ comma / ☒ point is used as the decimal separator.

This Test Report Form contains the particular requirements for the safety of hearing instruments and hearing instrument systems according to EN 60601-2-66. It can only be used together with EN 60601-1 Test Report.

General product information:

1. The ME equipment is body-worn ME equipment;
2. Mode of operation: continuous operation;
3. Mode of Supply: internal powered by recharged nickel-hydrogen battery: 1.5Vd.c.;
4. Max operation temperature: 40 °C;
5. Model differences description: All models are the same with measuring principle, insulation enclosure, except the some parameters, battery type, appearance.
6. JH-D26(HA70) and JH-118 are with the same recharged nickel-hydrogen battery, the charging box is suitable only for JH-D26(HA70) and JH-118,the internal battery for other models are primary battery and JH-D31 external dimension is smaller than others, unless otherwise specified, all the tests are conducted on model JH-D26(HA70) and JH-D31 to represent other models;
7. Manufacturers do not evaluate the adapter for the charging box, the relevant experiment with DC source test.

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Clause	Requirement + Test	Result - Remark	Verdict

201.4	**GENERAL REQUIREMENTS**		
201.4.1	Requirements of this standard applied in NORMAL USE and reasonably foreseeable misuse		P
201.4.3	HEARING INSTRUMENTS do not have an ESSENTIAL PERFORMANCE		—
201.4.6	Subclause 4.6 of the general standard does not apply.	Refer to IEC/EN 60601-1 report	—
201.4.10	Subclause 4.10 of the general standard does not apply.	Refer to IEC/EN 60601-1 report	—
201.4.11	Subclause 4.11 of the general standard does not apply.	Refer to IEC/EN 60601-1 report	—

201.5	**GENERAL REQUIREMENTS FOR TESTING ME EQUIPMENT**		
201.5.2	TYPE TESTS conducted on one representative sample under investigation; multiple samples used simultaneously when validity of results was not significantly affected .....:	Conducted on one representative sample	P
201.5.3	Tests conducted within the environmental conditions specified in technical description	See below	P
	Temperature (ºC), Relative Humidity (%) .....:	-10ºC-40ºC, 30%-75%RH	P
	Atmospheric Pressure (kPa).....:	860-1060hPa	P
201.5.4	aa) Inventory stocking conditions are specified by manufacturer	Refer to user manual	P
	bb) Transport conditions are specified by manufacturer	Refer to user manual	P
201.5.5	a) Effect of deviation of supply voltage from its rated value taken into account		P
	b) Supply voltage during tests was the least favourable of the voltages specified in 4.10 or voltages marked on ME EQUIPMENT (V).....:		N/A
	c) HEARING INSTRUMENTS tested with alternative ACCESSORIES and components specified in ACCOMPANYING DOCUMENTS to result in the least favourable conditions .....:	Considered	P
	d) ME EQUIPMENT connected to a separate power supply as specified in instructions for use	Internal powered	N/A
201.5.7	ME EQUIPMENT or parts thereof affected by climatic conditions were set up completely, or partially, with covers detached and subjected to a humidity preconditioning prior to tests of Clauses 201.8.7.4	Considered	P
	Manually detachable parts removed and treated concurrently with major parts and manually removable ACCESS COVERS were opened and detached		P

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Clause	Requirement + Test	Result - Remark	Verdict
	ME EQUIPMENT heated to a temperature between T and T + 4 °C for at least 4 h and placed in a humidity chamber with a relative humidity of 93 % ± 3 % and an ambient within 2 °C of T in the range of + 20 °C to + 32 °C for 48 h for IPX0 EQUIPMENT	IP41	N/A
	ME EQUIPMENT heated to a temperature between T and T + 4 °C for at least 4 h and placed in a humidity chamber with a relative humidity of 93 % ± 3 % and an ambient within 2 °C of T in the range of + 20 °C to + 32 °C for 168 h for higher ingress protection	IP41	P
201.5.9	**Determination of APPLIED PARTS and ACCESSIBLE PARTS**		P
201.5.9.1	The HEARING INSTRUMENT and other parts that have to be in contact with the patient are TYPE B APPLIED PARTS		—
201.5.9.1	ACCESSIBLE PARTS		P
201.5.9.2.1	Additional tests performed with the small finger probe of Fig.1 IEC 60601-1-11:2010	Could not accessible	P
201.5.201	Sound pressure level measured in decibels (dB) according to IEC 60118-0:2015	Measured : 115.6dB The TEST is subcontracted in Lab: VoiceX Acoustics(Shenzhen) Ltd.	P
201.6	**CLASSIFICATION OF ME EQUIPMENT AND ME SYSTEMS**		
201.6.2	The insulation between SUPPLY MAINS and the HEARING INSTRUMENTS, if they have connections to mains supplied equipment, is provided within power supply, charger or other ACCESSORY.	Internal powered	P
	The HEARING INSTRUMENT is a TYPE B APPLIED PART		—
201.6.3	Protection against harmful ingress of water or particulate matter	See clause 201.11.6.5.	—
201.6.6	HEARING INSTRUMENTS are classified for CONTINUOUS OPERATION		—
201.7	**ME EQUIPMENT Identification, marking, and documents**		**P**
201.7.1.1	RISK of poor USABILITY associated with the design of ME EQUIPMENT'S identification, marking and documents addressed in the RISK MANAGEMENT PROCESS .....:	See USABILITY ENGINEERING FILE ,EVALUATED BY MANUFACTURE	N/E
	The USABILITY evaluated based on the PATIENT profile	See USABILITY ENGINEERING FILE ,EVALUATED BY MANUFACTURE	N/E
	The design should be simple and does not require reference to ACCOMPANYING DOCUMENTS	See USABILITY ENGINEERING FILE ,EVALUATED BY MANUFACTURE	N/E
201.7.1.2	Legibility of Markings Test for Markings specified in Clause 7.2-7.3 .....:	Complied	P
201.7.2	**Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts**		P

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Clause	Requirement + Test	Result - Remark	Verdict
201.7.2.1	Markings applied on the product .....:	See attached copy of Marking Plate	P
	Remaining markings fully recorded in ACCOMPANYING DOCUMENTS.....:	Refer to user manual	P
	Markings applied to individual packaging when impractical to apply to ME EQUIPMENT		P
201.7.2.2	MANUFACTURER's name or trademark marked on ME EQUIPMENT and detachable components except when worn in the ear.		P
	MODEL OR TYPE REFERENCE also marked, except when worn in the ear.		P
	Identification of right and left HEARING INSTRUMENT unless absence of this marking does not present an unacceptable RISK.....:	Not present an unacceptable RISK	N/A
	Serial number.....:	Refer to Marking Plate	P
	Year of manufacture	Refer to Marking Plate	P
201.7.2.5	Subclause 7.2.5 of the general standard does not apply.	Refer to IEC/EN 60601-1 report	—
201.7.2.6	Subclause 7.2.6 of the general standard does not apply.	Refer to IEC/EN 60601-1 report	—
201.7.2.7	Subclause 7.2.7 of the general standard does not apply.	Refer to IEC/EN 60601-1 report	—
201.7.2.8	Subclause 7.2.8 of the general standard does not apply.	Refer to IEC/EN 60601-1 report	—
201.7.2.10	Subclause 7.2.10 of the general standard does not apply.	Refer to IEC/EN 60601-1 report	—
201.7.2.17	Packaging marked with special handling instructions for transport and/or storage.....:	No such pecial handling instructions	N/A
201.7.8.1	Colours of indicator lights and their meaning stated in instructions for use		P
201.7.9.1	ME EQUIPMENT accompanied by documents containing at least instructions for use, and a technical description	Refer to user manual chapter "II. INTENDED USE"	P
	ACCOMPANYING DOCUMENTS identify ME EQUIPMENT by the following, as applicable:		P
	- Name or trade-name of the MANUFACTURER (contact information)	See the bottom of the User Manual	P
	- Model or type reference	Refer to user manual	P
	- Warning to RISK of impairing remaining hearing	Refer to user manual chapter "III. IMPORTANT SAFETY INSTRUCTIONS"	P

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Clause	Requirement + Test	Result - Remark	Verdict
	When ACCOMPANYING DOCUMENTS provided electronically (e.g., on CDROM), RISK MANAGEMENT PROCESS includes instructions as to what is required in hard copy or as markings on ME EQUIPMENT (for emergency operation)	Not provided electronically. Provided on paper.	N/A
	ACCOMPANYING DOCUMENTS written at a level consistent with education, training, and other needs of individuals for whom they are intended	No such requirements.	N/A
201.7.9.2	Instructions for use include the required information		P
201.7.9.2.1	– name or trademark and address of the MANUFACTURER	See the bottom of the User Manual	P
	- MODEL OR TYPE REFERENCE	Refer to user manual	P
	– intended use of ME EQUIPMENT,	Refer to user manual chapter “II. INTENDED USE”	P
	– frequently used functions, and	Refer to user manual chapter “II. INTENDED USE”	P
	– known side effects associated with use of ME EQUIPMENT	Refer to user manual chapter “II. INTENDED USE”	P
	– Written in a language which is acceptable to the intended operator	Provided in English	P
	– easily understood diagrams, illustrations or photographs of assembled and connected HEARING INSTRUMENT	Refer to user manual	P
	– restrictions on locations and environment	Refer to user manual	P
	– advice for assistance and to report unexpected operations and events	Refer to user manual	P
201.7.9.2.2	Instructions for use include all warning and safety notices	Refer to user manual chapter “III. IMPORTANT SAFETY INSTRUCTIONS”	P
	Specific warnings stated in the instructions for use, where relevant	See table 201.7.9.2.2	P
201.7.9.2.4	Instruction for use contains warning to remove battery if leakage would result in an unacceptable risk.	No such unacceptable risk	N/A
201.7.9.2.5	Instruction for use includes a description of the HEARING INSTRUMENT and how it operates	Refer to user manual	P
	Instruction for use includes a warning only to connect to equipment that conforms with international safety standards, if externally connected.	No externally connected.	N/A
201.7.9.2.9	The instructions for use contain all information necessary to operate the HEARING INSTRUMENT in accordance with its specification. Explanation included of the functions of controls, battery compartment and signals as well as connection and disconnection of detachable parts and ACCESSORIES.	Refer to user manual chapter “V. PREPARATION” and “VI. OPERATION”	P

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Clause	Requirement + Test	Result - Remark	Verdict
	Meanings of figures, symbols, warning statements, abbreviations and indicator lights described in instructions for use	Refer to user manual chapter "IX. NORMALIZED SYMBOLS"	P
201.7.9.2.12	Information provided about cleaning and maintenance of HEARING INSTRUMENT and where applicable:	Refer to user manual chapter "VII HEARING aids CARE"	P
	– washing the ear mould	Refer to user manual chapter "VII HEARING aids CARE" and "VI. MAINTENANCE AND CLEAN"	P
	– replacing tubing, filters and other parts	Refer to user manual chapter "VI. MAINTENANCE AND CLEAN"	P
	– storing the HEARING INSTRUMENT	Refer to user manual	P
	– maintenance for rechargeable batteries	Refer to user manual chapter "VI. MAINTENANCE AND CLEAN"	P
	– information on repair services	Refer to user manual chapter "VI. MAINTENANCE AND CLEAN"	P
201.7.9.2.14	A list of ACCESSORIES, detachable parts, and materials for use with ME EQUIPMENT provided	Refer to user manual chapter "IV. KNOW YOUR DEVICE"	P
	If the HEARING INSTRUMENT is rechargeable, the instructions for use sufficiently specify the recharger equipment to ensure compliance with the requirements of this standard.	Rechargeable batteries used for JH-D26(HA70)	P
201.7.9.2.15	Instructions for use contain information about dispose of batteries, the HEARING INSTRUMENT, any part that may provide a risk	Refer to user manual chapter "X. MAINTENANCE, STORAGE AND DISPOSAL"	P
201.7.9.2.16	Instructions for use include information specified in 201.7.9.3 or identify where it can be found (e.g. in a service manual)	Contained in user manual	P
201.7.9.3	Technical description		P
201.7.9.3.1	The technical description provides all data that is essential for safe operation, transport and storage.	Refer to user manual chapter "X. MAINTENANCE, STORAGE AND DISPOSAL"	P
	A technical data sheet shall be available for the professional OPERATOR fitting the HEARING INSTRUMENT. The data sheet shall include:	Refer to user manual chapter "VIII. SPECIFCATIONS AND TYPE"	P
	- brief description of the HEARING INSTRUMENTS significant physical and performance characteristics	Refer to user manual	P
	- technical characteristics according to IEC 60118-0	Refer to user manual	P
	- unique version identifier such as date of issue		P

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Clause	Requirement + Test	Result - Remark	Verdict
	- warning statement addressing hazards from unauthorized modification	Refer to user manual chapter "III. IMPORTANT SAFETY INSTRUCTIONS"	P
201.8	**PROTECTION AGAINST ELECTRICAL HAZARDS FROM ME EQUIPMENT**		**P**
201.8.1	A separate power source, if used, is in compliance with the relevant standards IEC 60601-1, IEC 60065, IEC 60950-1 or other applicable safety standards	JH-D26(HA70) is with recharged lithium battery, the charging box is suitable only for JH-D26(HA70), Manufacturers do not evaluate the adapter for the charging box, other models are used primary battery	N/A
	Relevant tests are performed with the HEARING INSTRUMENT connected.		N/A
	The specification is described in the ACCOMPANYING DOCUMENTS		N/A
201.8.2.1	Separate power source is in compliance with the relevant standard IEC 60601-1, IEC 60065, IEC 60950 or other applicable safety standards	See above	N/A
	Relevant tests are performed with the HEARING INSTRUMENT connected to the separate power supply.		N/A
	Specification of separate power supply in ACCOMPANYING DOCUMENTS		N/A
201.8.3	A HEARING INSTRUMENT is classified as a TYPE B APPLIED PART.	TYPE B APPLIED PART	—
201.8.4.2	ACCESSIBLE PARTS including APPLIED PARTS		P
	a) Where applicable, Currents from, to, or between PATIENT CONNECTIONS did not exceed limits for PATIENT LEAKAGE CURRENT.....:	No exceed limits	P
	b) LEAKAGE CURRENTS CONNECTED TO ELECTRICAL EQUIPMENT IN COMPLIANCE WITH STANDARDS OTHER THAN IEC 60601 .....:	No such ELECTRICAL EQUIPMENT	N/A
201.8.5	Separation of parts	See clause 201.8.1	P
201.8.7.1	a) Electrical isolation providing protection against electric shock limits currents to values in 201.8.7.3.:		P
	b) Specified values of EARTH LEAKAGE, TOUCH, PATIENT LEAKAGE, and PATIENT AUXILIARY CURRENTS applied in combination of conditions in appended Table 8.7.....:	No leakage	P
201.8.7.2	Subclause 8.7.2 of the general standard does not apply.	Refer to IEC/EN 60601-1 report	—
201.8.7.3	Allowable Values	100 uA	P
201.8.7.4	LEAKAGE and PATIENT AUXILIARY CURRENTS measurements at operating temperatures.....:	Refer to Appended table 8.7 in EN 60601-1 Report	P

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Clause	Requirement + Test	Result - Remark	Verdict

201.8.7.4.6	This Subclause is covered by the requirements of 201.8.7.4.7	Refer to IEC/EN 60601-1 report	—
201.8.8	Test according to 8.7 is done after drop test	Refer to IEC/EN 60601-1 report	P
201.8.9	Subclause 8.9 of the general standard does not apply.	Refer to IEC/EN 60601-1 report	—
201.8.10	Subclause 8.10 of the general standard does not apply.	Refer to IEC/EN 60601-1 report	—
201.8.11	Subclause 8.11 of the general standard does not apply.	Refer to IEC/EN 60601-1 report	—

201.9	**PROTECTION AGAINST MECHANICAL HAZARDS OF ME EQUIPMENT AND ME SYSTEMS**		**P**
201.9.1	Considerable hazards are covered by subclause 201.9.3, 201.9.6, 201.9.101, 201.9.102	See below	—
201.9.2	Subclause 9.2 of the general standard does not apply.	Refer to IEC/EN 60601-1 report	—
201.9.3	Rough surfaces, sharp corners and edges of ME EQUIPMENT that could result in an unacceptable RISK avoided or covered. Attention is paid to moulded edges, battery doors and connector flanges.....:	With smooth surface, corner	P
201.9.4	Subclause 9.4 of the general standard does not apply.	Refer to IEC/EN 60601-1 report	—
201.9.5	Subclause 9.5 of the general standard does not apply.	Refer to IEC/EN 60601-1 report	—
201.9.6	Special warning notice if a maximum output sound pressure level above 132dB is possible		N/A
	No exposition of a sound pressure level above 132dB in NORMAL and SINGLE FAULT condition is possible due to the design.	Not exceed 132dB	P
201.9.7	Subclause 9.7 of the general standard does not apply.	Refer to IEC/EN 60601-1 report	—
201.9.8	Subclause 9.8 of the general standard does not apply.	Refer to IEC/EN 60601-1 report	—
201.9.101	Cables and lanyards of HEARING INSTRUMENTS or ACCESSORIES worn by the PATIENT around the neck do not pose a RISK of injury or strangulation.	No such cables used	N/A
	The disconnection force is not greater than 40N.		N/A
201.9.102	The HEARING INSTRUMENT is safely retrievable by the PATIENT otherwise a method to detect and retrieve is provided in the instructions for use.		P
	Design ensures that parts do not come loose.	Not loose	P
	Resistant force of at least 3N is given (N).....:	No less 3N	P

201.10	**PROTECTION AGAINST UNWANTED AND EXCESSIVE RADIATION HAZARDS**		N/A
	Clause 10 of the general standard does not apply, except for subclause 10.4.	No X-Radiation produced in ME equipmen	N/A

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Clause	Requirement + Test	Result - Remark	Verdict

201.11	**PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER HAZARDS**		
201.11.1.1	Maximum temperature during NORMAL USE	Refer to Appended table 11.1.1 in IEC/EN 60601-1 report	P
201.11.1.2	The requirements of this subclause are included in 201.11.1.1.		—
201.11.1.3	Measurements not made when engineering judgment and rationale by MANUFACTURER indicated temperature limits could not exceed, as documented in RISK MANAGEMENT FILE.....:	Test conducted	N/A
	Test corner not used where engineering judgment and rationale by MANUFACTURER indicated test corner will not impact measurements, as documented in RISK MANAGEMENT FILE	Test corner not used	P
	Probability of occurrence and duration of contact for parts likely to be touched and for APPLIED PARTS documented in RISK MANAGEMENT FILE		P
201.11.2	Subclause 11.2 of the general standard does not apply.	Refer to IEC/EN 60601-1 report	—
201.11.3	Subclause 11.3 of the general standard does not apply.	Refer to IEC/EN 60601-1 report	—
201.11.6.2	Subclause 11.6.2 of the general standard does not apply.	Refer to IEC/EN 60601-1 report	—
201.11.6. 3	Subclause 11.6.3 of the general standard does not apply.	Refer to IEC/EN 60601-1 report	—
201.11.6.4	Subclause 11.6.4 of the general standard does not apply.	Refer to IEC/EN 60601-1 report	—
201.11.6.5	If risk assessment requires protection against ingress of water or particular matter, IP class is not less than the level required for safe operation according to IEC 60529	IP41,Refer to Appended table 11.6 in IEC/EN 60601-1 report	P
201.11.6.6	- Capability of withstanding cleaning or disinfection	Refer to Appended table 11.6 in IEC/EN 60601-1 report	P
	- Effects of multiple cleaning during EXPECTED SERVICE LIFE are evaluated and no unacceptable risk occurs		P
201.11.6.7	Subclause 11.6.7 of the general standard does not apply.	Refer to IEC/EN 60601-1 report	—

201.12	**ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS**		**P**
201.12.2	PRIMARY OPERATING FUNCTIONS of HEARING INSTRUMENTS and SYSTEMS are identified during USABILITY ENGINEERING.	Evaluated by manufacture	N/E
201.12.4.2	Subclause 12.4.2 of the general standard does not apply.	Refer to IEC/EN 60601-1 report	—
201.12.4.4	Output power does not increase if the control is disconnected or defective.		P

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Clause	Requirement + Test	Result - Remark	Verdict
	Software controlled maximum power settings do not exceed the selected value due to corrupt data transfer		N/A
201.12.4.5	Subclause 12.4.5 of the general standard does not apply.	Refer to IEC/EN 60601-1 report	—

201.13	**HAZARDOUS SITUATIONS AND FAULT CONDITIONS**		**P**
201.13.1.2	Following HAZARDOUS SITUATIONS SHALL not occur:		P
	– unintentional exposure to a SPL above 132 dB	Not exceed 132 dB	N/A
	– Emission of flames, molten metal, poisonous or ignitable substance in hazardous quantities did not occur		N/A
	– Deformation of ENCLOSURE impairing compliance with 201.15.3.1 did not occur	No deformation of ENCLOSURE	P
	– temperatures of HEARING INSTRUMENTS that are likely to be touched, exceeding 50 °C when measured and adjusted as described in 201.11.1.3 of the general standard: (°C).....:	Not exceed 50 °C	N/A
	– exceeding the allowable values for “other components and materials” identified in Table 22 of the general standard times 1,5 minus 12,5 °C. ...:	Not exceed	N/A
	Supply circuit limits the power in SINGLE FAULT CONDITION to less than 15W / 900J	See below	N/A
	Power (W).....:		N/A
	Energy (J) .....:		N/A
	or		N/A
	Secondary circuits meet all of the following conditions:		P
	- mounted on material with flammability classification of FV1 or better		P
	- energized at a voltage of 60 V d.c. or 42.2 V peak or less in normal and SINGLE FAULT CONDITION	Internal battery: 1.5Vd.c.	P
	- limited to 100 VA or 6 000 J in SINGLE FAULT CONDITION	Less than 100 VA	P
	Wire insulation of type PVC, TFE, PTFE, FEP, polychloropene or polybromide employed		P
	or		N/A
	Component with HIGH INTEGRITY CHARACTERISTIC used		N/A
	or		N/A
	Completely contained within a fire enclosure		N/A
201.13. 2	**SINGLE FAULT CONDITIONS**		P
201.13.2.1	During application of SINGLE FAULT CONDITIONS in 13.2.2 -13.2.13, inclusive, NORMAL CONDITIONS in 8.1 a) applied in least favourable combination.....:	No hazard	P

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Clause	Requirement + Test	Result - Remark	Verdict

201.13.2.2	Electrical SINGLE FAULT CONDITION	See appended Table 13.2 in IEC/EN 60601-1 report	P
201.13.2.3 - 201.13.2.11	Subclause 13.2.3- 13.2.11 of the general standard does not apply.	Refer to IEC/EN 60601-1 report	—
201.13.2.12	Failure of parts that might result in a MECHANICAL HAZARD	No such MECHANICAL HAZARD	N/A
201.13.2.13	Subclause 13.2.13 of the general standard does not apply.	Refer to IEC/EN 60601-1 report	—

201.14	**PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)**		**N/A**
201.14.1	Embedded and fitting software conforms to IEC 62304	No such PEMS used	N/A
	The software classification is justified by the RISK MANAGEMENT FILE		N/A
	Documents produced from application of Clause 14 are maintained and form a part of RISK MANAGEMENT FILE in addition to RECORDS and documents required by ISO 14971.....:		N/A
	Documents required by Clause 14 reviewed, approved, issued and changed in accordance with a formal document control PROCEDURE		N/A
201.14.3	RISK MANAGEMENT plan required by 3.5 of ISO 14971 includes reference to PEMS VALIDATION plan		N/A
201.14.4	Subclause 14.4 of the general standard does not apply.		—
201.14.5	Subclause 14.5 of the general standard does not apply.		—
201.14.6	RISK MANAGEMENT PROCESS		N/A
201.14.6.1	MANUFACTURER considered HAZARDS associated with software and hardware aspects of PEMS including NETWORK/DATA COUPLING, components of third-party origin, legacy subsystems when compiling list of known or foreseeable HAZARDS		N/A
	In addition to the material in ISO 14971, Annex D, list of possible sources for HAZARDS associated with PEMS includes specified causes		N/A
	– failure of NETWORK/DATA COUPLING to provide characteristics necessary for PEMS to achieve its BASIC SAFETY or ESSENTIAL PERFORMANCE		N/A
	– undesired feedback [physical and data] (such as unsolicited/ out of range/ inconsistent input or input from electromagnetic interference)		N/A
	– unavailable data		N/A
	– lack of integrity of data		N/A
	– incorrect data		N/A

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Clause	Requirement + Test	Result - Remark	Verdict

	– incorrect timing of data		N/A
	– unintended interactions within & among PESS		N/A
	– unknown aspects or quality of third-party software		N/A
	– unknown aspects or quality of third-party PESS		N/A
	– lack of data security, particularly vulnerability to tampering, unintended interaction with other programs and viruses		N/A
201.14.6.2	Subclause 14.6.2 of the general standard does not apply.		—
201.14.7	Subclause 14.7 of the general standard does not apply.		—
201.14.8	Subclause 14.8 of the general standard does not apply.		—
201.14.9	Subclause 14.9 of the general standard does not apply.		—
201.14.10	Subclause 14.10 of the general standard does not apply.		—
201.14.11	A PEMS VALIDATION plan containing validation of BASIC SAFETY & ESSENTIAL PERFORMANCE and requiring checks for unintended functioning of PEMS to perform and document PEMS VALIDATION		N/A
	The person with overall responsibility for PEMS VALIDATION is independent of design team, and no member of a design team is responsible for PEMS VALIDATION of their own design		N/A
	All professional relationships of members of PEMS VALIDATION team with members of design team documented in RISK MANAGEMENT FILE providing methods & results of PEMS VALIDATION		N/A
201.14.12	Subclause 14.12 of the general standard does not apply.		—
201.14.13	Subclause 14.13 of the general standard does not apply.		—

201.15	**CONSTRUCTION OF ME EQUIPMENT**		**P**
201.15.1	Subclause 15.1 of the general standard does not apply.	Refer to IEC/EN 60601-1 report	—
201.15.2	A period is accessible for inspection, replacement and maintenance.		P
201.15.3	**Mechanical strength**		P
201.15.3.1	Mechanical stress like pushing, impact, dropping and rough handling does not lead to an unacceptable RISK.	Dropping not result in an unacceptable risk	P
	For HEARING INSTRUMENT-related ACCESSORIES IEC 60065, IEC 60950-1 or other applicable IEC safety standards apply.		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Battery doors do require a tool or a force of at least 10N to remove the battery, if intended for use by infant under 36 months.		P
	Detachable parts are removable without a tool or with a force of at less than 10N, if intended for use by infant under 36 months.		P
201.15.3.2	Subclause 15.3.2 of the general standard does not apply.	Refer to IEC/EN 60601-1 report	—
201.15.3.3	Subclause 15.3.3 of the general standard does not apply.	Refer to IEC/EN 60601-1 report	—
201.15.3.4	A free fall does not result in an unacceptable risk		P
201.15.3.5	Subclause 15.3.5 of the general standard does not apply.	Refer to IEC/EN 60601-1 report	—
201.15.3.6	Subclause 15.3.6 of the general standard does not apply.	Refer to IEC/EN 60601-1 report	—
201.15.3.7	INTENDED USE, EXPECTED SERVICE LIFE and transport / storage is taken into account by selecting the materials		P
	During the expected service life, corrosion, ageing, mechanical wear, degradation of biological materials due to moisture, sweat, humidity, hair care products or toiletries does not reduce the mechanical properties in a way that results in an unacceptable RISK.		P
201.15.4	**ME EQUIPMENT components and general assembly**		P
201.15.4.1	Subclause 15.4.1 of the general standard does not apply.	Refer to IEC/EN 60601-1 report	—
201.15.4.2	Subclause 15.4.2 of the general standard does not apply.	Refer to IEC/EN 60601-1 report	—
201.15.4.3	Batteries		P
201.15.4.3.1	Battery compartments prevent accidental short circuiting of battery when this could result in a HAZARDOUS SITUATION as verified by examination of design and RISK MANAGEMENT FILE	See Appended RM Results Table 15.4.3.1 in IEC/EN 60601-1 report	P
15.4.3.2	Means provided to prevent incorrect connection of polarity when a HAZARDOUS SITUATION may develop by incorrect connection or replacement of a battery .....:		P
15.4.3.3	Overcharging of battery prevented by virtue of design when it could result in an unacceptable RISK as verified by review of design .....:	JH-D26(HA70) is with recharged lithium battery, See Appended RM Results Table 15.4.3.1 in IEC/EN 60601-1 report	P
201.15.4.3.4	Subclause 15.4.3.4 of the general standard does not apply.	Refer to IEC/EN 60601-1 report	—
201.15.4.3.5	Subclause 15.4.3.5 of the general standard does not apply.	Refer to IEC/EN 60601-1 report	—
201.15.4.3.101	Batteries comply with relevant international standards		P

IEC/EN 60601-2-66			
Clause	Requirement + Test	Result - Remark	Verdict

	Wrong inserted batteries do not cause overheating above 50°C.	Can't load the battery when it's backwards	N/A
201.15.4.4	HEARING INSTRUMENTS do not require any indicators for the PATIENT		P
201.15.4.5	Subclause 15.4.5 of the general standard does not apply.	Refer to IEC/EN 60601-1 report	—
201.15.4.6	Subclause 15.4.6 of the general standard does not apply.	Refer to IEC/EN 60601-1 report	—
201.15.4.7	Subclause 15.4.7 of the general standard does not apply.	Refer to IEC/EN 60601-1 report	—
201.15.4.8	Subclause 15.4.8 of the general standard does not apply.	Refer to IEC/EN 60601-1 report	—
201.15.4.9	Subclause 15.4.9 of the general standard does not apply.	Refer to IEC/EN 60601-1 report	—
201.15.5	Subclause 15.5 of the general standard does not apply.	Refer to IEC/EN 60601-1 report	—

201.16	**ME SYSTEMS**		**N/A**
	Voltage to earth or ACCESSIBLE PARTS are within the defined limits in NORMAL and SINGLE FAULT CONDITION.....:	Just ME Equipment	N/A
	Voltage and energy limits also apply to internal parts that can be touched through an opening in the enclosure.		N/A
	Voltage and energy limits also apply to internal parts that can be touched by a metal rod with a diameter of 4mm through an opening in the enclosure.		N/A

201.17	**ELECTROMAGNETIC COMPATIBILITY OF ME EQUIPMENT AND ME SYSTEMS**		N/E
	Risks are addressed associated with the electromagnetic environment	Not evaluated in this report	N/E
	Electromagnetic compatibility is tested according to IEC 60118-13 or to relevant international radio standards if applicable.		N/E

201.7.9.2.2	TABLE: Warning and safety notices	P
Specific warnings / statements	**Document Ref./chapter in IFU**	**Verdict**
Warning to keep small parts out of children´s reach	Refer to user manual chapter "III. IMPORTANT SAFETY INSTRUCTIONS"	P
Warning not to use in explosive or oxygen-enriched atmospheres	Refer to user manual chapter "III. IMPORTANT SAFETY INSTRUCTIONS"	P
Warning that it must only be used by intended person	Refer to user manual chapter "III. IMPORTANT SAFETY INSTRUCTIONS"	P
Warning to check for electronic or wireless restrictions	Refer to user manual chapter "III. IMPORTANT SAFETY INSTRUCTIONS"	P
Statement about the special needs of particular Patient groups	Refer to user manual chapter "III. IMPORTANT SAFETY INSTRUCTIONS"	P
Warning about common conditions that could damage the device	Refer to user manual chapter "III. IMPORTANT SAFETY INSTRUCTIONS"	P
Warnings that result from the RISK MANAGEMENT FILE	Refer to user manual chapter "III. IMPORTANT SAFETY INSTRUCTIONS"	P
Permissible environmental conditions of transport and storage	Refer to user manual chapter "III. IMPORTANT SAFETY INSTRUCTIONS"	P
Each warning/safety contains: nature of Hazard; likely consequences; precautions	Refer to user manual chapter "III. IMPORTANT SAFETY INSTRUCTIONS"	P
Supplementary information:		

-- End of Report --