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| <p><b>IEC 60601-1</b><br/> <b>Medical electrical equipment</b></p> <p><b>Part 1: General requirements for basic safety and essential performance</b></p>  |  |
| <p>This test report is a “Test Only” report. This report documents electrical testing and electrical isolation evaluation requested by the manufacturer for the MRIaudio PREM 1000 &amp; 1001. This report is intended to demonstrate that the system evaluated meets the “fundamental electrical safety” requirements contained within the standard ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (based on IEC 60601-1:2005) as confirmed by the manufacturer.</p> <p>This report contains test data for the tests detailed on page 4 of the report. Clauses 7, 14 and 17 were not evaluated and therefore not included in this test report. This test report is not a complete evaluation of the referenced product to the requirements of the standard mentioned above. It is not intended to represent a certification of the product and no “Listing” is associated with this report.</p> |  |
| Report Reference No. .... :   | 340891   |
| Date of issue ..... :   | 09 January, 2018   |
| Total number of pages ..... :   | 110  |
| CB Testing Laboratory ..... :   | Nemko USA Inc. <span style="float: right;">Phone: +1 760 444 3500</span>                                   |
| Address ..... :   | 2210 Faraday Avenue, Suite 150, Carlsbad, CA 92008, USA  |
| Applicant’s name..... :   | MRI Audio  |
| Address ..... :   | 2720 Loker Avenue West, Suite N, 92008 Carlsbad CA, USA  |
| <b>Test specification:</b>  |  |
| Standard..... :   | IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012<br>(or IEC 60601-1: 2012 reprint) |
| Test procedure..... :   | Test report  |
| Non-standard test method.....:  | N/A  |
| Test Report Form No. .... :   | IEC60601_1K  |
| Test Report Form Originator .....   | UL(US)   |
| Master TRF .....  | 2015-11  |
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| <b>General disclaimer:</b>  |  |
| <p>The test results presented in this report relate only to the object tested.</p> <p>This report shall not be reproduced, except in full, without the written approval of the Issuing CB testing laboratory. The authenticity of this Test Report and its contents can be verified by contacting the NCB, responsible for this Test Report.</p>  |  |

This Test Report, when bearing the Nemko name and logo is only valid when issued by a Nemko laboratory, or by a laboratory having special agreement with Nemko.

|  |  |  |
|--|--|--|
| <b>Test item description</b> .....                     | MRI Audio System (Headset & Transducer)  |  |
| <b>Trade Mark</b> .....                                |    |  |
| <b>Manufacturer</b> .....                              | Same as Applicant  |  |
| <b>Model/Type reference</b> .....                      | MRIaudio PREM 1000 & 1001  |  |
| <b>Ratings</b> .....                                   | External PSU (Amplifier): Input: 1.3A, 100-240V~,50/60Hz<br>Output: 24Vdc, 2A<br>Amplifier: 24Vdc, 2A<br>Transducer: 8Ω, 35W |  |
| <b>Testing procedure and testing location:</b>         |  |  |
| <input checked="" type="checkbox"/>                    | <b>CB Testing Laboratory:</b>  | Nemko USA Inc.   |
| <b>Testing location/ address</b> .....                 |  | 2210 Faraday Ave. Suite 150, Carlsbad, CA 92008, USA   |
| <input type="checkbox"/>                               | <b>Associated CB Testing Laboratory:</b>   |  |
| <b>Testing location/ address</b> .....                 |  |  |
| <b>Tested by (name, function, signature)</b> .....     |  | Jeff Busch<br>(Project Engineer)  |
| <b>Approved by (name, function, signature)</b> .....   |  | Luis Gonzalez<br>(Reviewer)      |
| <input type="checkbox"/>                               | <b>Testing procedure: CTF Stage 1:</b>   |  |
| <b>Testing location/ address</b> .....                 |  |  |
| <b>Tested by (name, function, signature)</b> .....     |  |  |
| <b>Approved by (name, function, signature)</b> .....   |  |  |
| <input type="checkbox"/>                               | <b>Testing procedure: CTF Stage 2:</b>   |  |
| <b>Testing location/ address</b> .....                 |  |  |
| <b>Tested by (name, function, signature)</b> .....     |  |  |
| <b>Witnessed by (name, function, signature)</b>        |  |  |
| <b>Approved by (name, function, signature)</b> .....   |  |  |
| <input type="checkbox"/>                               | <b>Testing procedure: CTF Stage 3:</b>   |  |
| <input type="checkbox"/>                               | <b>Testing procedure: CTF Stage 4:</b>   |  |
| <b>Testing location/ address</b> .....                 |  |  |
| <b>Tested by (name, function, signature)</b> .....     |  |  |
| <b>Witnessed by (name, function, signature)</b>        |  |  |
| <b>Approved by (name, function, signature)</b> .....   |  |  |
| <b>Supervised by (name, function, signature)</b> ..... |  |  |

|  |
|--|
| <b>List of Attachments (including a total number of pages in each attachment):</b> |
| None   |

| <b>Summary of testing</b> |   |   |
|---------------------------|---|---|
| <b>Clause</b>             | <b>Remarks</b>                                  | <b>Information / Comments</b>   |
| All                       |   | <p>The report is by request of the manufacturer and covered requested testing on the MRI Audio intramuscular MRIaudio PREM 1000 &amp; 1001.</p> <p>The testing included in this report is intended to demonstrate that the system evaluated meets the “fundamental electrical safety” requirements contained within the IEC60601-1:2005 standard, as confirmed by the manufacturer.</p>   |
| 1.3                       | Collateral standards                            | No collateral standards were evaluated as part of this test report.   |
| 4.8<br>8.11.3             | Components of ME equipment<br>Power supply cord | <p>The external Power Supply Unit (PSU), provided for the amplifier, RDL model PS-24V2 has been separately tested and approved by UL according to UL 60950-1.</p> <p>The PSU was accepted based on the active UL Listing. A report for the power supply was not made available to Nemko.</p> <p>External PSU is class I, which is separately certified. The equipment shall be provided with an approved power cord type for connection to the mains outlet, and complying with the national regulations of the countries in which the appliance is to be sold.</p> |
| 8.5.5                     | Defibrillation proof applied parts.             | The manufacturer does not specify that the equipment is provided with a defibrillation proof applied part.  |
| 11.7                      | Biocompatibility                                | The manufacturer has declared that the equipment complies with requirements of ISO 10993-1. Compliance documented by the manufacturer.  |
| 12.2                      | Usability                                       | Usability was not evaluated as part of this test report.  |
| 14                        | Programmable Electrical Medical Systems (PEMS)  | PEMS was not evaluated for this test report.  |
| 17                        | Electromagnetic compatibility                   | The manufacturer has declared that the equipment complies with requirements of IEC 60601-1-2. Compliance documented by the manufacturer.  |

**Summary of testing****Tests performed (name of test and test clause):**

All testing according to this standard tested at:

4.11 Power input test  
5.7 Humidity preconditioning treatment test  
5.9.2.1 Accessible part  
8.7 Leakage current measurement test  
- Touch current measurement (Fig. 14)  
- Patient leakage current measurement (Fig. 15)  
8.8.3 Dielectric voltage withstand  
9.4.2 Stability and transportability test.  
11.1.1 Temperature test  
11.6.6 Cleaning  
11.8 Interruption of power supply  
13 Abnormal operation and single fault conditions  
- 13.2.2 Electrical single fault conditions according to 8.1.  
15.3.2 Push test  
15.3.3 Impact test  
15.3.4.1 Drop test

**Testing location:**

Nemko USA Inc.  
2210 Faraday Ave. Suite 150,  
Carlsbad, CA 92008, USA

**Summary of compliance with National Differences**

List of countries addressed:

The list of countries recognizing the CB Scheme is actively updated on the IECEE website.

All CENELEC members according to European Countries, EN 60601-1 (2006) + A11 (2011) + AM1 (2013) + A12 (2014)

All CB members as listed in the IECEE Online Bulletin.

Included in this report are published deviation for: Canada, Japan, Korea, Switzerland and United States

The product fulfils the requirements of IEC/EN 60601-1 Edition 3.0 + AM1

| GENERAL INFORMATION  |  |
|--|--|
| <b>Test item particulars (see also Clause 6):</b>                |  |
| Classification of installation and use..... :                    | Headphones: patient applied parts, Type B, body worn.<br>Transducer: Speaker, floor mounted, receives audio signal from amplifier, Operator access only.<br><br>Amplifier: Class III, provided with external PSU. Operator access only.<br>External PSU: Class I, Operator access only |
| Device type (component/sub-assembly/ equipment/ system):         | Medical system   |
| Intended use (Including type of patient, application location) : | See general product information.   |
| Mode of operation..... :   | Continuous   |
| Supply connection .....  | External PSU is Class I, provided with appliance inlet.<br>Amplifier is powered from the external PSU.<br>Transducer receives audio signal from amplifier.   |
| Accessories and detachable parts included..... :                 | Headphones and Transducer are medical equipment.<br><br>See General Product description for complete list of system components, Operators Manual.  |
| Other options include .....                                      | None   |
| <b>Testing</b>   |  |
| Date of receipt of test item(s) .....                            | December 2017  |
| Dates tests performed..... :                                     | December 2017 – January 2018   |
| <b>Possible test case verdicts:</b>                              |  |
| - test case does not apply to the test object .....              | N/A  |
| - test object does meet the requirement .....                    | Pass (P)   |
| - test object was not evaluated for the requirement .....        | N/E (collateral standards only)  |
| - test object does not meet the requirement..... :               | Fail (F)   |
| <b>Abbreviations used in the report:</b>                         |  |
| - normal condition .....   | : N.C.   |
| - means of Operator protection .....                             | : MOOP   |
| - single fault condition .....                                   | : S.F.C.   |
| - means of Patient protection .... :                             | MOPP   |

**General remarks:**

**Before starting to use the TRF please read carefully the 4 instructions pages at the end of the report on how to complete the new version “J” of TRF for IEC for 60601-1 3<sup>rd</sup> edition with Amendment 1.**

"(See Attachment #)" refers to additional information appended to the report.

"(See appended table)" refers to a table appended to the report.

The tests 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 testing laboratory.

List of test equipment must be kept on file and available for review.

Additional test data and/or information provided in the attachments to this report.

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

**Manufacturer’s Declaration per sub-clause 4.2.5 of IEC 60601-1:2012**

The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided ..... :  Yes  Not applicable

**When differences exist; they shall be identified in the General product information section.**

**Name and address of factory (ies)..... :**

**MRI Audio**

**2720 Loker Avenue West, Suite N, 92008 Carlsbad CA, USA**

**General product information:**

This test report is a "Test Only" report. This report documents electrical testing and electrical isolation evaluation requested by the manufacturer for the MRIaudio PREM 1000 & 1001. This report is intended to demonstrate that the system evaluated meets the "fundamental electrical safety" requirements contained within the standard ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (based on IEC 60601-1:2005) as confirmed by the manufacturer.

This report contains test data for the tests detailed on page 4 of the report. Clauses 7, 14 and 17 were not evaluated and therefore not included in this test report. This test report is not a complete evaluation of the referenced product to the requirements of the standard mentioned above. It is not intended to represent a certification of the product and no "Listing" is associated with this report.

Intended use: The MRIaudioPREM system is an MRI conditional audio system that provides MRI patients with music, direct communication and hearing protection.

Intended users: EUT is intended for use by trained healthcare professionals such as doctors (MDs, DOs), registered nurses (RNs), nurse practitioners (NPs), and licensed practical/vocational nurses (LPNs/LVNs).

Intended use environments: EUT is intended for use in clinics, private practices, hospitals, and other large clinical settings where MRI's are employed.

Equipment evaluated as a medical system. The system includes medical equipment, evaluated in this test report. Additionally the system includes non-medical equipment that is not located on the patient environment. The non-medical equipment was accepted based on previous evaluation, along with limited evaluation in this test report.

Additionally the manufacturer defines the equipment into 3 separate categories of use:

MRI Safe – Equipment is completely nonmagnetic and is acceptable for use inside the MRI.

MRI Conditional – Equipment may contain magnetic or electrical components that are acceptable for use in close proximity to the MRI.

MRI Unsafe – Equipment not recommend for use in or near the MRI.

The equipment consist of an audio amplifier, located in a separate room from the MRI, that integrates several inputs, and outputs an electrical signal to a transducer, located in the MRI room. The transducer, converts the electrical signal to an audio signal. The audio signal is connected to nonconductive headphones inside the MRI via pneumatic tubing.

**Medical Equipment:**

Over Ear headphones – Type B applied part, used for scans that do not require limited space, provide hearing protection in addition to audio communication.

In Ear Headphones – Type B applied part, used for scans that do require limited space.

Both types of Headphones are composed entirely of non-conductive material.

Pneumatic Tubing - The pneumatic tubing is considered to provide 2MOPP of insulation for the Headphones. Headphones are connected to the Transducer through a 3 meter long pneumatic tube. No conductive connection is provided or possible from the Headphones to the Transducer.

Transducer: - The Transducer converts the audio signal from the Amplifier to an acoustic signal that can be transmitted through the Pneumatic Tubing. The Transducer is installed near the MRI. It is not accessible to the patient and is evaluated for operator access only. Since it is installed in the MRI exam room, it is considered medical equipment as part of the evaluation in this test report.

**Non-Medical Equipment:**

All non-medical equipment is located in a separate room from the MRI, as such, it is not considered to be in or near the patient environment.

Amplifier – The amplifier provides the audio signal for the Transducer. All other non-medical equipment

**General product information:**

provide power of signal inputs to the Amplifier. The Amplifier is separately evaluated to the requirements of UL60950-1 (as declared by the manufacturer) and was accepted, based upon that declaration and limited testing in this test report.

External PSU – The external PSU supplies 24Vdc to the Amplifier. The PSU is Listed by UL to the requirements of UL6095-1. The PSU was accepted based on the UL Listing and limited evaluation in this test report.

External Speakers – Provides the operator of the Amplifier to hear the same signal the patient is hearing. External speakers are provided with a Class II Direct plug-in PSU for power that was not evaluated in this test report.

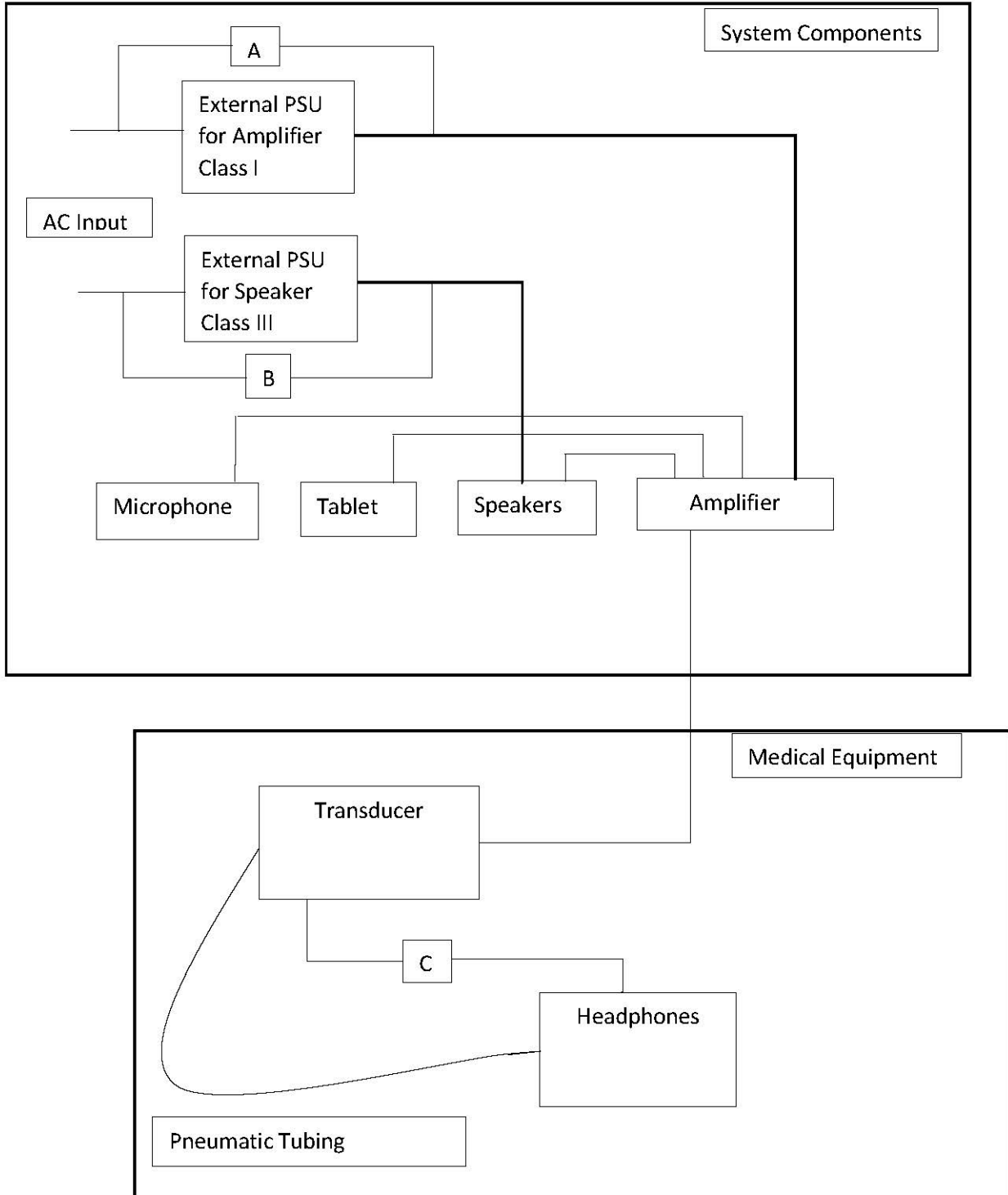
Tablet – The tablet provides audio music files for the Amplifier.

Cables – Various cables, that provide connection from the Amplifier to the Transducer, in the MRI room.



| IEC 60601-1 |                    |                 |         |
|-------------|--------------------|-----------------|---------|
| Clause      | Requirement + Test | Result - Remark | Verdict |

**INSULATION DIAGRAM**



| IEC 60601-1 |                    |                 |         |
|-------------|--------------------|-----------------|---------|
| Clause      | Requirement + Test | Result - Remark | Verdict |

| TABLE: INSULATION DIAGRAM                                    |   | P |
|--|---|---|
| Pollution degree.....  | 2   | — |
| Overvoltage category.....                                    | II  | — |
| Altitude.....  | 3000 m  | — |
| Additional details on parts considered as applied parts..... | <input checked="" type="checkbox"/> None <input type="checkbox"/> Areas _____<br>(See Clause 4.6 for details) | — |

| Area | Number and type of Means of Protection: MOOP, MOPP | CTI  | Working voltage  |                 | Required creepage (mm) | Required clearance (mm) | Measured creepage (mm) | Measured clearance (mm) | Remarks                      |
|------|--|------|------------------|-----------------|------------------------|-------------------------|------------------------|-------------------------|------------------------------|
|      |  |      | V <sub>rms</sub> | V <sub>pk</sub> |                        |                         |                        |                         |                              |
| A    | 2 MOOP   | IIIb | 240              | 340             | 5.0                    | 4.0                     | 5.0                    | 4.0                     | Mains to Secondary 1) 2)     |
| B    | 2 MOOP   | IIIb | 240              | 340             | 5.0                    | 4.0                     | 5.0                    | 4.0                     | Mains to Secondary 1) 2)     |
| C    | 2 MOPP   | IIIb | 240              | 504             | 8.0                    | 5.0                     | 3000                   | 3000                    | Secondary to applied part 3) |

**Supplementary Information:**

- 1) Measured values based on minimum required values for power supplies certified to UL 60950-1.
- 2) Areas A and B are considered equivalent to 1MOPP.
- 3) Connection from Transducer to Headphones via pneumatic tubing (3 meters long). No conductive connection from Transducer to Headphones.

**INSULATION DIAGRAM CONVENTIONS and GUIDANCE:**

A measured value must be provided in the value columns for the device under evaluation. The symbol > (greater than sign) must not be used. Switch-mode power supplies must be re-evaluated in the device under evaluation therefore N/A must not be used with a generic statement that the component is certified.

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:

- All isolation barriers are identified by letters between separate parts of diagram, for example separate transformer windings, optocouplers, wire insulation, creepage and clearance distances.
- Parts connected to earth with large dots are protectively earthed. Other connections to earth are functional
- Applied parts are extended beyond the equipment enclosure and terminated with an arrow.
- Parts accessible to the operator only are extended outside of the enclosure, but are not terminated with an arrow.

| IEC 60601-1  |   |  |            |
|--------------|---|--|------------|
| Clause       | Requirement + Test  | Result - Remark  | Verdict    |
| <b>4</b>     | <b>GENERAL REQUIREMENTS</b>   |  | <b>P</b>   |
| <b>4.1</b>   | <b>Requirements of this standard applied in NORMAL USE and reasonably foreseeable misuse</b>  |  | <b>P</b>   |
| <b>4.2</b>   | <b>RISK MANAGEMENT PROCESS FOR ME EQUIPMENT OR ME SYSTEMS</b>   |  | <b>NE</b>  |
| <b>4.2.2</b> | <b>General requirement for RISK MANAGEMENT - PROCESS complies with ISO14971 (2007) .....</b>  |  | <b>NE</b>  |
| <b>4.2.3</b> | <b>Evaluating RISK</b>  |  | <b>NE</b>  |
| <b>4.3</b>   | <b>Performance of clinical functions necessary to achieve INTENDED USE or that could affect the safety of the ME EQUIPMENT or ME SYSTEM were identified during RISK ANALYSIS.</b>   |  | <b>NE</b>  |
| <b>4.4</b>   | <b>EXPECTED SERVICE LIFE stated in RISK MANAGEMENT FILE .....</b>   |  | <b>NE</b>  |
| <b>4.5</b>   | <b>Alternative RISK CONTROL methods utilized:</b>   |  | <b>NE</b>  |
|              | <b>RESIDUAL RISK resulting from the alternative RISK CONTROL measures or tests is acceptable and comparable to RESIDUAL RISK resulting from application of this standard.....</b><br><b>(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)</b> |  | <b>NE</b>  |
| <b>4.6</b>   | <b>RISK MANAGEMENT PROCESS identifies parts that can come into contact with PATIENT but not defined as APPLIED PARTS, subjected to the requirements for APPLIED PARTS, except for Clause 7.2.10 .....</b>                       | Type B applied part.   | <b>NE</b>  |
| <b>4.7</b>   | <b>ME EQUIPMENT remained SINGLE FAULT SAFE, or the RISK remained acceptable as determined by Clause 4.2 .....</b>   | Equipment remained single fault safe during testing.   | <b>P</b>   |
|              | <b>MANUFACTURER RISK ANALYSIS was used to determine failures to be tested.....</b><br><b>(ISO 14971 Cl. 4.2-4.4)</b>  | No other single faults have been identified other than those required as part of testing according to this standard. No RMF consideration necessary. | <b>N/A</b> |
|              | <b>Failure of any one component at a time that could result in a HAZARDOUS SITUATION, including those in 13.1, simulated physically or theoretically .....</b>  | See appended Table 13.2 for simulated physical test.   | <b>P</b>   |
| <b>4.8</b>   | <b>All components and wiring whose failure could result in a HAZARDOUS SITUATION used according to their applicable ratings, unless specified ...</b>   | All components are suitable and used within their ratings. No additional risk management consideration is necessary.                                 | <b>N/A</b> |

| IEC 60601-1   |   |   |            |
|---------------|---|---|------------|
| Clause        | Requirement + Test  | Result - Remark   | Verdict    |
|               | <b>Components and wiring exception in the standard or by RISK MANAGEMENT PROCESS</b>  | Evaluated according to standard. No component other than certified components which are accepted based on certification.  | <b>N/A</b> |
|               | <b>RISK MANAGEMENT PROCESS assesses components to identify components where the failure results in a HAZARDOUS SITUATION for components used outside their ratings..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)</b> | The device does not use any components outside their ratings.   | <b>N/A</b> |
|               | <b>MANUFACTURER identified components where the failure results in a HAZARDOUS SITUATION... :</b>   |   | <b>N/A</b> |
|               | <b>Components determined to be acceptable where used as a MEANS OF PROTECTION..... :</b>  | See appended Table 8.10   | <b>P</b>   |
|               | <b>Reliability of components used as MEANS OF PROTECTION assessed for conditions of use in ME EQUIPMENT, and they complied with one of the following</b>  | See below.  | <b>P</b>   |
|               | <b>a) Applicable safety requirements of a relevant IEC or ISO standard</b>  |   | <b>NE</b>  |
|               | <b>b) Requirements of this standard applied in the absence of a relevant IEC or ISO standard</b>  | See appended Table 8.10.  | <b>P</b>   |
| <b>4.9</b>    | <b>A COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS provided and selected appropriately..... :</b>   | All components are suitable and used within their ratings. No additional high-integrity characteristics review necessary. | <b>N/A</b> |
|               | <b>RISK MANAGEMENT FILE includes an assessment to determine if the failure of components results in unacceptable RISK..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)</b>  | No additional RMF consideration is necessary.   | <b>N/A</b> |
|               | <b>Components identified and required to be COMPONENTS WITH HIGH INTEGRITY CHARACTERISTIC:</b>  |   | <b>N/A</b> |
| <b>4.10</b>   | <b>Power supply</b>   |   | <b>P</b>   |
| <b>4.10.1</b> | <b>ME EQUIPMENT is suitable for connection to indicated power source (select applicable)..... :</b>   | Amplifier is powered from separately certified external PSU.  | <b>P</b>   |
| <b>4.10.2</b> | <b>Maximum rated voltage for ME EQUIPMENT intended to be connected to SUPPLY MAINS:</b>   | See below.  | <b>P</b>   |
|               | <b>- 250 V for HAND-HELD ME EQUIPMENT (V) ..... :</b>   | Amplifier is powered from separately certified external PSU.  | <b>P</b>   |
|               | <b>- 250 V d.c. or single-phase a.c., or 500 V poly-phase a.c. for ME EQUIPMENT and ME SYSTEMS with a RATED input ≤ 4 kVA (V) ..... :</b>   | External Power Supply is single phase and rated 100-240V. Not rated over 250 V.   | <b>P</b>   |

| IEC 60601-1 |   |                         |         |
|-------------|---|-------------------------|---------|
| Clause      | Requirement + Test  | Result - Remark         | Verdict |
|             | – 500 V for all other ME EQUIPMENT and ME SYSTEMS   |                         | N/A     |
| 4.11        | Power input   |                         | P       |
|             | Steady-state measured input of ME EQUIPMENT or ME SYSTEM at RATED voltage or voltage range and at operating settings indicated in instructions for use didn't exceed marked rating by more than 10%.....: | See appended Table 4.11 | P       |

|     |   |  |     |
|-----|---|--|-----|
| 5   | <b>GENERAL REQUIREMENTS FOR TESTING ME EQUIPMENT</b>  |  | P   |
| 5.1 | Test not performed when analysis indicated condition being tested was adequately evaluated by other tests or methods.....:  | This report is based on type test.   | P   |
|     | RISK MANAGEMENT FILE identifies combinations of simultaneous independent faults that could result in a HAZARDOUS SITUATION.<br>(ISO 14971 Cl. 4.2-4.4)  | Type test conducted according to the standard are sufficient. No combinations of simultaneous faults considered necessary. | N/A |
| 5.3 | Tests conducted within the environmental conditions specified in technical description  | Documentation not evaluated.   | N/A |
|     | Temperature (°C), Relative Humidity (%) .....   |  | —   |
|     | Atmospheric Pressure (kPa) .....  |  | —   |
| 5.5 | a) Supply voltage during tests was the least favourable of the voltages specified in 4.10.2 or voltages marked on ME EQUIPMENT (V) .....  | Least favorable voltages were used.  | P   |
|     | b) ME EQUIPMENT marked with a RATED frequency range tested at the least favourable frequency within the range (Hz).....:  | Least favorable frequencies were used.   | P   |
|     | c) ME EQUIPMENT with more than one RATED voltage, both a.c./ d.c. or both external power and INTERNAL ELECTRICAL POWER SOURCE tested in conditions (see 5.4) related to the least favourable voltage, nature of supply, and type of current ..... | Amplifier is supplied by the certified external PSU, and is rated for only one voltage range (100-240V).                   | N/A |
|     | d) ME EQUIPMENT intended for only d.c. supply connection tested with d.c. and influence of polarity considered.....:  |  | N/A |
|     | e)ME EQUIPMENT tested with alternative ACCESSORIES and components specified in ACCOMPANYING DOCUMENTS to result in the least favourable conditions.....:  | Equipment tested with all specified accessories.   | N/A |
|     | f) ME EQUIPMENT connected to a separate power supply as specified in instructions for use   | Equipment tested with the certified external power supply.   | N/A |

| IEC 60601-1 |  |   |         |
|-------------|--|---|---------|
| Clause      | Requirement + Test   | Result - Remark   | Verdict |
| 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 8.7.4 and 8.8.3 ..... | Climatic preconditioning performed.                         | P       |
|             | ME EQUIPMENT heated to a temperature between T and T + 4°C for at least 4 h and placed in a humidity chamber and ambient within 2 °C of T in range of +20°C to +32°C for indicated time                              | 40°C, 93% RH, 120 hrs.<br>By request of the manufacturer.   | —       |
| 5.9         | Determination of APPLIED PARTS and ACCESSIBLE PARTS  |   | P       |
| 5.9.1       | APPLIED PARTS identified by inspection and reference to ACCOMPANYING DOCUMENTS.....  | Headphones are defined as Type B applied parts.             | P       |
| 5.9.2       | ACCESSIBLE PARTS   |   | P       |
| 5.9.2.1     | Accessibility determined using standard test finger of Fig. 6  | See Appended Table 5.9.2. All parts of equipment evaluated. | P       |
| 5.9.2.2     | Test hook of Fig. 7 inserted in all openings of ME EQUIPMENT and pulled with a force of 20 N for 10 s  |   | N/A     |
| 5.9.2.3     | Conductive parts of actuating mechanisms of electrical controls accessible after removal of handles, knobs, levers and the like regarded as ACCESSIBLE PARTS.....  | No actuating control mechanisms are used.                   | N/A     |
|             | Conductive parts of actuating mechanisms not considered ACCESSIBLE PARTS when removal of handles, knobs, required use of a TOOL .....  |   | N/A     |

|     |  |   |     |
|-----|--|---|-----|
| 6   | CLASSIFICATION OF ME EQUIPMENT AND ME SYSTEMS  |   | P   |
| 6.2 | CLASS I ME EQUIPMENT, externally powered   | Amplifier is supplied by the certified external power supply which is Class I. Equipment is provided with an appliance inlet. | P   |
|     | CLASS II ME EQUIPMENT, externally powered  |   | N/A |
|     | INTERNALLY POWERED ME EQUIPMENT  |   | N/A |
|     | EQUIPMENT with means of connection to a SUPPLY MAINS complied with CLASS I or CLASS II ME EQUIPMENT requirements when so connected, and when not connected to SUPPLY MAINS with INTERNALLY POWERED ME EQUIPMENT requirements | Equipment complies with Class I requirements while is supplied by certified external power supply.                            | P   |
|     | TYPE B APPLIED PART  | Type B applied part.  | P   |
|     | TYPE BF APPLIED PART   |   | N/A |
|     | TYPE CF APPLIED PART   |   | N/A |
|     | DEFIBRILLATION-PROOF APPLIED PARTS   |   | N/A |

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| Clause      | Requirement + Test   | Result - Remark   | Verdict |
| 6.3         | ENCLOSURES classified according to degree of protection against ingress of water and particulate matter as per IEC 60529.....:       | Not rated for ingress of water.                                 | N/A     |
| 6.4         | ME EQUIPMENT or its parts intended to be sterilized classified according to method(s) of sterilization in instructions for use.....: | No sterilization required part. Cleaning instructions provided. | N/A     |
| 6.5         | ME EQUIPMENT and ME SYSTEMS intended for use in an OXYGEN RICH ENVIRONMENT classified for such use and complied with 11.2.2          | Not intended for flammable environment.                         | N/A     |
| 6.6         | CONTINUOUS or Non-CONTINUOUS OPERATION .....   | Equipment is for continuous operation. See summary of testing.  | P       |

|          |   |   |          |
|----------|---|---|----------|
| <b>8</b> | <b>PROTECTION AGAINST ELECTRICAL HAZARDS FROM ME EQUIPMENT</b>  |   | <b>P</b> |
| 8.1      | Limits specified in Clause 8.4 not exceeded for ACCESSIBLE PARTS and APPLIED PARTS in NORMAL or SINGLE FAULT CONDITIONS   | Limits not exceeded.  | P        |
|          | RISK MANAGEMENT FILE identifies conductors and connectors where breaking free results in a HAZARDOUS SITUATION ..... : (ISO 14971 Cl. 4.3)  |   | NE       |
| 8.2      | Requirements related to power sources   |   | N/A      |
| 8.2.1    | Connection to a separate power source   |   | N/A      |
|          | When ME EQUIPMENT specified for connection to a separate power source other than SUPPLY MAINS, separate power source considered as part of ME EQUIPMENT or combination considered as an ME SYSTEM | Amplifier provided with an external Class I power supply.   | N/A      |
|          | Tests performed with ME EQUIPMENT connected to separate power supply when one specified   |   | N/A      |
|          | When a generic separate power supply specified, specification in ACCOMPANYING DOCUMENTS examined  |   | N/A      |
| 8.2.2    | Connection to an external d.c. power source   |   | N/A      |
|          | No HAZARDOUS SITUATION as described in 13.1 developed when a connection with wrong polarity made for ME EQUIPMENT from an external d.c. source  | No hazard. External power supply comes with polarized plug. | N/A      |
|          | ME EQUIPMENT connected with correct polarity maintained BASIC SAFETY and ESSENTIAL PERFORMANCE  | See above.  | N/A      |
|          | Protective devices that can be reset by anyone without a TOOL returns to NORMAL CONDITION on reset  | None provided.  | N/A      |
| 8.3      | Classification of APPLIED PARTS   |   | P        |

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| Clause       | Requirement + Test  | Result - Remark   | Verdict    |
|              | <b>a) APPLIED PART specified in ACCOMPANYING DOCUMENTS as suitable for DIRECT CARDIAC APPLICATION IS TYPE CF</b>  |   | <b>N/A</b> |
|              | <b>b) An APPLIED PART provided with a PATIENT CONNECTION intended to deliver electrical energy or an electrophysiological signal to or from PATIENT IS TYPE BF or CF APPLIED PART</b>   |   | <b>N/A</b> |
|              | <b>c) An APPLIED PART not covered by a) or b) is a TYPE B, BF, or CF</b>  | Applied part is type B.   | <b>P</b>   |
| <b>8.4</b>   | <b>Limitation of voltage, current or energy</b>   |   | <b>P</b>   |
| <b>8.4.2</b> | <b>ACCESSIBLE PARTS and APPLIED PARTS</b>   |   | <b>P</b>   |
|              | <b>a) Currents from, to, or between PATIENT CONNECTIONS did not exceed limits for PATIENT LEAKAGE CURRENT &amp; PATIENT AUXILIARY CURRENT :</b>   | See appended Table 8.7  | <b>P</b>   |
|              | <b>b) LEAKAGE CURRENTS from, to, or between ACCESSIBLE PARTS did not exceed limits for TOUCH CURRENT..... :</b>   | See appended Table 8.7  | <b>P</b>   |
|              | <b>c) Limits specified in b) not applied to parts when probability of a connection to a PATIENT, directly or through body of OPERATOR, is negligible in NORMAL USE, and the OPERATOR is appropriately instructed</b>  | I/O ports on rear of the Amplifier. Max voltage of 24V dc.  | <b>P</b>   |
|              | <b>Voltage to earth or to other ACCESSIBLE PARTS did not exceed 42.4 V peak a.c. or 60 V d.c. for above parts in NORMAL or single fault condition (V a.c. or d.c.)..... :</b>   | All accessible connections on rear of amplifier are 24Vdc. or below.<br>Amplifier is located in a separate room, not possible for the operator to touch the patient and connections at the same time. | <b>N/A</b> |
|              | <b>Energy did not exceed 240 VA for longer than 60 s or stored energy available did not exceed 20 J at a potential of 2 V or more (VA or J)..... :</b>  | No such accessible connections.   | <b>N/A</b> |
|              | <b>d) Voltage and energy limits specified in c) above also applied to the following:</b>  |   | <b>N/A</b> |
|              | <b>– internal parts touchable by test pin in Fig 8 inserted through an opening in an ENCLOSURE; and</b>   |   | <b>N/A</b> |
|              | <b>– internal parts touchable by a metal test rod with a diameter of 4 mm and a length 100 mm, inserted through any opening on top of ENCLOSURE or through any opening provided for adjustment of pre-set controls by RESPONSIBLE ORGANIZATION in NORMAL USE using a TOOL</b> |   | <b>N/A</b> |
|              | <b>Test pin or the test rod inserted through relevant openings with minimal force of no more than 1 N</b>   |   | <b>N/A</b> |



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| Clause      | Requirement + Test   | Result - Remark                                   | Verdict |
|             | Test rod inserted in every possible position through openings provided for adjustment of pre-set controls that can be adjusted in NORMAL USE, with a force of 10 N   | No preset controls.                               | N/A     |
|             | Test repeated with a TOOL specified in instructions for use  |   | N/A     |
|             | Test rod freely and vertically suspended through openings on top of ENCLOSURE  |   | N/A     |
|             | e) Devices used to de-energize parts when an ACCESS COVER opened without a TOOL gives access to parts at voltages above levels permitted by this Clause comply with 8.11.1 for mains isolating switches and remain effective in SINGLE FAULT CONDITION | No such covers.                                   | N/A     |
|             | A TOOL is required when it is possible to prevent the devices from operating   |   | N/A     |
| 8.4.3       | Worst case voltage between pins of plug and between either supply pin and ENCLOSURE did not exceed 60 V one sec after disconnecting the plug of ME EQUIPMENT or its parts (V) ..... :  | Evaluated as part of certified external PSU.      | N/A     |
|             | When voltage exceeded 60 V, calculated or measured stored charge didn't exceed 45 µC.. :   |   | P       |
| 8.4.4       | Residual voltage of conductive parts of capacitive circuits, having become accessible after ME EQUIPMENT was de-energized after removal of ACCESS COVERS, didn't exceed 60V or calculated stored charge didn't exceed 45µC .. :                        | No such covers.                                   | N/A     |
|             | A device manually discharging capacitors used when automatic discharging was not possible and ACCESS COVERS could be removed only with aid of a TOOL   |   | N/A     |
|             | Capacitor(s) and connected circuitry marked with symbol 24 of Table D.1, and manual discharging device specified in technical description..... :   |   | N/A     |
| 8.5         | Separation of parts  |   | P       |
| 8.5.1       | MEANS OF PROTECTION (MOP)  |   | P       |
| 8.5.1.1     | Two MEANS of PROTECTION provided for ME EQUIPMENT to prevent APPLIED and other ACCESSIBLE PARTS from exceeding limits in 8.4   | See Insulation diagram and appended Tables 8.8.3. | P       |
|             | Varnishing, enamelling, oxidation, and similar protective finishes and coatings with sealing compounds re-plasticizing at temperatures expected during operation and sterilization disregarded as MEANS OF PROTECTION                                  | Not used as a means of protection.                | N/A     |
|             | Components and wiring forming a MEANS OF PROTECTION comply with 8.10   | See appended Table 8.10.                          | P       |
| 8.5.1.2     | MEANS OF PATIENT PROTECTION (MOPP)   |   | P       |

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|----------------|---|--|------------|
| Clause         | Requirement + Test  | Result - Remark  | Verdict    |
|                | <b>Solid insulation forming a MEANS OF PATIENT PROTECTION complied with dielectric strength test..... :</b>   | See Insulation diagram. Headphones evaluated as MOPP.  | <b>P</b>   |
|                | <b>CREEPAGE and CLEARANCES forming a MEANS OF PATIENT PROTECTION complied with Table 12</b>   | See Insulation diagram. Distance form output of Transducer to patient headphones verified as 2 MOPP. | <b>P</b>   |
|                | <b>PROTECTIVE EARTH CONNECTIONS forming a MEANS OF PATIENT PROTECTION complied with Cl. 8.6</b>   |  | <b>N/A</b> |
| <b>8.5.1.3</b> | <b>MEANS OF OPERATOR PROTECTION (MOOP)</b>  | 2 MOOP provided by external PSU for the Amplifier.   | <b>P</b>   |
|                | <b>Solid insulation forming a MEANS OF OPERATOR PROTECTION complied with:</b>   | See Insulation diagram. External power supply separately certified as MOOP.                          | <b>P</b>   |
|                | <b>– dielectric strength test ..... :</b>   |  | <b>P</b>   |
|                | <b>– requirements of IEC 60950-1 for INSULATION CO-ORDINATION</b>   | External PSU separately certified to the requirements of UL 60950-1.                                 | <b>P</b>   |
|                | <b>CREEPAGE and CLEARANCES forming a MEANS OF OPERATOR PROTECTION complied with:</b>  |  | <b>N/A</b> |
|                | <b>– limits of Tables 13 to 16 (inclusive); or</b>  |  | <b>N/A</b> |
|                | <b>– requirements of IEC 60950-1 for INSULATION CO-ORDINATION</b>   | UL 60950-1 certified PSU provides 2 MOOP.  | <b>P</b>   |
|                | <b>PROTECTIVE EARTH CONNECTIONS forming a MEANS OF OPERATOR PROTECTION complied with Cl. 8.6</b>  |  | <b>N/A</b> |
|                | <b>– or with requirements and tests of IEC 60950-1 for protective earthing..... :</b>   |  | <b>N/A</b> |
|                | <b>A Y2 (IEC 60384-14) capacitor is considered one MEANS OF OPERATOR PROTECTION..... :</b>  |  | <b>N/A</b> |
|                | <b>A Y1 (IEC 60384-14 ) capacitor is considered two MEANS OF OPERATOR PROTECTION..... :</b>   |  | <b>N/A</b> |
|                | <b>Two capacitors used in series each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance</b>   |  | <b>N/A</b> |
|                | <b>Voltage Total Working (V) and C Nominal (µF)..... :</b>  |  | <b>—</b>   |
|                | <b>Points and applied parts at which impedances of components, CREEPAGE, CLEARANCES, PROTECTIVE EARTH CONNECTIONS or insulation, prevent ACCESSIBLE PARTS from exceeding limits in 8.4 were examined whether a failure at any of these points is to be regarded as a NORMAL or SINGLE FAULT CONDITION</b> |  | <b>N/A</b> |

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| Clause         | Requirement + Test  | Result - Remark                                 | Verdict    |
|                | <b>A MEANS OF PROTECTION protecting APPLIED PARTS, or parts identified by 4.6 as parts subject to the same requirements, considered MEANS OF PATIENT PROTECTION .....</b> :                     |   | <b>N/A</b> |
|                | <b>A MEANS OF PROTECTION protecting other parts considered MEANS OF OPERATOR PROTECTION .....</b> :   |   | <b>N/A</b> |
| <b>8.5.2</b>   | <b>Separation of PATIENT CONNECTIONS</b>  |   | <b>P</b>   |
| <b>8.5.2.1</b> | <b>PATIENT CONNECTIONS of F-TYPE APPLIED PART separated from all other parts by equivalent to one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to the MAX. MAINS VOLTAGE .....</b> : | Type B applied parts.                           | <b>N/A</b> |
|                | <b>Separation requirement not applied between multiple functions of a single F-TYPE APPLIED PART</b>  |   | <b>N/A</b> |
|                | <b>PATIENT CONNECTIONS treated as one APPLIED PART in the absence of electrical separation between PATIENT CONNECTIONS of same or another function</b>  | One applied part.                               | <b>N/A</b> |
|                | <b>MANUFACTURER has defined if multiple functions are to be considered as all within one APPLIED PART or as multiple APPLIED PARTS .....</b> :  | Single function applied part.                   | <b>N/A</b> |
|                | <b>Classification as TYPE BF, CF, OR DEFIBRILLATION-PROOF applied to one entire APPLIED PART</b>  | Type B applied part.                            | <b>N/A</b> |
|                | <b>LEAKAGE CURRENT tests conducted per 8.7.4.....</b> :   |   | <b>N/A</b> |
|                | <b>Dielectric strength test conducted per 8.8.3.....</b> :  |   | <b>N/A</b> |
|                | <b>CREEPAGE and CLEARANCES measured .....</b> :   |   | <b>N/A</b> |
|                | <b>A protective device connected between PATIENT CONNECTIONS of an F-TYPE APPLIED PART and ENCLOSURE to protect against excessive voltages did not operate below 500 V r.m.s</b>                | Such device not used.                           | <b>N/A</b> |
| <b>8.5.2.2</b> | <b>PATIENT CONNECTIONS of a TYPE B APPLIED PART not PROTECTIVELY EARTHED are separated by one MEANS OF PATIENT PROTECTION from metal ACCESSIBLE PARTS not PROTECTIVELY EARTHED .....</b> :      | See Insulation diagram.<br>Type B applied part. | <b>P</b>   |
|                | <b>– except when metal ACCESSIBLE PART is physically close to APPLIED PART and can be regarded as a part of APPLIED PART; and</b>   |   | <b>N/A</b> |
|                | <b>– RISK that metal ACCESSIBLE PART will make contact with a source of voltage or LEAKAGE CURRENT above permitted limits is acceptably low</b>   |   | <b>N/A</b> |
|                | <b>LEAKAGE CURRENT tests conducted per 8.7.4.....</b> :   | See table 8.7.4.                                | <b>P</b>   |
|                | <b>Dielectric strength test conducted per 8.8.3.....</b> :  | See table 8.8.3.                                | <b>P</b>   |

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|----------------|--|---|------------|
| Clause         | Requirement + Test   | Result - Remark   | Verdict    |
|                | <b>Relevant CREEPAGE and CLEARANCES measured</b>   | See Insulation diagram.<br>Distance form output of Transducer to patient headphones verified as 2 MOPP. | <b>P</b>   |
|                | <b>RISK MANAGEMENT FILE includes an assessment of the RISK of metal ACCESSIBLE PARTS contacting a source of voltage or LEAKAGE CURRENT above the limits.....: (ISO 14971 Cl. 4.2-4.4, 5)</b>   | Not a type B applied part. No RMF considered necessary.   | <b>N/A</b> |
| <b>8.5.2.3</b> | <b>A connector on a PATIENT lead or PATIENT cable located at the end of the lead or cable remote from PATIENT, with conductive part not separated from all PATIENT CONNECTIONS by one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to MAXIMUM MAINS VOLTAGE</b> |   | <b>N/A</b> |
|                | <b>- cannot be connected to earth or hazardous voltage while the PATIENT CONNECTIONS are in contact with PATIENT..... :</b>  | Connector for headphones is nonconductive. No access to patient at end of the cable.                    | <b>N/A</b> |
|                | <b>– conductive part of connector not separated from all PATIENT CONNECTIONS did not come into contact with a flat conductive plate of not less than 100 mm diameter</b>   |   | <b>N/A</b> |
|                | <b>– CLEARANCE between connector pins and a flat surface is at least 0.5 mm</b>  |   | <b>N/A</b> |
|                | <b>– conductive part pluggable into a mains socket protected from making contact with parts at MAINS VOLTAGE by insulation with a CREEPAGE DISTANCE of at least 1.0 mm, a 1500 V dielectric strength and complying with 8.8.4.1</b>  |   | <b>N/A</b> |
|                | <b>– required test finger did not make electrical contact with conductive part when applied against access openings with a force of 10 N,</b>  |   | <b>N/A</b> |
|                | <b>Test finger test (10 N)..... :</b>  |   | <b>N/A</b> |
|                | <b>Except when RISK MANAGEMENT PROCESS includes an assessment of RISKS resulting from contact with objects other than mains sockets or flat surfaces..... : (ISO 14971 Cl. 4.2-4.4, 5)</b>   |   | <b>N/A</b> |
| <b>8.5.4</b>   | <b>WORKING VOLTAGE</b>   |   | <b>P</b>   |
|                | <b>– Input supply voltage to ME EQUIPMENT was RATED voltage or voltage within RATED range resulting in highest measured value (V)..... :</b>   | External power supply separately certified and rated 100-240V.  | <b>P</b>   |
|                | <b>– WORKING VOLTAGE for d.c. voltages with superimposed ripple was average value when peak-to-peak ripple less than 10% of average value or peak voltage when peak-to-peak ripple exceeding 10% of average value (V)..... :</b>   |   | <b>N/A</b> |

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| Clause      | Requirement + Test   | Result - Remark                                     | Verdict |
|             | – WORKING VOLTAGE for each MEANS OF PROTECTION forming DOUBLE INSULATION was voltage DOUBLE INSULATION, as a whole, subjected to (V)..... :  | See Insulation Diagram and Insulation Table         | P       |
|             | – Intentional or accidental earthing of PATIENT regarded as a NORMAL CONDITION for WORKING VOLTAGE involving a PATIENT CONNECTION not connected to earth   |   | P       |
|             | – WORKING VOLTAGE between PATIENT CONNECTIONS of an F-TYPE APPLIED PART and ENCLOSURE was highest voltage appearing across insulation in NORMAL USE including earthing of any part of APPLIED PART (V) ..... :                 |   | N/A     |
|             | – WORKING VOLTAGE for DEFIBRILLATION-PROOF APPLIED PARTS determined disregarding possible presence of defibrillation voltages  |   | N/A     |
|             | – WORKING VOLTAGE was equal to resonance voltage in case of motors provided with capacitors between the point where a winding and a capacitor are connected together and a terminal for external conductors (V)..... :         | No such motors provided.                            | N/A     |
| 8.5.5       | DEFIBRILLATION-PROOF APPLIED PARTS   |   | N/A     |
| 8.5.5.1     | Classification “DEFIBRILLATION-PROOF APPLIED PART” applied to one APPLIED PART in its entirety   | No defibrillation proof applied parts.              | N/A     |
|             | Isolation of PATIENT CONNECTIONS of a DEFIBRILLATION-PROOF APPLIED PART from other parts of ME EQUIPMENT accomplished as follows:  |   | N/A     |
|             | a) No hazardous electrical energies appear during a discharge of cardiac defibrillator ..... :   |   | N/A     |
|             | b) ME EQUIPMENT complied with relevant requirements of this standard, providing BASIC SAFETY and ESSENTIAL PERFORMANCE following exposure to defibrillation voltage, and recovery time stated in ACCOMPANYING DOCUMENTS..... : |   | N/A     |
| 8.5.5.2     | Means provided to limit energy delivered to a 100 Ω load ..... :   |   | N/A     |
| 8.6         | Protective and functional earthing and potential equalization of ME EQUIPMENT  |   | P       |
| 8.6.1       | Requirements of 8.6.2 to 8.6.8 applied   |   | P       |
|             | Parts complying with IEC 60950-1 for protective earthing and serving as MEANS OF OPERATOR PROTECTION but not PATIENT PROTECTION exempted from requirements of 8.6.2 to 8.6.8   | External PSU is separately certified to UL 60950-1. | P       |
| 8.6.2       | PROTECTIVE EARTH TERMINAL is suitable for connection to an external protective earthing system by a PROTECTIVE EARTH CONDUCTOR in a POWER SUPPLY CORD and a suitable plug or by a FIXED PROTECTIVE EARTH CONDUCTOR ..... :     | Appliance inlet provided.                           | P       |

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| Clause       | Requirement + Test   | Result - Remark                                     | Verdict    |
|              | <b>Clamping means of PROTECTIVE EARTH TERMINAL of ME EQUIPMENT for FIXED supply conductors or POWER SUPPLY CORDS comply with 8.11.4.3, and cannot be loosened without TOOL</b>   |   | <b>N/A</b> |
|              | <b>Screws for internal PROTECTIVE EARTH CONNECTIONS completely covered or protected against accidental loosening from outside .... :</b>   |   | <b>N/A</b> |
|              | <b>Earth pin of APPLIANCE INLET forming supply connection to ME EQUIPMENT regarded as PROTECTIVE EARTH TERMINAL</b>  | Appliance inlet provided.                           | <b>P</b>   |
|              | <b>PROTECTIVE EARTH TERMINAL not used for mechanical connection between different parts of ME EQUIPMENT or securing components not related to protective or functional earthing</b>  |   | <b>P</b>   |
| <b>8.6.3</b> | <b>PROTECTIVE EARTH CONNECTION not used for a moving part,</b>   | No earthed moving parts.                            | <b>N/A</b> |
|              | <b>except when MANUFACTURER demonstrated in RISK MANAGEMENT FILE connection will remain reliable during EXPECTED SERVICE LIFE ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)</b>  | No RMF consideration necessary.                     | <b>N/A</b> |
| <b>8.6.4</b> | <b>a) PROTECTIVE EARTH CONNECTIONS carried fault currents reliably and without excessive voltage drop.....:</b>  | External PSU is separately certified to UL 60950-1. | <b>N/A</b> |
|              | <b>b) Allowable TOUCH CURRENT and PATIENT LEAKAGE CURRENT in SINGLE FAULT CONDITION were not exceeded, when impedance of PROTECTIVE EARTH CONNECTIONS exceeded values in 8.6.4 a) and Table 8.6.4, due to limited current capability of relevant circuits..... :</b> |   | <b>N/A</b> |
| <b>8.6.5</b> | <b>Surface coatings</b>  |   | <b>N/A</b> |
|              | <b>Poorly conducting surface coatings on conductive elements removed at the point of contact</b>   | No coatings provided.                               | <b>N/A</b> |
|              | <b>Coating not removed when requirements for impedance and current-carrying capacity met</b>   |   | <b>N/A</b> |
| <b>8.6.6</b> | <b>Plugs and sockets</b>   |   | <b>N/A</b> |
|              | <b>PROTECTIVE EARTH CONNECTION where connection between SUPPLY MAINS and ME EQUIPMENT or between separate parts of ME EQUIPMENT made via a plug and socket was made before and interrupted after supply connections</b>  | No such connection.                                 | <b>N/A</b> |
|              | <b>- applied also where interchangeable parts are PROTECTIVELY EARTHED</b>   | None provided.                                      | <b>N/A</b> |
| <b>8.6.7</b> | <b>Terminal for connection of a POTENTIAL EQUALIZATION CONDUCTOR</b>   |   | <b>N/A</b> |
|              | <b>- Terminal is accessible to OPERATOR with ME EQUIPMENT in any position of NORMAL USE</b>  | No protective or functional earthing.               | <b>N/A</b> |

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| Clause      | Requirement + Test   | Result - Remark                   | Verdict |
|             | –accidental disconnection avoided in NORMAL USE  |                                   | N/A     |
|             | – Terminal allows conductor to be detached without a TOOL  |                                   | N/A     |
|             | – Terminal not used for a PROTECTIVE EARTH CONNECTION  |                                   | N/A     |
|             | – Terminal marked with symbol 8 of Table D.1   |                                   | N/A     |
|             | – Instructions for use contain information on function and use of POTENTIAL EQUALIZATION CONDUCTOR together with a reference to requirements of this standard  |                                   | N/A     |
|             | POWER SUPPLY CORD does not incorporate a POTENTIAL EQUALIZATION CONDUCTOR  |                                   | N/A     |
| 8.6.8       | FUNCTIONAL EARTH TERMINAL not used to provide a PROTECTIVE EARTH CONNECTION  | None provided.                    | N/A     |
| 8.6.9       | Class II ME EQUIPMENT  |                                   | N/A     |
|             | Third conductor of POWER SUPPLY CORD connected to protective earth contact of MAINS PLUG provided with CLASS II ME EQUIPMENT with isolated internal screens used as functional earth connection to the screen's FUNCTIONAL EARTH TERMINAL, coloured green and yellow | External power supply is Class I. | N/A     |
|             | ACCOMPANYING DOCUMENTS include a statement that the third conductor in the POWER SUPPLY CORD is only a functional earth.   |                                   | N/A     |
|             | Two MEANS OF PROTECTION provided between insulation of internal screens and all internal wiring connected to them and ACCESSIBLE PARTS   |                                   | N/A     |
| 8.7         | LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS  |                                   | P       |
| 8.7.1       | a) Electrical isolation providing protection against electric shock limits currents to values in 8.7.3..... :  | See appended Tables 8.7           | P       |
|             | b) Specified values of EARTH LEAKAGE, TOUCH, PATIENT LEAKAGE, and PATIENT AUXILIARY CURRENTS applied in combination of conditions in appended Table 8.7..... :   | See appended Tables 8.7           | P       |
| 8.7.2       | Allowable values specified in 8.7.3 applied under SINGLE FAULT CONDITIONS of 8.1 b), except  | See appended Tables 8.7           | P       |
|             | – where insulation used in conjunction with a PROTECTIVE EARTH CONNECTION, insulation short circuited only under conditions in 8.6.4 b)  | See appended Tables 8.7           | P       |
|             | – the only SINGLE FAULT CONDITION for EARTH LEAKAGE CURRENT was interruption of one supply conductor at a time   | See appended Tables 8.7           | P       |

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| Clause      | Requirement + Test   | Result - Remark                              | Verdict |
|             | – LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENT not measured in SINGLE FAULT CONDITION of short circuiting of one constituent part of DOUBLE INSULATION   |  | N/A     |
|             | SINGLE FAULT CONDITIONS not applied at same time as special test conditions of MAXIMUM MAINS VOLTAGE on APPLIED PARTS and non-PROTECTIVELY EARTHED parts of ENCLOSURE  |  | P       |
| 8.7.3       | <b>Allowable Values</b>  |  | P       |
|             | a) Allowable values in 8.7.3 b), c), and d) measured based on, and are relative to currents in Fig 12 a), or by a device measuring frequency contents of currents as in Fig 12 b. :                              | See appended Table 8.7                       | P       |
|             | b) Allowable values of PATIENT LEAKAGE and AUXILIARY CURRENTS are according to Tables 3 & 4, and values of a.c. are relative to currents having a frequency not less than 0.1Hz..... :                           | See appended Table 8.7                       | P       |
|             | c) TOUCH CURRENT did not exceed 100 $\mu$ A in NORMAL CONDITION and 500 $\mu$ A in SINGLE FAULT CONDITION ( $I_{TNC}$ , $I_{TSFC}$ )..... :  | See appended Table 8.7                       | P       |
|             | d) EARTH LEAKAGE CURRENT did not exceed 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION ( $I_{ENC}$ , $I_{ESFC}$ )..... :   | No accessible earthed components.            | N/A     |
|             | Higher values of EARTH LEAKAGE CURRENT permitted for PERMANENTLY INSTALLED ME EQUIPMENT connected to a supply circuit supplying only this ME EQUIPMENT according to local regulations or IEC 60364-7-710 ..... : | Not permanently installed.                   | N/A     |
|             | e) LEAKAGE CURRENTS, regardless of waveform and frequency, did not exceed 10 mA r.m.s. in NORMAL or in SINGLE FAULT CONDITION (measured with a non-frequency-weighted device..... :                              | See appended Table 8.7                       | P       |
|             | f) LEAKAGE CURRENTS flowing in a FUNCTIONAL EARTH CONDUCTOR in a non-PERMANENTLY INSTALLED ME EQUIPMENT are 5 mA in NORMAL CONDITION, 10 mA in SINGLE FAULT CONDITION ..... :                                    |  | N/A     |
| 8.7.4       | LEAKAGE and PATIENT AUXILIARY CURRENTS measurements ..... :  | See appended Table 8.7                       | P       |
| 8.8         | <b>Insulation</b>  |  | P       |
| 8.8.1       | Insulation relied on as MEANS OF PROTECTION, including REINFORCED INSULATION subjected to testing  | See Insulation Diagram and Insulation Table. | P       |
|             | Insulation exempted from test (complies with clause 4.8)   | See Insulation Diagram and Insulation Table. | P       |
|             | Insulation forming MEANS OF OPERATOR PROTECTION and complying with IEC 60950-1 for INSULATION CO-ORDINATION not tested as in 8.8   | Not used.                                    | N/A     |
| 8.8.2       | Distance through solid insulation or use of thin sheet material  |  | P       |



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| Clause      | Requirement + Test   | Result - Remark  | Verdict    |
|             | <b>Solid insulation forming SUPPLEMENTARY or REINFORCED INSULATION for a PEAK WORKING VOLTAGE greater than 71 V provided with:</b>   | Evaluated as part of the certified external power supply unit. No solid insulation is considered necessary for 1 MOP or for voltages below 71Vp. | <b>P</b>   |
|             | <b>a) 0.4 mm, min, distance through insulation, or</b>   | Evaluated as part of the certified external power supply unit.   | <b>P</b>   |
|             | <b>b) does not form part of an ENCLOSURE and not subject to handling or abrasion during NORMAL USE, and comprised of:</b>  | Evaluated as part of the certified external power supply unit.   | <b>P</b>   |
|             | – at least two layers of material, each passed the appropriate dielectric strength test .....  |  | <b>N/A</b> |
|             | – or three layers of material, for which all combinations of two layers together passed the appropriate dielectric strength test .....   | Evaluated as part of the certified external power supply unit.   | <b>P</b>   |
|             | <b>Dielectric strength test for one or two layers was same as for one MEANS OF PROTECTION for SUPPLEMENTARY INSULATION</b>   |  | <b>N/A</b> |
|             | <b>Dielectric strength test for one or two layers was same as for two MEANS OF PROTECTION for REINFORCED INSULATION</b>  | Evaluated as part of the certified external power supply unit.   | <b>P</b>   |
|             | <b>BASIC, SUPPLEMENTARY, and REINFORCED INSULATION required between windings of wound components separated by interleaved insulation complying with a) or b), or both, except when</b> | Evaluated as part of the certified external power supply unit.   | <b>P</b>   |
|             | <b>c) Wire with solid insulation, other than solvent based enamel, complying with a)</b>   | Evaluated as part of the certified external power supply unit.   | <b>P</b>   |
|             | <b>d) Wire with multi-layer extruded or spirally wrapped insulation complying with b) and complying with Annex L</b>   | Evaluated as part of the certified external power supply unit.   | <b>P</b>   |
|             | <b>e) Finished wire with spirally wrapped or multi-layer extruded insulation, complying with Annex L</b>   | Evaluated as part of internal PSU. See appended PSU report.  | <b>P</b>   |
|             | – BASIC INSULATION: minimum two wrapped layers or one extruded layer   |  | <b>N/A</b> |
|             | – SUPPLEMENTARY INSULATION: minimum two layers, wrapped or extruded  |  | <b>N/A</b> |
|             | – REINFORCED INSULATION: minimum three layers, wrapped or extruded   | Evaluated as part of the certified external power supply unit.   | <b>P</b>   |

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| Clause      | Requirement + Test   | Result - Remark   | Verdict |
|             | In d) and e), for spirally wrapped insulation with CREEPAGE DISTANCES between layers less than in Table 12 or 16 (Pollution Degree 1) depending on type of insulation, path between layers sealed as a cemented joint in 8.9.3.3 and test voltages of TYPE TESTS in L.3 equal 1.6 times of normal values |   | N/A     |
|             | Protection against mechanical stress provided where two insulated wires or one bare and one insulated wire are in contact inside wound component, crossing at an angle between 45° and 90° and subject to winding tension..... :   |   | N/A     |
|             | Finished component complied with routine dielectric strength tests of 8.8.3..... :   | See appended Table 8.8.3  | P       |
|             | Tests of Annex L not repeated since material data sheets confirm compliance..... :   | See Table 8.10.   | P       |
| 8.8.3       | Dielectric Strength  |   | P       |
|             | Solid insulating materials with a safety function withstood dielectric strength test voltages ..... :  | See appended Table 8.8.3  | P       |
| 8.8.4       | Insulation other than wire insulation  |   | P       |
| 8.8.4.1     | Resistance to heat retained by all insulation and insulating partition walls during EXPECTED SERVICE LIFE of ME EQUIPMENT  |   | N/A     |
|             | ME EQUIPMENT and design documentation examined..... :  |   | N/A     |
|             | RISK MANAGEMENT FILE examined in conjunction with resistance to moisture, dielectric strength, and mechanical strength tests..... :<br>(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)   | Parts considered requiring the test were tested. Additionally, see 8.8.3, 11.6 and 15.3.<br><br>Compliance is achieved by the pertinent clause tests evaluated for this Standard. No RMF consideration necessary. | N/A     |
|             | Satisfactory evidence of compliance provided by manufacturer for resistance to heat..... :   | Test conducted.   | N/A     |
|             | Tests conducted in absence of satisfactory evidence for resistance to heat..... :  |   | N/A     |
|             | a) ENCLOSURE and other external parts of insulating material, except insulation of flexible cords and parts of ceramic material, subjected to ball-pressure test using Fig 21 apparatus... :   |   | N/A     |
|             | b) Parts of insulating material supporting uninsulated parts of MAINS PART subjected to ball-pressure test in a), except at 125 °C ± 2 ° C or ambient indicated in technical description ±2°C plus temperature rise determined during test of 11.1 of relevant part, if higher (°C)..... :               | Evaluated as part of the certified external power supply unit.  | P       |

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| Clause      | Requirement + Test   | Result - Remark   | Verdict |
|             | Test not performed on parts of ceramic material, insulating parts of commutators, brush-caps, and similar, and on coil formers not used as REINFORCED INSULATION   |   | N/A     |
| 8.8.4.2     | Resistance to environmental stress   |   | P       |
|             | Insulating characteristics and mechanical strength of all MEANS OF PROTECTION not likely to be impaired by environmental stresses including deposition of dirt resulting from wear of parts within EQUIPMENT, potentially reducing CREEPAGE and CLEARANCES below 8.9 | Enclosures are of adequate strength and insulation, no wearing of parts or concern for environmental conditions.                                  | P       |
|             | Ceramic and similar materials not tightly sintered, and beads alone not used as SUPPLEMENTARY OF REINFORCED INSULATION   | Not used.   | N/A     |
|             | Insulating material with embedded heating conductors considered as one MEANS OF PROTECTION but not two MEANS OF PROTECTION   | No heaters.   | N/A     |
|             | Parts of natural latex rubber aged by suspending samples freely in an oxygen cylinder containing commercial oxygen to a pressure of 2.1 MPa ± 70 kPa, with an effective capacity of at least 10 times volume of samples  | Latex rubber not used.  | N/A     |
|             | There were no cracks visible to naked eyes after samples kept in cylinder at 70 °C ± 2 °C for 96h, and afterwards, left at room temperature for at least 16h   |   | N/A     |
| 8.9         | CREEPAGE DISTANCES and AIR CLEARANCES  |   | P       |
| 8.9.1.1     | CREEPAGE DISTANCES and AIR CLEARANCES are equal to or greater than values in Tables 12 to 16 (inclusive)..... :  | See Insulation Diagram and Insulation Table.  | P       |
| 8.9.1.15    | CREEPAGE DISTANCES and AIR CLEARANCES for DEFIBRILLATION-PROOF APPLIED PARTS are 4 mm or more to meet 8.5.5.1  | No defibrillation-proof applied parts.  | N/A     |
| 8.9.2       | a) Short circuiting of each single one of CREEPAGE DISTANCES and CLEARANCES in turn did not result in a HAZARDOUS SITUATION , min CREEPAGE and CLEARANCES not applied..... :   |   | N/A     |
| 8.9.3       | Spaces filled by insulating compound   |   | P       |
| 8.9.3.1     | Only solid insulation requirements applied where distances between conductive parts filled with insulating compound  | Opto couplers in the certified external power supply have been accepted based on certification of power supply. See Insulation Diagram and table. | P       |
|             | Thermal cycling, humidity preconditioning, and dielectric strength tests   |   | N/A     |

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| Clause      | Requirement + Test   | Result - Remark  | Verdict |
| 8.9.3.2     | For insulating compound forming solid insulation between conductive parts, a single sample subjected to thermal cycling PROCEDURE of 8.9.3.4 followed by humidity preconditioning per 5.7 (for 48 hours), followed by dielectric strength test (cl. 8.8.3 at 1,6 x test voltage) ..... |  | N/A     |
|             | Cracks or voids in insulating compound affecting homogeneity of material didn't occur  |  | N/A     |
| 8.9.3.3     | Where insulating compound forms a cemented joint with other insulating parts, three samples tested for reliability of joint  |  | N/A     |
|             | A winding of solvent-based enamelled wire replaced for the test by a metal foil or by a few turns of bare wire placed close to cemented joint, and three samples tested as follows:  |  | N/A     |
|             | – One sample subjected to thermal cycling PROCEDURE of 8.9.3.4, and immediately after the last period at highest temperature during thermal cycling followed by dielectric strength test of cl. 8.8.3 at 1.6 x the test voltage .....  |  | N/A     |
|             | – The other two samples subjected to humidity preconditioning of 5.7, except for 48 hours only followed by a dielectric strength test of cl. 8.8.3 at 1.6 times the test voltage   |  | N/A     |
| 8.9.4       | Minimum spacing of grooves transvers to the CREEPAGE DISTANCES considered a MEANS OF OPERATOR PROTECTION adjusted based on pollution degree .....  | Pollution degree: 2  | P       |
|             | Force was applied between bare conductors and outside metal enclosure when measuring CREEPAGE DISTANCES and AIR CLEARANCES   | Refer to Insulation Diagram supplemental information for location and force used | P       |
| 8.10        | Components and wiring  |  | P       |
| 8.10.1      | Components of ME EQUIPMENT likely to result in an unacceptable RISK by their movements mounted securely .....  | See appended table 8.10. Components are adequately secured.                      | P       |
|             | RISK MANAGEMENT FILE includes an assessment of RISKS related to unwanted movement of components .....  |  | NE      |
|             | (ISO 14791 Cl. 4.2-4.4, 5, 6.2-6.5)  |  |         |
| 8.10.2      | Conductors and connectors of ME EQUIPMENT adequately secured or insulated to prevent accidental detachment .....   | No hazard associated with wiring.  | P       |
|             | Stranded conductors are not solder-coated when secured by clamping means to prevent HAZARDOUS SITUATIONS   | Conductors not soft soldered.  | P       |

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| Clause      | Requirement + Test   | Result - Remark   | Verdict |
| 8.10.3      | Interconnecting flexible cords detachable without a TOOL used provided with means for connection to comply with requirements for metal ACCESSIBLE PARTS when a connection is loosened or broken .....                            | No such cords.  | N/A     |
| 8.10.4      | Cord-connected HAND-HELD parts and cord-connected foot-operated control devices  |   | N/A     |
| 8.10.4.1    | Control devices of ME EQUIPMENT and their connection cords contain only conductors and components operating at 42.4 V peak a.c., max, or 60 V d.c. in circuits isolated from MAINS PART by two MEANS OF PROTECTION               | Headphones are body worn.<br>Provided with a nonconductive connection to Transducer.                    | N/A     |
| 8.10.4.2    | Connection and anchorage of a flexible cord to a HAND-HELD or foot-operated control device of ME EQUIPMENT, at both ends of the cable to the control device, complies with the requirements for POWER SUPPLY CORDS in Cl. 8.11.3 |   | N/A     |
|             | Other HAND-HELD parts, if disturbance or breaking of one or more of the connections could result in a HAZARDOUS SITUATION, also comply with tests of Cl. 8.11.3  |   | N/A     |
| 8.10.5      | Mechanical protection of wiring  |   | P       |
|             | a) Internal cables and wiring adequately protected against contact with a moving part or from friction at sharp corners and edges .....  |   | P       |
|             | b) Wiring, cord forms, or components are not likely to be damaged during assembly or during opening or closing of ACCESS COVERS  | No wiring or components likely to be damaged during assembly or service.                                | P       |
| 8.10.6      | Guiding rollers prevent bending of movable insulated conductors around a radius of less than five times the outer diameter of the lead   | No guiding rollers.   | N/A     |
| 8.10.7      | a) Insulating sleeve adequately secured .....  | No sleeving relied on for insulation.   | N/A     |
|             | b) Sheath of a flexible cord not used as a MEANS OF PROTECTION inside ME EQUIPMENT when it is subject to mechanical or thermal stresses beyond its RATED characteristics   |   | N/A     |
|             | c) Insulated conductors of ME EQUIPMENT subject to temperatures exceeding 70 °C.....   | No temperature > 70°C.  | N/A     |
| 8.11        | MAINS PARTS, components and layout   |   | P       |
| 8.11.1      | a) ME EQUIPMENT provided with means of electrically isolating its circuits from SUPPLY MAINS simultaneously on all poles.....  | External PSU provided with an appliance inlet. The appliance inlet is considered the disconnect device. | P       |

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|-------------|---|---|------------|
| Clause      | Requirement + Test  | Result - Remark                                   | Verdict    |
|             | <b>PERMANENTLY INSTALLED ME EQUIPMENT connected to a poly-phase SUPPLY MAINS equipped with a device not interrupting neutral conductor, provided local installation conditions prevent voltage on neutral conductor from exceeding limits in 8.4.2 c)</b>                                       | Not permanently installed equipment.              | <b>N/A</b> |
|             | <b>PERMANENTLY INSTALLED ME EQUIPMENT provided with means to isolate its circuits electrically from the SUPPLY MAINS are capable of being locked in the off position</b>  | Not permanently installed equipment.              | <b>N/A</b> |
|             | <b>- the isolation device specified in the ACCOMPANYING DOCUMENTS</b>   |   | <b>N/A</b> |
|             | <b>b) Means of isolation incorporated in ME EQUIPMENT, or if external, described in technical description .....</b>   | Appliance inlet provided.                         | <b>P</b>   |
|             | <b>c) A SUPPLY MAINS switch used to comply with 8.11.1 a) complies with CREEPAGE / CLEARANCES for a MAINS TRANSIENT VOLTAGE of 4 kV .....</b>   | No such mains switch.                             | <b>N/A</b> |
|             | <b>d) A SUPPLY MAINS switch not incorporated in a POWER SUPPLY CORD or external flexible lead</b>   | Appliance inlet provided as part of external PSU. | <b>P</b>   |
|             | <b>e) Actuator of a SUPPLY MAINS switch used to comply with 8.11.1 a) complies with IEC 60447</b>   |   | <b>N/A</b> |
|             | <b>f) A suitable plug device used in non-PERMANENTLY INSTALLED ME EQUIPMENT with no SUPPLY MAINS SWITCH .....</b>   | Appliance inlet provided.                         | <b>P</b>   |
|             | <b>g) A fuse or a semiconductor device not used as an isolating means</b>   | Such components not used.                         | <b>P</b>   |
|             | <b>h) ME EQUIPMENT not provided with a device causing disconnection of ME EQUIPMENT from SUPPLY MAINS by producing a short circuit resulting in operation of an overcurrent protection device</b>   | Such components not used.                         | <b>P</b>   |
|             | <b>i) Parts within ENCLOSURE of ME EQUIPMENT with a circuit &gt; 42.4 V peak a.c. or 60 V d.c. that cannot be disconnected from its supply by an external switch or a plug device accessible at all times is protected against touch even after opening ENCLOSURE by an additional covering</b> |   | <b>N/A</b> |
|             | <b>A clear warning notice is marked on outside of ME EQUIPMENT to indicate it exceeds allowable touch voltage</b>   |   | <b>N/A</b> |
|             | <b>For a part that could not be disconnected from supply by an external switch or a plug device accessible at all times, the required cover or warning notice complied with this clause</b>   |   | <b>N/A</b> |
|             | <b>Standard test finger applied</b>   |   | <b>N/A</b> |

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| Clause      | Requirement + Test   | Result - Remark  | Verdict |
| 8.11.2      | <b>MULTIPLE SOCKET-OUTLETS integral with ME EQUIPMENT complied with 16.2 d), second dash; and 16.9.2</b>   | No MSO.  | N/A     |
| 8.11.3      | <b>POWER SUPPLY CORDS</b>  |  | P       |
| 8.11.3.1    | <b>MAINS PLUG not fitted with more than one POWER SUPPLY CORD</b>  | Appliance inlet provided as part of external PSU.<br>Power cord not evaluated in this test report. | P       |
| 8.11.3.2    | <b>POWER SUPPLY CORDS are no less robust than ordinary tough rubber sheathed flexible cord (IEC 60245-1:2003, Annex A, designation 53) or ordinary polyvinyl chloride sheathed flexible cord (IEC 60227-1:1993, Annex A, design 53)... :</b> |  | N/A     |
|             | <b>Only polyvinyl chloride insulated POWER SUPPLY CORD with appropriate temperature rating used for ME EQUIPMENT having external metal parts with a temperature &gt; 75 °C touchable by the cord in NORMAL USE .....</b> :                   | No such parts.   | N/A     |
| 8.11.3.3    | <b>NOMINAL cross-sectional area of conductors of POWER SUPPLY CORDS of ME EQUIPMENT is not less than in Table 17.....</b> :  |  | N/A     |
| 8.11.3.4    | <b>APPLIANCE COUPLERS complying with IEC 60320-1 are considered to comply with 8.11.3.5 and 8.11.3.6 .....</b> :   | External PSU provided with an appliance inlet that complies with IEC60320-1                        | P       |
| 8.11.3.5    | <b>Cord anchorage</b>  |  | N/A     |
|             | <b>a) Conductors of POWER SUPPLY CORD provided with strain relief and insulation protected from abrasion at point of entry to ME EQUIPMENT or a MAINS CONNECTOR by a cord anchorage</b>  | Appliance inlet provided as part of external PSU.  | N/A     |
|             | <b>b) Cord anchorage of POWER SUPPLY CORD is an insulating material, or</b>  |  | N/A     |
|             | <b>– metal, insulated from conductive ACCESSIBLE PARTS non-PROTECTIVELY EARTHED by a MEANS OF PROTECTION, or</b>   |  | N/A     |
|             | <b>– metal provided with an insulating lining affixed to cord anchorage</b>  |  | N/A     |
|             | <b>c) Cord anchorage prevents cord from being clamped by a screw bearing directly on cord insulation</b>   |  | N/A     |
|             | <b>d) Screws to be operated when replacing POWER SUPPLY CORD do not serve to secure any components</b>   |  | N/A     |
|             | <b>e) Conductors of POWER SUPPLY CORD arranged to prevent PROTECTIVE EARTH CONDUCTOR against strain as long as phase conductors are in contact with their terminals</b>  |  | N/A     |

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| Clause          | Requirement + Test  | Result - Remark                                   | Verdict    |
|                 | <b>f) Cord anchorage prevents POWER SUPPLY CORD from being pushed into ME EQUIPMENT OR MAINS CONNECTOR</b>  |   | <b>N/A</b> |
|                 | <b>Conductors of POWER SUPPLY CORD supplied by MANUFACTURER disconnected from terminals or from MAINS CONNECTOR and cord subjected 25 times to a pull applied with no jerks, each time for 1 s, on sheath of the value in Table 18..... :</b> |   | <b>N/A</b> |
|                 | <b>Cord subjected to a torque in Table 18 for one minute immediately after pull tests</b>   |   | <b>N/A</b> |
|                 | <b>Cord anchorage did not allow cord sheath to be longitudinally displaced by more than 2 mm or conductor ends to move over a distance of more than 1 mm from their connected position</b>  |   | <b>N/A</b> |
|                 | <b>CREEPAGE and CLEARANCES not reduced below limits in 8.9</b>  |   | <b>N/A</b> |
|                 | <b>It was not possible to push the cord into ME EQUIPMENT OR MAINS CONNECTOR to an extent the cord or internal parts would be damaged</b>   |   | <b>N/A</b> |
| <b>8.11.3.6</b> | <b>POWER SUPPLY CORDS protected against excessive bending at inlet opening of equipment</b>   | Appliance inlet provided as part of external PSU. | <b>N/A</b> |
|                 | <b>Cord guard complied with test of IEC 60335-1:2001, Clause 25.14, or</b>  |   | <b>N/A</b> |
|                 | <b>ME EQUIPMENT placed such that axis of cord guard projected at an angle of 45° with cord free from stress, and a mass equal 10 x D<sup>2</sup> gram attached to the free end of cord (g)..... :</b>   |   | <b>N/A</b> |
|                 | <b>Cord guard of temperature-sensitive material tested at 23 °C ± 2 °C, and flat cords bent in the plane of least resistance</b>  |   | <b>N/A</b> |
|                 | <b>Curvature of the cord radius, immediately after mass attached, was not less than 1.5 x D..... :</b>  |   | <b>N/A</b> |
| <b>8.11.4</b>   | <b>MAINS TERMINAL DEVICES</b>   |   | <b>N/A</b> |
| <b>8.11.4.1</b> | <b>PERMANENTLY INSTALLED and ME EQUIPMENT with non-DETACHABLE POWER SUPPLY CORD provided with MAINS TERMINAL DEVICES ensuring reliable connection</b>   | Not permanently installed equipment.              | <b>N/A</b> |
|                 | <b>Terminals alone are not used to keep conductors in position</b>  |   | <b>N/A</b> |
|                 | <b>Terminals of components other than terminal blocks complying with requirements of this Clause and marked accordingly used as terminals intended for external conductors</b>  |   | <b>N/A</b> |
|                 | <b>Screws and nuts clamping external conductors do not serve to secure any other component</b>  |   | <b>N/A</b> |
| <b>8.11.4.2</b> | <b>Arrangement of MAINS TERMINAL DEVICES</b>  |   | <b>N/A</b> |



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| Clause      | Requirement + Test   | Result - Remark                      | Verdict |
|             | a) Terminals provided for connection of external cords or POWER SUPPLY CORDS together with PROTECTIVE EARTH TERMINAL grouped to provide convenient means of connection                             | Not permanently installed equipment. | N/A     |
|             | d) MAINS TERMINAL DEVICES not accessible without use of a TOOL   |                                      | N/A     |
|             | e) A MEANS OF PROTECTION are not short circuited when one end of a flexible conductor with NOMINAL cross-sectional area is stripped 8 mm and a single free wire is bent in each possible direction |                                      | N/A     |
| 8.11.4.3    | Internal wiring not subjected to stress and CREEPAGE and CLEARANCES not reduced after fastening and loosening a conductor of largest cross-sectional area 10 times                                 |                                      | N/A     |
| 8.11.4.4    | Terminals with clamping means for a rewirable flexible cord did not require special preparation of conductors and conductors were not damaged and did not slip out when clamping means tightened   |                                      | N/A     |
| 8.11.4.5    | Adequate space provided inside ME EQUIPMENT designed for FIXED wiring or a rewirable POWER SUPPLY CORD to allow for connection of conductors   |                                      | N/A     |
|             | Correct connection and positioning of conductors before ACCESS COVER verified by an installation test  |                                      | N/A     |

|              |  |  |            |
|--------------|--|--|------------|
| <b>9</b>     | <b>PROTECTION AGAINST MECHANICAL HAZARDS OF ME EQUIPMENT AND ME SYSTEMS</b>  |  | <b>P</b>   |
| <b>9.2</b>   | <b>HAZARDS associated with moving parts</b>  |  | <b>N/A</b> |
| <b>9.2.1</b> | <b>When ME EQUIPMENT with moving parts PROPERLY INSTALLED, used per ACCOMPANYING DOCUMENTS or under foreseeable misuse, RISKS associated with moving parts reduced to an acceptable level .....</b>  |  | <b>N/A</b> |
|              | <b>RISK from contact with moving parts reduced to an acceptable level using protective measures, (access, function, shape of parts, energy, speed of motion, and benefits to PATIENT considered)</b> |  | <b>NE</b>  |
|              | <b>RESIDUAL RISK associated with moving parts considered acceptable when exposure was needed for ME EQUIPMENT to perform its intended function, and</b>  |  | <b>NE</b>  |
|              | <b>RISK CONTROLS implemented .....</b>   |  | <b>NE</b>  |

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| Clause           | Requirement + Test  | Result - Remark     | Verdict    |
|                  | <b>RISK MANAGEMENT FILE includes an assessment of RISKS associated with moving parts ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)</b>  |                     | <b>NE</b>  |
|                  | <b>All RISKS associated with moving parts have been reduced to an acceptable level</b>  | See above.          | <b>NE</b>  |
| <b>9.2.2</b>     | <b>TRAPPING ZONE</b>  |                     | <b>N/A</b> |
| <b>9.2.2.1</b>   | <b>ME EQUIPMENT with a TRAPPING ZONE complied with one or more of the following as feasible:</b>  | No trapping zone.   | <b>N/A</b> |
|                  | – Gaps in Clause 9.2.2.2, or  |                     | <b>N/A</b> |
|                  | – Safe distances in Clause 9.2.2.3, or  |                     | <b>N/A</b> |
|                  | – GUARDS and other RISK CONTROL measures in 9.2.2.4, or   |                     | <b>N/A</b> |
|                  | – Continuous activation in Clause 9.2.2.5   |                     | <b>N/A</b> |
|                  | <b>Control of relevant motion complied with 9.2.2.6 when implementation of above protective measures were inconsistent with INTENDED USE of ME EQUIPMENT or ME SYSTEM</b>   |                     | <b>N/A</b> |
| <b>9.2.2.2</b>   | <b>A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when gaps of TRAPPING ZONE complied with dimensions per Table 20 ..... :</b>   |                     | <b>N/A</b> |
| <b>9.2.2.3</b>   | <b>A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when distances separating OPERATOR, PATIENT, and others from TRAPPING ZONES exceeded values in ISO 13857:2008 ..... :</b>  |                     | <b>N/A</b> |
| <b>9.2.2.4</b>   | <b>GUARDS and other RISK CONTROL measures</b>   |                     | <b>N/A</b> |
| <b>9.2.2.4.1</b> | <b>A TRAPPING ZONE do not to present a MECHANICAL HAZARD when GUARDS or other RISK CONTROL measures are of robust construction, not easy to bypass or render non-operational, and did not introduce additional unacceptable RISK .... :</b> | No trapping zone.   | <b>N/A</b> |
| <b>9.2.2.4.2</b> | <b>FIXED GUARDS held in place by systems that can only be dismantled with a TOOL</b>  | No guards required. | <b>N/A</b> |
| <b>9.2.2.4.3</b> | <b>Movable GUARDS that can be opened without a TOOL remained attached when GUARD was open</b>   |                     | <b>N/A</b> |
|                  | – they are associated with an interlock preventing relevant moving parts from starting to move while TRAPPING ZONE is accessible, and stops movement when the GUARD is opened,  |                     | <b>N/A</b> |
|                  | – absence or failure of one of their components prevents starting, and stops moving parts   |                     | <b>N/A</b> |
|                  | <b>Movable GUARDS complied with any applicable tests</b>  |                     | <b>N/A</b> |
| <b>9.2.2.4.4</b> | <b>Other RISK CONTROL designed and incorporated into to the control system stops movement and</b>   | No control system.  | <b>N/A</b> |

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| Clause      | Requirement + Test  | Result - Remark           | Verdict |
|             | – SINGLE FAULT CONDITIONS have a second RISK CONTROL, or  |                           | N/A     |
|             | ME EQUIPMENT is SINGLE FAULT SAFE   |                           | N/A     |
| 9.2.2.5     | <b>Continuous activation</b>  |                           | N/A     |
|             | <b>Continuous activation used as a RISK CONTROL, complies with the following</b>  | No trapping zone.         | N/A     |
|             | a) movement was in OPERATOR'S field of view   |                           | N/A     |
|             | b) movement of ME EQUIPMENT or its parts was possible only by continuous activation of control by OPERATOR  |                           | N/A     |
|             | c) a second RISK CONTROL provided for SINGLE FAULT CONDITION of continuous activation system, or  |                           | N/A     |
|             | - the continuous activation system is SINGLE FAULT SAFE   |                           | N/A     |
| 9.2.2.6     | <b>Speed of movement(s) positioning parts of ME EQUIPMENT or PATIENT limited to allow OPERATOR control of the movement</b>  |                           | N/A     |
|             | <b>Over travel of such movement occurring after operation of a control to stop movement, did not result in an unacceptable RISK</b>   |                           | N/A     |
| 9.2.3       | <b>Other MECHANICAL HAZARDS associated with moving parts</b>  |                           | N/A     |
| 9.2.3.1     | <b>Controls positioned, recessed, or protected by other means so that they cannot be accidentally actuated</b>  |                           | N/A     |
|             | - unless for the intended PATIENT, the USABILITY ENGINEERING PROCESS concludes otherwise (e.g. PATIENT with special needs), or  |                           | NE      |
|             | - activation does not result in an unacceptable RISK  |                           | NE      |
| 9.2.3.2     | <b>Over travel past range limits of the ME EQUIPMENT prevented..... :</b>   | Over travel not possible. | N/A     |
|             | <b>Over travel means provided with mechanical strength to withstand loading in NORMAL CONDITION &amp; reasonably foreseeable misuse ... :</b>   |                           | N/A     |
| 9.2.4       | <b>Emergency stopping devices</b>   |                           | N/A     |
|             | <b>Where necessary to have one or more emergency stopping device(s), emergency stopping device complied with all the following, except for actuating switch capable of interrupting all power ..... :</b> |                           | N/A     |
|             | a) Emergency stopping device reduced RISK to an acceptable level  |                           | N/A     |

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|-------------|---|---|---------|
| Clause      | Requirement + Test  | Result - Remark   | Verdict |
|             | RISK MANAGEMENT FILE indicates the use of an emergency stopping device reduces the RISK to an acceptable level ..... :<br>(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.6)                                   | No emergency stopping device. No RMF consideration necessary. | N/A     |
|             | b) Proximity and response of OPERATOR to actuate emergency stopping device could be relied upon to prevent HARM   |   | N/A     |
|             | c) Emergency stopping device actuator was readily accessible to OPERATOR  |   | N/A     |
|             | d) Emergency stopping device(s) are not part of normal operation of ME EQUIPMENT  |   | N/A     |
|             | e) Emergency switching operation or stopping means neither introduced further HAZARD nor interfered with operation necessary to remove original MECHANICAL HAZARD                               |   | N/A     |
|             | f) Emergency stopping device was able to break full load of relevant circuit, including possible stalled motor currents and the like  |   | N/A     |
|             | g) Means for stopping of movements operate as a result of one single action   |   | N/A     |
|             | h) Emergency stopping device provided with an actuator in red and easily distinguishable and identifiable from other controls   |   | N/A     |
|             | i) An actuator interrupting/opening mechanical movements marked on or immediately adjacent to face of actuator with symbol 18 of Table D.1 or "STOP"  |   | N/A     |
|             | j) Emergency stopping device, once actuated, maintained ME EQUIPMENT in disabled condition until a deliberate action, different from that used to actuate it, was performed                     |   | N/A     |
|             | k) Emergency stopping device is suitable for its application  |   | N/A     |
| 9.2.5       | Means provided to permit quick and safe release of PATIENT in event of breakdown of ME EQUIPMENT or failure of power supply, activation of a RISK CONTROL measure, or emergency stopping .....: |   | N/A     |
|             | – and uncontrolled or unintended movement of ME EQUIPMENT that could result in an unacceptable RISK prevented   |   | N/A     |
|             | – Situations where PATIENT is subjected to unacceptable RISKS due to proximity of moving parts, removal of normal exit routes, or other HAZARDS prevented                                       |   | N/A     |
|             | – Measures provided to reduce RISK to an acceptable level when after removal of counterbalanced parts, other parts of ME EQUIPMENT can move in a hazardous way                                  |   | N/A     |

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| Clause      | Requirement + Test  | Result - Remark  | Verdict |
|             | <b>RISK MANAGEMENT FILE includes an assessment of RISKS to the PATIENT related to breakdown of the ME EQUIPMENT ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)</b> | No patient restrained. No RMF consideration necessary.           | N/A     |
| 9.3         | <b>Rough surfaces, sharp corners and edges of ME EQUIPMENT that could result in injury or damage avoided or covered ..... :</b>                                 | No rough edges or sharp corners.                                 | N/A     |
| 9.4         | <b>Instability HAZARDS</b>  |  | P       |
| 9.4.1       | <b>ME EQUIPMENT and its parts, other than FIXED, for placement on a surface did not overbalance (tip over) or move unexpectedly in NORMAL USE</b>               | See below.   | P       |
| 9.4.2       | <b>Instability – overbalance</b>  |  | P       |
| 9.4.2.1     | <b>ME EQUIPMENT or its parts did not overbalance when prepared per ACCOMPANYING DOCUMENTS, or when tested ..... :</b>   | The unit did not overbalance at 10°. See appended table 9.4.2.1. | P       |
| 9.4.2.2     | <b>Instability excluding transport</b>  |  | P       |
|             | <b>ME EQUIPMENT or its did not overbalance when placed in different positions of NORMAL USE,... :</b>   | Tested at 10° and passed. See appended table 9.4.2.2.            | P       |
|             | <b>A warning provided when overbalance occurred during 10° inclined plane test</b>  |  | N/A     |
| 9.4.2.3     | <b>Instability from horizontal and vertical forces</b>  |  | N/A     |
|             | <b>a) ME EQUIPMENT or its parts with a mass of 25kg or more, intended to be used on the floor, didn't overbalance due to pushing, leaning against it</b>        |  | N/A     |
|             | <b>Surfaces of ME EQUIPMENT or its parts where a RISK of overbalancing exists from pushing, etc., permanently marked with a warning of the RISK</b>             |  | N/A     |
|             | <b>ME EQUIPMENT did not overbalance when tested according to Cl. 9.4.2.3 a)</b>   |  | N/A     |
|             | <b>b) ME EQUIPMENT, for use on the floor or on a table, did not overbalance due to sitting or stepping</b>  |  | N/A     |
|             | <b>ME EQUIPMENT or its parts, for use on the floor or on a table, where RISK of overbalancing exists, permanently marked with the RISK warning ..... :</b>      |  | N/A     |
|             | <b>ME EQUIPMENT did not overbalance when tested according to Cl. 9.4.2.3b)..... :</b>   |  | N/A     |
| 9.4.2.4     | <b>Castors and wheels</b>   |  | N/A     |
| 9.4.2.4.1   | <b>Means used for transportation of MOBILE ME EQUIPMENT did not result in an unacceptable RISK when MOBILE ME EQUIPMENT moved or parked in NORMAL USE</b>       |  | N/A     |

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|-------------|---|---------------------------------------|---------|
| Clause      | Requirement + Test  | Result - Remark                       | Verdict |
| 9.4.2.4.2   | Force required to move MOBILE ME EQUIPMENT did not exceed 200 N .....   | Not mobile equipment.                 | N/A     |
| 9.4.2.4.3   | MOBILE ME EQUIPMENT exceeding 45 kg able to pass over threshold .....   |                                       | N/A     |
| 9.4.3       | Instability from unwanted lateral movement (including sliding)  |                                       | N/A     |
| 9.4.3.1     | a) Brakes of power-driven MOBILE ME EQUIPMENT normally activated and could only be released by continuous actuation of a control  | Not power driven Mobile ME Equipment. | N/A     |
|             | b) MOBILE ME EQUIPMENT provided with locking means to prevent unwanted movements  |                                       | N/A     |
|             | c) No unwanted lateral movement resulted when MOBILE ME EQUIPMENT placed in its transport position when test per 9.4.3.1  |                                       | N/A     |
| 9.4.3.2     | Instability excluding transport   |                                       | N/A     |
|             | a) MOBILE ME EQUIPMENT provided with wheel locks or braking system compliant with 5° tilt test .....  | Not mobile equipment.                 | N/A     |
|             | b) MOBILE ME EQUIPMENT provided with wheel locks or braking system compliant with lateral stability test  |                                       | N/A     |
| 9.4.4       | Grips and other handling devices  |                                       | N/A     |
|             | a) ME EQUIPMENT with a mass of over 20 kg requiring lifting in NORMAL USE or transport provided with suitable handling means, or ACCOMPANYING DOCUMENTS specify safe lifting method | Equipment less than 20 kg.            | N/A     |
|             | Handles, suitably placed to enable ME EQUIPMENT or its part to be carried by two or more persons and by examination of EQUIPMENT, its part, or ACCOMPANYING DOCUMENTS               |                                       | N/A     |
|             | b) PORTABLE ME EQUIPMENT with a mass > 20 kg provided with one or more carrying-handles suitably placed to enable carrying by two or more persons as confirmed by actual carrying   | Equipment less than 20 kg.            | N/A     |
|             | c) Carrying handles and grips and their means of attachment withstood loading test .....  |                                       | N/A     |
| 9.5         | Expelled parts HAZARD   |                                       | N/A     |
| 9.5.1       | Suitability of means of protecting against expelled parts determined by assessment and examination of RISK MANAGEMENT FILE .....  | No expelled parts.                    | N/A     |
|             | (ISO 14971 Cl. 4.3, 4.4, 5, 6.2-6.5)  |                                       |         |
|             | All identified RISKS associated with expelled parts mitigated to an acceptable level  |                                       | N/A     |
| 9.5.2       | Cathode Ray tube(s) complied with IEC 60065:2001, Clause 18, or IEC 61965 .....   |                                       | N/A     |

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|--------------|---|---|------------|
| Clause       | Requirement + Test  | Result - Remark   | Verdict    |
| <b>9.6.3</b> | <b>Hand-transmitted vibration</b>   |   | <b>N/A</b> |
|              | <b>Means provided to protect PATIENT and OPERATOR when hand-transmitted frequency-weighted r.m.s. acceleration generated in NORMAL USE exceeds specified values</b>   | No vibration associated with equipment.   | <b>N/A</b> |
|              | – 2.5 m/s <sup>2</sup> for a cumulative time of 8 h during a 24 h period (m/s <sup>2</sup> )..... :   |   | <b>N/A</b> |
|              | – Accelerations for different times, inversely proportional to square root of time (m/s <sup>2</sup> )..... :   |   | <b>N/A</b> |
| <b>9.7</b>   | <b>Pressure vessels and parts subject to pneumatic and hydraulic pressure</b>   |   | <b>N/A</b> |
| <b>9.7.2</b> | <b>Pneumatic and hydraulic parts of ME EQUIPMENT or ACCESSORIES met requirements based on examination of RISK MANAGEMENT FILE ..... : (ISO 14971 Cl. 4.3-4.4, 5, 6.2-6.5)</b>   | No pneumatic and hydraulic pressure parts in ME equipment.<br>No RMF consideration necessary. | <b>N/A</b> |
|              | – No unacceptable RISK resulted from loss of pressure or loss of vacuum   |   | <b>N/A</b> |
|              | – No unacceptable RISK resulted from a fluid jet caused by leakage or a component failure   |   | <b>N/A</b> |
|              | – Elements of ME EQUIPMENT or an ACCESSORY, especially pipes and hoses leading to an unacceptable RISK protected against harmful external effects   |   | <b>N/A</b> |
|              | – Reservoirs and similar vessels leading to an unacceptable RISK are automatically depressurized when ME EQUIPMENT is isolated from its power supply  |   | <b>N/A</b> |
|              | Means provided for isolation, or local depressurizing reservoirs and similar vessels, and pressure indication when above not possible   |   | <b>N/A</b> |
|              | – All elements remaining under pressure after isolation of ME EQUIPMENT or an ACCESSORY from its power supply resulting in an unacceptable RISK provided with clearly identified exhaust devices, and a warning to depressurize these elements before setting or maintenance activity |   | <b>N/A</b> |
| <b>9.7.3</b> | <b>Maximum pressure a part of ME EQUIPMENT can be subjected to in NORMAL and SINGLE FAULT CONDITIONS considered to be highest of following:</b>   | No pressurized parts.   | <b>N/A</b> |
|              | a) RATED maximum supply pressure from an external source  |   | <b>N/A</b> |
|              | b) Pressure setting of a pressure-relief device provided as part of assembly  |   | <b>N/A</b> |

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| Clause       | Requirement + Test   | Result - Remark       | Verdict    |
|              | <b>c) Max pressure that can develop by a source of pressure that is part of assembly, unless pressure limited by a pressure-relief device</b>  |                       | <b>N/A</b> |
| <b>9.7.4</b> | <b>Max pressure in NORMAL and SINGLE FAULT CONDITIONS did not exceed MAXIMUM PERMISSIBLE WORKING PRESSURE for EQUIPMENT part, except as allowed in 9.7.7, confirmed by inspection of THE MANUFACTURER'S data for the component, ME EQUIPMENT, and by functional tests..... :</b> |                       | <b>N/A</b> |
| <b>9.7.5</b> | <b>A pressure vessel withstood a HYDRAULIC TEST PRESSURE when pressure was more than 50 kPa, and product of pressure and volume was more than 200 kPal ..... :</b>   |                       | <b>N/A</b> |
| <b>9.7.6</b> | <b>Pressure-control device regulating pressure in ME EQUIPMENT with pressure-relief device completed 100,000 cycles of operation under RATED load and prevented pressure from exceeding 90 % of setting of pressure-relief device in different conditions of NORMAL USE . :</b>  |                       | <b>N/A</b> |
| <b>9.7.7</b> | <b>Pressure-relief device(s) used where MAXIMUM PERMISSIBLE WORKING PRESSURE could otherwise be exceeded met the following, as confirmed by MANUFACTURER'S data, ME EQUIPMENT, RISK MANAGEMENT FILE, and functional tests ..... :</b>  |                       | <b>N/A</b> |
|              | <b>a) Connected as close as possible to pressure vessel or parts of system it is to protect</b>  |                       | <b>N/A</b> |
|              | <b>b) Installed to be readily accessible for inspection, maintenance, and repair</b>   |                       | <b>N/A</b> |
|              | <b>c) Could be adjusted or rendered inoperative without a TOOL</b>   | No pressurized parts. | <b>N/A</b> |
|              | <b>d) With discharge opening located and directed as to not to release material towards any person</b>   |                       | <b>N/A</b> |
|              | <b>e) With discharge opening located and directed as to not to deposit material on parts that could result in an unacceptable RISK</b>   |                       | <b>N/A</b> |
|              | <b>f) Adequate discharge capacity provided to ensure that pressure will not exceed MAXIMUM PERMISSIBLE WORKING PRESSURE of system it is connected to by more than 10 % when failure occurs in control of supply pressure</b>   |                       | <b>N/A</b> |
|              | <b>g) No shut-off valve provided between a pressure-relief device and parts it is to protect</b>   |                       | <b>N/A</b> |
|              | <b>h) Min number of cycles of operation 100 000, except for one-time use devices (bursting disks)</b>  |                       | <b>N/A</b> |



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|--------------|--|---|------------|
| Clause       | Requirement + Test   | Result - Remark   | Verdict    |
|              | <b>RISK MANAGEMENT FILE includes an assessment of the risks associated with the discharge opening of the pressure relief device ..... :</b><br><b>(ISO 14971 Cl. 4.3, 4.4, 5, 6.2-6.5)</b>   | No pressure-relief device.<br>No RMF consideration necessary. | <b>N/A</b> |
| <b>9.8</b>   | <b>HAZARDS associated with support systems</b>   |   | <b>N/A</b> |
| <b>9.8.1</b> | <b>ME EQUIPMENT parts designed to support loads or provide actuating forces when a mechanical fault could constitute an unacceptable RISK .. :</b>   | No support systems.   | <b>N/A</b> |
|              | – Construction of support, suspension, or actuation system complied with Table 21 and TOTAL LOAD   |   | <b>N/A</b> |
|              | – Means of attachment of ACCESSORIES prevent possibility of incorrect attachment that could result in an unacceptable RISK   |   | <b>N/A</b> |
|              | – RISK ANALYSIS of support systems included MECHANICAL HAZARDS from static, dynamic, vibration, foundation and other movements, impact and pressure loading, temperature, environmental, manufacture and service conditions ..... :<br><b>(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)</b>                  | No support systems. No RMF consideration necessary.           | <b>N/A</b> |
|              | – RISK ANALYSIS included effects of failures such as excessive deflection, plastic deformation, ductile/brittle fracture, fatigue fracture, instability (buckling), stress-assisted corrosion cracking, wear, material creep and deterioration, and residual stresses from manufacturing PROCESSES | No RMF consideration necessary.                               | <b>N/A</b> |
|              | – Instructions on attachment of structures to a floor, wall, ceiling, included in ACCOMPANYING DOCUMENTS making adequate allowances for quality of materials used to make the connection and list the required materials   |   | <b>N/A</b> |
|              | Additional instructions provided on checking adequacy of surface of structure parts will be attached to  |   | <b>N/A</b> |
| <b>9.8.2</b> | <b>Support systems maintain structural integrity during EXPECTED SERVICE LIFE, and TENSILE SAFETY FACTORS are not less than in Table 21, except when an alternative method used to demonstrate structural integrity throughout EXPECTED SERVICE LIFE, or for a foot rest</b>                       | No support systems.   | <b>N/A</b> |
|              | Compliance with 9.8.1 and 9.8.2 confirmed by examination of ME EQUIPMENT, RISK MANAGEMENT FILE, specifications and material processing.. :   |   | <b>N/A</b> |
|              | <b>RISK MANAGEMENT FILE includes an assessment of the structural integrity of support system.. :</b><br><b>(ISO 14971 Cl. 4.3-4.4, 5, 6.2-6.5)</b>   | No RMF consideration necessary.                               | <b>N/A</b> |

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| Clause         | Requirement + Test  | Result - Remark  | Verdict    |
|                | <b>All identified RISKS are mitigated to an acceptable level</b>  |  | <b>N/A</b> |
|                | <b>When test were conducted, testing consisted of application of a test load to support assembly equal to TOTAL LOAD times required TENSILE SAFETY FACTOR while support assembly under test was in equilibrium after 1 min, or not resulted in an unacceptable RISK .....</b> : |  | <b>N/A</b> |
|                | <b>Where the equipment is not at equilibrium after 1 min, the RISK MANAGEMENT FILE includes an assessment of the test results.....</b> :<br><b>(ISO 14971 Cl. 4.3-4.4, 5, 6.2-6.5)</b>  | No support systems.<br>No RMF consideration necessary. | <b>N/A</b> |
| <b>9.8.3</b>   | <b>Strength of PATIENT or OPERATOR support or suspension systems</b>  |  | <b>N/A</b> |
| <b>9.8.3.1</b> | <b>ME EQUIPMENT parts supporting or immobilizing PATIENTS presents no unacceptable RISK of physical injuries and accidental loosening of secured joints .....</b> :   | No support or suspension systems.                      | <b>N/A</b> |
|                | <b>RISK MANAGEMENT FILE includes assessment of the RISKS associated with physical injuries and accidental loosening of fixings.....</b> :<br><b>(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)</b>   | No RMF consideration necessary.                        | <b>N/A</b> |
|                | <b>SAFE WORKING LOAD of ME EQUIPMENT or its parts supporting or suspending PATIENTS or OPERATORS is sum of mass of PATIENTS or mass of OPERATORS plus mass of ACCESSORIES supported by ME EQUIPMENT or its parts</b>  |  | <b>N/A</b> |
|                | <b>Supporting and suspending parts for adult human PATIENTS or OPERATORS designed for a PATIENT or OPERATOR with a min mass of 135 kg and ACCESSORIES with a min mass of 15 kg, unless stated by MANUFACTURER</b>   |  | <b>N/A</b> |
|                | <b>Maximum mass of PATIENT included in SAFE WORKING LOAD of ME EQUIPMENT or its parts supporting or suspending PATIENTS adapted when MANUFACTURER specified applications</b>  |  | <b>N/A</b> |
|                | <b>Max allowable PATIENT mass &lt; 135 kg marked on ME EQUIPMENT and stated in ACCOMPANYING DOCUMENTS</b>   |  | <b>N/A</b> |
|                | <b>Max allowable PATIENT mass over 135 kg stated in ACCOMPANYING DOCUMENTS</b>  |  | <b>N/A</b> |
|                | <b>Examination of markings, ACCOMPANYING DOCUMENTS, and RISK MANAGEMENT FILE confirmed compliance .....</b> :   |  | <b>N/A</b> |
| <b>9.8.3.2</b> | <b>a) Entire mass of PATIENT or OPERATOR distributed over an area of 0.1 m<sup>2</sup> on a foot rest temporarily supporting a standing PATIENT or OPERATOR .....</b> :   | No support or suspension systems.                      | <b>N/A</b> |

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|----------------|---|-----------------------------------|------------|
| Clause         | Requirement + Test  | Result - Remark                   | Verdict    |
|                | <b>Compliance confirmed by examination of ME EQUIPMENT specifications of materials and their processing, and tests .....</b> :  |                                   | <b>N/A</b> |
|                | <b>b) Deflection of a support surface from PATIENT or OPERATOR loading on an area of support/ suspension where a PATIENT or OPERATOR can sit did not result in an unacceptable RISK</b>                           |                                   | <b>N/A</b> |
|                | <b>Compliance confirmed by examination of ME EQUIPMENT, specifications of materials and their processing, and by a test .....</b> :   |                                   | <b>N/A</b> |
| <b>9.8.3.3</b> | <b>Dynamic forces that can be exerted on equipment parts supporting or suspending a PATIENT or OPERATOR in NORMAL USE maintained BASIC SAFETY and ESSENTIAL PERFORMANCE confirmed test</b>                        | No support or suspension systems. | <b>N/A</b> |
| <b>9.8.4</b>   | <b>Systems with MECHANICAL PROTECTIVE DEVICES</b>   |                                   | <b>N/A</b> |
| <b>9.8.4.1</b> | <b>a) A MECHANICAL PROTECTIVE DEVICE provided for the support system</b>  | No mechanical protective devices. | <b>N/A</b> |
|                | <b>b) MECHANICAL PROTECTIVE complies with the requirements as follows:</b>  |                                   | <b>N/A</b> |
|                | – <b>Designed based on TOTAL LOAD</b>   |                                   | <b>N/A</b> |
|                | – <b>Has TENSILE SAFETY FACTORS for all parts not less than Table 21, row 7</b>   |                                   | <b>N/A</b> |
|                | – <b>Activated before travel produced an unacceptable RISK</b>  |                                   | <b>N/A</b> |
|                | – <b>Takes into account Clauses 9.2.5 and 9.8.4.3</b>   |                                   | <b>N/A</b> |
|                | <b>Compliance confirmed by examination of ME EQUIPMENT over travel calculations and evaluation plus functional tests .....</b> :  |                                   | <b>N/A</b> |
| <b>9.8.4.2</b> | <b>Activation of MECHANICAL PROTECTIVE DEVICE is made obvious to OPERATOR when ME EQUIPMENT can still be used after failure of suspension or actuation means and activation of a MECHANICAL PROTECTIVE DEVICE</b> | No mechanical protective devices. | <b>N/A</b> |
|                | <b>MECHANICAL PROTECTIVE DEVICE requires use of a TOOL to be reset or replaced</b>  |                                   | <b>N/A</b> |
| <b>9.8.4.3</b> | <b>MECHANICAL PROTECTIVE DEVICE intended to function once</b>   |                                   |            |
|                | – <b>use of ME EQUIPMENT not possible until replacement of MECHANICAL PROTECTIVE DEVICE :</b>   | No mechanical protective devices. | <b>N/A</b> |
|                | – <b>ACCOMPANYING DOCUMENTS provided with required information on replacement by service personal</b>   |                                   | <b>N/A</b> |
|                | – <b>ME EQUIPMENT permanently marked with safety sign 2 of Table D.</b>   |                                   | <b>N/A</b> |
|                | – <b>Marking is adjacent to MECHANICAL PROTECTIVE DEVICE</b>  |                                   | <b>N/A</b> |

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| Clause       | Requirement + Test   | Result - Remark                 | Verdict    |
|              | <b>– Compliance confirmed by examination and following test .....</b> :  |                                 | <b>N/A</b> |
|              | <b>A chain, cable, band, spring, belt, jack screw nut, pneumatic or hydraulic hose, structural part or the like, employed to support a load, defeated by a convenient means causing maximum normal load to fall from most adverse position permitted by construction of ME EQUIPMENT</b> |                                 | <b>N/A</b> |
|              | <b>Load included SAFE WORKING LOAD in 9.8.3.1 when system was capable of supporting a PATIENT OR OPERATOR</b>  |                                 | <b>N/A</b> |
|              | <b>No evidence of damage to MECHANICAL PROTECTIVE DEVICE affecting its ability to perform its intended function</b>  |                                 | <b>N/A</b> |
| <b>9.8.5</b> | <b>Systems without MECHANICAL PROTECTIVE DEVICES</b>   |                                 | <b>N/A</b> |
|              | <b>Support Systems does not require MECHANICAL PROTECTIVE DEVICES .....</b> :  | No support systems.             | <b>N/A</b> |
|              | <b>RISK MANAGEMENT FILE includes an assessment of RISKS associated with wear on the support system.....</b> :<br><b>(ISO 14971 Cl. 4.3,4.4,5,6.2-6.5)</b>  | No RMF consideration necessary. | <b>N/A</b> |

|               |  |  |            |
|---------------|--|--|------------|
| <b>10</b>     | <b>PROTECTION AGAINST UNWANTED AND EXCESSIVE RADIATION HAZARDS</b>   |  | <b>N/A</b> |
| <b>10.1</b>   | <b>X-Radiation</b>   |  | <b>N/A</b> |
| <b>10.1.1</b> | <b>The air kerma did not exceed 5 µGy/hat 5 cm from surface of ME EQUIPMENT .....</b> :  | No such radiation associated with equipment.   | <b>N/A</b> |
|               | <b>Annual exposure reduced taking into account the irradiated body part, national regulations, and/or international recommendations for ME EQUIPMENT that has permanent proximity to a PATIENT as part of the INTENDED USE</b> |  | <b>N/A</b> |
| <b>10.1.2</b> | <b>RISK from unintended X-radiation from ME EQUIPMENT producing X-radiation for diagnostic and therapeutic purposes addressed application of applicable particular and collateral standards, or.....</b> :                     | No X-radiation.  | <b>N/A</b> |
|               | <b>RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE.....</b> :<br><b>(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)</b>   | Equipment does not produce diagnostic or therapeutic X-radiation.<br>No RMF consideration necessary. | <b>N/A</b> |
| <b>10.2</b>   | <b>RISK associated with alpha, beta, gamma, neutron, and other particle radiation, addressed in RISK MANAGEMENT PROCESS as shown in RISK MANAGEMENT FILE .....</b> :<br><b>(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)</b>             | No alpha, beta, gamma, neutron & other particle radiation.<br>No RMF consideration necessary.        | <b>N/A</b> |

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| Clause      | Requirement + Test  | Result - Remark   | Verdict |
| 10.3        | The power density of unintended microwave radiation at frequencies between 1 GHz and 100 GHz does not exceed 10 W/m <sup>2</sup>  | No radiation. No RMF consideration necessary.                               | N/A     |
|             | Microwave radiation is propagated intentionally   |   | N/A     |
| 10.4        | Relevant requirements of IEC 60825-1:2007 applied to lasers, laser light barriers or similar with a wavelength range of 180nm to 1 mm.  |   | N/A     |
| 10.5        | Risk associated with visible electromagnetic radiation other than emitted by lasers and LEDs, when applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5) | No other visible electromagnetic radiation. No RMF consideration necessary. | N/A     |
| 10.6        | Risk associated with infrared radiation other than emitted by lasers and LEDs addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)                                  | No infrared radiation. No RMF consideration necessary.                      | N/A     |
| 10.7        | Risk associated with ultraviolet radiation other than emitted by lasers and LEDs addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)                               | No ultraviolet radiation.   | N/A     |

|          |  |   |            |
|----------|--|---|------------|
| 11       | <b>PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER HAZARDS</b>   |   | <b>P</b>   |
| 11.1     | <b>Excessive temperatures in ME EQUIPMENT</b>  |   | <b>P</b>   |
| 11.1.1   | Temperatures on ME EQUIPMENT parts did not exceed values in Tables 22 and ..... :  | See appended Table 11.1.1   | <b>P</b>   |
|          | Surfaces of test corner did not exceed 90 °C   | No temperatures exceeded 90°C external to the equipment, no test corner considered necessary. | <b>P</b>   |
|          | THERMAL CUT-OUTS did not operate in NORMAL CONDITION   | No thermal cut-out provided.  | <b>N/A</b> |
|          | RISK MANAGEMENT FILE includes an assessment of the duration of contact for all APPLIED PARTS and ACCESSIBLE PARTS..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5) | Device complies with the limits of Table 22, 23 and 24. No RMF consideration necessary.       | <b>N/A</b> |
| 11.1.2   | <b>Temperature of APPLIED PARTS</b>  |   | <b>P</b>   |
| 11.1.2.1 | APPLIED PARTS (hot or cold intended to supply heat to a PATIENT comply..... :  | No applied intended to supply heat to the patient.  | <b>N/A</b> |
|          | Clinical effects determined and documented in the RISK MANAGEMENT FILE (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)   | See above. No RMF consideration necessary.  | <b>N/A</b> |

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|-------------|---|---|------------|
| Clause      | Requirement + Test  | Result - Remark   | Verdict    |
|             | <b>Temperature (hot or cold) of APPLIED PARTS intended to supply heat to a PATIENT disclosed in the instructions for use</b>  | See above.  | <b>N/A</b> |
| 11.1.2.2    | <b>APPLIED PARTS not intended to supply heat to a PATIENT complies with the limits of Table 24 in NORMAL CONDITION and SINGLE FAULT CONDITION. :</b>  | See appended Table 11.1.1   | <b>P</b>   |
|             | <b>APPLIED PARTS surface temperature exceeds 41°C disclosed in the instruction manual:</b>  |   | <b>P</b>   |
|             | <b>Maximum Temperature..... :</b>   |   | <b>—</b>   |
|             | <b>Conditions for safe contact, e.g. duration or condition of the PATIENT ..... :</b>   |   | <b>—</b>   |
|             | <b>Clinical effects with respect to characteristics taken or surface pressure documented in the RISK MANAGEMENT FILE<br/>(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)</b>  | Applied parts do not exceed 41°C. No RMF consideration necessary.   | <b>N/A</b> |
|             | <b>APPLIED PARTS surface temperature of equal to or less than 41°C</b>  | See appended Table 11.1.1   | <b>P</b>   |
|             | <b>Analysis documented in the RISK MANAGEMENT FILE show that APPLIED PART temperatures are not affected by operation of the ME EQUIPMENT including SINGLE FAULT CONDITIONS.<br/>Measurement of APPLIED PART temperature according to 11.1.3 is not conducted..... :</b> | Measurement conducted.  | <b>N/A</b> |
|             | <b>Surfaces of APPLIED PARTS that are cooled below ambient temperatures evaluated in the RISK MANAGEMENT PROCESS..... :<br/>(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)</b>   | No applied parts are cooled below ambient temperature. No RMF consideration necessary.                      | <b>N/A</b> |
| 11.1.3      | <b>Measurements not made when engineering judgment and rationale by MANUFACTURER indicated temperature limits could not exceed, as documented in RISK MANAGEMENT FILE ..... :<br/>(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)</b>   | Measurements made. No RMF consideration necessary.  | <b>N/A</b> |
|             | <b>Test corner not used where engineering judgment and rationale by MANUFACTURER indicated test corner will not impact measurements, as documented in RISK MANAGEMENT FILE..... :<br/>(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)</b>   | All temperature measurements performed. No temperatures measured over 90°C. No RMF consideration necessary. | <b>N/A</b> |
|             | <b>Probability of occurrence and duration of contact for parts likely to be touched and for APPLIED PARTS documented in RISK MANAGEMENT FILE..... :<br/>(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)</b>   | No RMF consideration necessary.   | <b>N/A</b> |
|             | <b>e) Where thermal regulatory devices make this method inappropriate, alternative methods for measurement are justified in the RISK MANAGEMENT FILE..... :</b>   | No alternative methods for measurement. No RMF consideration necessary.                                     | <b>N/A</b> |

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| Clause      | Requirement + Test  | Result - Remark  | Verdict    |
| 11.1.4      | <b>GUARDS preventing contact with hot or cold accessible surfaces removable only with a TOOL</b>  | No such guards.  | <b>N/A</b> |
| 11.2        | <b>Fire prevention</b>  |  | <b>P</b>   |
| 11.2.1      | <b>ENCLOSURE has strength and rigidity necessary to prevent a fire and met mechanical strength tests for ENCLOSURES in 15.3</b>   | See appended table 8.10 and clause 15.3.   | <b>P</b>   |
| 11.2.2      | <b>Me equipment and me systems used in conjunction with OXYGEN RICH ENVIRONMENTS</b>  |  | <b>N/A</b> |
| 11.2.2.1    | <b>RISK of fire in an OXYGEN RICH ENVIRONMENT reduced by means limiting spread of ..... :</b>   | Equipment not intended to be used in such environments.                                    | <b>N/A</b> |
|             | <b>a) No sources of ignition discovered in an OXYGEN RICH ENVIRONMENT under any of the following conditions</b>   |  | <b>N/A</b> |
|             | <b>1) when temperature of material raised to its ignition temperature</b>   |  | <b>N/A</b> |
|             | <b>2) when temperatures affected solder or solder joints causing loosening, short circuiting, or other failures causing sparking or increasing material temperature to its ignition temperature</b>                       |  | <b>N/A</b> |
|             | <b>3) when parts affecting safety cracked or changed outer shape exposing temperatures higher than 300°C or sparks due to overheating</b>   |  | <b>N/A</b> |
|             | <b>4) when temperatures of parts or components exceeded 300°C, atmosphere was 100 % oxygen, contact material solder, and fuel cotton</b>  |  | <b>N/A</b> |
|             | <b>5) when sparks provided adequate energy for ignition by exceeding limits of Figs 35 to 37 (inclusive), atmosphere was 100 % oxygen, contact material solder, and fuel cotton</b>                                       |  | <b>N/A</b> |
|             | <b>Deviations from worst case limits in 4) and 5) above based on lower oxygen concentrations or less flammable fuels justified and documented in RISK MANAGEMENT FILE..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)</b>      | Equipment is not for use in an oxygen rich environment.<br>No RMF consideration necessary. | <b>N/A</b> |
|             | <b>Alternative test in this clause did not identify existence of ignition sources at highest voltage or current, respectively ..... :</b>   |  | <b>N/A</b> |
|             | <b>A safe upper limit determined by dividing upper limit of voltage or current, respectively, with safety margin factor of three..... :</b>   |  | <b>N/A</b> |
|             | <b>b) RESIDUAL RISK of fire in an OXYGEN RICH ENVIRONMENT as determined by application of RISK MANAGEMENT PROCESS is based on following configurations, or in combination ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)</b> | No RMF consideration necessary.  | <b>N/A</b> |

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| Clause      | Requirement + Test   | Result - Remark   | Verdict |
|             | 1) Electrical components in an OXYGEN RICH ENVIRONMENT provided with power supplies having limited energy levels lower than those considered sufficient for ignition in 11.2.2.1 a) as determined by examination, measurement or calculation of power, energy, and temperatures in NORMAL and SINGLE FAULT CONDITIONS identified in 11.2.3 ..... |   | N/A     |
|             | 2) Max oxygen concentration measured until it did not exceed 25 % in ventilated compartments with parts that can be a source of ignition only in SINGLE FAULT CONDITION and can be penetrated by oxygen due to an undetected leak (%) .....  |   | N/A     |
|             | 3) A compartment with parts or components that can be a source of ignition only under SINGLE FAULT CONDITION separated from another compartment containing an OXYGEN RICH ENVIRONMENT by sealing all joints and holes for cables, shafts, or other purposes  |   | N/A     |
|             | Effect of possible leaks and failures under SINGLE FAULT CONDITION that could cause ignition evaluated using a RISK ASSESSMENT to determine maintenance intervals by examination of documentation and RISK MANAGEMENT FILE .....   |   | N/A     |
|             | 4) Fire initiated in ENCLOSURE of electrical components in a compartment with OXYGEN RICH ENVIRONMENT that can become a source of ignition only under SINGLE FAULT CONDITIONS self-extinguished rapidly and no hazardous amount of toxic gases reached PATIENT as determined by analysis of gases .....  |   | N/A     |
| 11.2.2.2    | RISK of ignition did not occur and oxygen concentration did not exceed 25% in immediate surroundings due to location of external exhaust outlets of an OXYGEN RICH ENVIRONMENT   |   | N/A     |
| 11.2.2.3    | Electrical connections within a compartment containing an OXYGEN RICH ENVIRONMENT under NORMAL USE did not produce sparks  |   | N/A     |
|             | – Screw-attachments protected against loosening during use by varnishing, use of spring washers, or adequate torques   |   | N/A     |
|             | – Soldered, crimped, and pin-and-socket connections of cables exiting ENCLOSURE include additional mechanical securing means   |   | N/A     |
| 11.2.3      | SINGLE FAULT CONDITIONS related to OXYGEN RICH ENVIRONMENTS ME EQUIPMENT and ME SYSTEMS considered   |   | N/A     |
|             | – Failure of a ventilation system constructed in accordance with 11.2.2.1 b) 2).....   | Equipment not intended to be used in such environments. | N/A     |



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| Clause      | Requirement + Test  | Result - Remark   | Verdict    |
|             | – Failure of a barrier constructed in accordance with 11.2.2.1 b) 3)..... :   |   | N/A        |
|             | – Failure of a component creating a source of ignition (as defined in 11.2.2.1 a) ..... :   |   | N/A        |
|             | – Failure of solid insulation or creepage and clearances providing equivalent of at least one MEANS OF PATIENT PROTECTION but less than two MEANS OF PATIENT PROTECTION that could create a source of ignition defined in 11.2.2.1 a)..... :                        |   | N/A        |
|             | – Failure of a pneumatic component resulting in leakage of oxygen-enriched gas ..... :  |   | N/A        |
| 11.3        | <b>Constructional requirements for fire ENCLOSURES of ME EQUIPMENT</b>  |   | <b>P</b>   |
|             | <b>ME EQUIPMENT met this clause for alternate means of compliance with selected HAZARDOUS SITUATIONS and fault conditions in 13.1.2..... :</b>  | Enclosure of applicable equipment meets the requirement of a fire enclosure. See appended table 13.1.2. | <b>P</b>   |
|             | <b>Constructional requirements were met, or</b>   |   | <b>P</b>   |
|             | <b>- constructional requirements specifically analysed in RISK MANAGEMENT FILE ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)</b>  | No RMF consideration necessary.   | <b>N/A</b> |
|             | <b>Justification, when requirement not met..... :</b>   |   | <b>N/A</b> |
|             | <b>a) Flammability classification of insulated wire within fire ENCLOSURE is FV-1, or better, based on IEC 60695 series as determined by examination of data on materials..... :</b>  | Internal wires suitable rated, see appended Table 8.10  | <b>P</b>   |
|             | <b>Flammability classification of connectors, printed circuit boards, and insulating material on which components are mounted is FV-2, or better, based on IEC 60695-11-10 as decided by examination of materials data..... :</b>                                   | See above.  | <b>P</b>   |
|             | <b>If no FV Certification, FV tests based on IEC 60695-11-10 conducted on 3 samples of complete parts (or sections of it), including area with min. thickness, ventilation openings</b>   |   | <b>N/A</b> |
|             | <b>b) Fire ENCLOSURE met following:</b>   |   | <b>P</b>   |
|             | <b>1) No openings at bottom or, as specified in Fig 39, constructed with baffles as in Fig 38, or made of perforated metal as in Table 25, or a metal screen with a mesh <math>\leq 2 \times 2</math> mm centre to centre and wire diameter of at least 0.45 mm</b> | No bottom openings.   | <b>P</b>   |
|             | <b>2) No openings on the sides within the area included within the inclined line C in Fig 39</b>  | No opening on the sides.  | <b>P</b>   |
|             | <b>3) ENCLOSURE, baffles, and flame barriers have adequate rigidity and are made of appropriate metal or of non-metallic materials ..... :</b>  | Enclosure made of suitable flame rated. See appended Table 8.10.  | <b>P</b>   |
| 11.4        | <b>ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics</b>   |   | <b>N/A</b> |

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| Clause      | Requirement + Test   | Result - Remark  | Verdict    |
|             | <b>ME EQUIPMENT, ME SYSTEMS and parts described in ACCOMPANYING DOCUMENTS for use with flammable with Annex G</b>  | Equipment not intended to be used in such environments.  | <b>N/A</b> |
| <b>11.5</b> | <b>ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents</b>   |  | <b>N/A</b> |
|             | <b>MANUFACTURER'S RISK MANAGEMENT PROCESS addresses possibility of fire and associated mitigations as confirmed by examination of RISK MANAGEMENT FILE ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)</b> | Equipment is not intended to be used in conjunction with flammable agents. No RMF consideration necessary.                             | <b>N/A</b> |
| <b>11.7</b> | <b>ME EQUIPMENT, ME SYSTEM, and ACCESSORIES coming into direct or indirect contact with biological tissues, cells, or body fluids assessed and documented</b>  | The manufacturer has declared that the equipment complies with requirements of ISO 10993-1. Compliance documented by the manufacturer. | <b>N/A</b> |
| <b>11.8</b> | <b>Interruption and restoration of power supply did not result in a loss of BASIC SAFETY or ESSENTIAL PERFORMANCE</b>  | No hazard with loss of power.  | <b>P</b>   |

|               |   |   |          |
|---------------|---|---|----------|
| <b>13</b>     | <b>HAZARDOUS SITUATIONS AND FAULT CONDITIONS</b>  |   | <b>P</b> |
| <b>13.1</b>   | <b>Specific HAZARDOUS SITUATIONS</b>  |   | <b>P</b> |
| <b>13.1.2</b> | <b>Emissions, deformation of ENCLOSURE or exceeding maximum temperature</b>   |   | <b>P</b> |
|               | <b>– Emission of flames, molten metal, poisonous or ignitable substance in hazardous quantities did not occur</b>                                     | No such emissions. Only limited testing considered necessary. | <b>P</b> |
|               | <b>– Deformation of ENCLOSURE impairing compliance with 15.3.1 did not occur</b>  | No deformation of enclosures.                                 | <b>P</b> |
|               | <b>– Temperatures of APPLIED PARTS did not exceed allowable values in Table 24 ..... :</b>  | See appended Table 13.2.                                      | <b>P</b> |
|               | <b>– Temperatures of ME EQUIPMENT parts that are not APPLIED PARTS likely to be touched did not exceed values in Table 23 ..... :</b>                 | See appended Table 13.2.                                      | <b>P</b> |
|               | <b>– Allowable values for “other components and materials” in Table 22 times 1.5 minus 12.5 °C were not exceeded</b>                                  | See appended Table 13.2.                                      | <b>P</b> |
|               | <b>Limits for windings in Tables 26, 27, and 31 not exceeded</b>  | See appended Table 13.2.                                      | <b>P</b> |
|               | <b>Table 22 not exceeded in all other cases</b>   |   | <b>P</b> |
|               | <b>After tests of this Clause, settings of THERMAL CUT-OUTS and OVER-CURRENT RELEASES did not change sufficiently to affect their safety function</b> | No change.  | <b>P</b> |

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| Clause      | Requirement + Test   | Result - Remark   | Verdict |
| 13.1.3      | – limits for LEAKAGE CURRENT in SINGLE FAULT CONDITION did not exceed .....  | During the testing, no temperatures measured that could impair isolation. No leakage measurements considered necessary. | N/A     |
|             | – voltage limits for ACCESSIBLE PARTS including APPLIED PARTS did not exceed.....  | No voltages exceeded accessible voltage limits.   | P       |
| 13.2        | SINGLE FAULT CONDITIONS  |   | P       |
| 13.2.1      | During the application of the SINGLE FAULT CONDITIONS listed in 13.2.2 to 13.2.13 (inclusive), the NORMAL CONDITIONS identified in 8.1 a) also applied in the least favourable combination   |   | P       |
|             | ME EQUIPMENT complied with 13.2.2 -13.2.12.....  |   | P       |
|             | RISK MANAGEMENT FILE includes and assessment of RISKS associated with leakage of liquid in a SINGLE FAULT CONDITION.....<br>(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)  |   | NE      |
|             | RISK MANAGEMENT FILE defines the appropriate test conditions.....  |   | NE      |
| 13.2.13     | ME EQUIPMENT remained safe after tests of 13.2.13.2 to 13.2.13.4, and cooling down to within 3 °C of test environment temperature  | Equipment remained safe after testing.<br>No heating elements.  | P       |
|             | ME EQUIPMENT examined for compliance or appropriate tests such as dielectric strength of motor insulation according to 8.8.3 conducted   |   | N/A     |
|             | For insulation of thermoplastic materials relied upon as a MEANS OF PROTECTION, the ball-pressure test specified in 8.8.4.1 a) performed at a temperature 25 °C higher than temperature of insulation measured during tests of 13.2.13.2 to 13.2.13.4 (inclusive). |   | N/A     |
| 13.2.13.2   | ME EQUIPMENT with heating elements   |   | N/A     |
|             | a 1) thermostatically controlled ME EQUIPMENT with heating elements for building-in, r for unattended operation, or with a capacitor not protected by a fuse connected in parallel with THERMOSTAT contacts met tests  | No heating element.   | N/A     |
|             | a 2) ME EQUIPMENT with heating elements RATED for non-CONTINUOUS OPERATION met tests   |   | N/A     |
|             | a 3) other ME EQUIPMENT with heating elements met test   |   | N/A     |
|             | When more than one test was applicable to same ME EQUIPMENT, tests performed consecutively   |   | N/A     |

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| Clause      | Requirement + Test   | Result - Remark | Verdict |
|             | Heating period stopped when a heating element or an intentionally weak part of a non-SELF-RESETTING THERMAL CUT-OUT ruptured, or current interrupted before THERMAL STABILITY without possibility of automatic restoration |                 | N/A     |
|             | Test repeated on a second sample when interruption was due to rupture of a heating element or an intentionally weak part   |                 | N/A     |
|             | Both samples met 13.1.2, and open circuiting of a heating element or an intentionally weak part in second sample not considered a failure by itself  |                 | N/A     |
|             | b) ME EQUIPMENT with heating elements without adequate heat discharge, and supply voltage set at 90 or 110 % of RATED supply voltage, least favourable of the two (V) .....  |                 | N/A     |
|             | Operating period stopped when a non-SELF-RESETTING THERMAL CUT-OUT operated, or current interrupted without possibility of automatic restoration before THERMAL STABILITY  |                 | N/A     |
|             | ME EQUIPMENT switched off as soon as THERMAL STABILITY established and allowed to cool to room temperature when current not interrupted  |                 | N/A     |
|             | Test duration was equal to RATED operating time for non-CONTINUOUS OPERATION   |                 | N/A     |
|             | c) Heating parts of ME EQUIPMENT tested with ME EQUIPMENT operated in NORMAL CONDITION at 110 % of RATED supply voltage and as in 11.1, and  |                 | N/A     |
|             | 1) Controls limiting temperature in NORMAL CONDITION disabled, except THERMAL CUT-OUTS   |                 | N/A     |
|             | 2) When more than one control provided, they were disabled in turn   |                 | N/A     |
|             | 3) ME EQUIPMENT operated at RATED DUTY CYCLE until THERMAL STABILITY achieved, regardless of RATED operating time  |                 | N/A     |
| 13.2.13.3   | ME EQUIPMENT with motors   |                 | N/A     |
|             | a 1) For the motor part of the ME EQUIPMENT, compliance checked by tests of 13.2.8- 13.2.10, 13.2.13.3 b), 13.2.13.3 c), and 13.2.13.4, as applicable  | No motors.      | N/A     |
|             | To determine compliance with 13.2.9 and 13.2.10 motors in circuits running at 42.4 V peak a.c./ 60 V d.c. or less are covered with a single layer of cheesecloth which did not ignite during the test                      | See above.      | N/A     |

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| Clause      | Requirement + Test   | Result - Remark                                      | Verdict |
|             | a 2) Tests on ME EQUIPMENT containing heating parts conducted at prescribed voltage with motor & heating parts operated simultaneously to produce the least favourable condition                                   | No heating parts.                                    | N/A     |
|             | a 3) Tests performed consecutively when more tests were applicable to the same ME EQUIPMENT  |  | N/A     |
|             | b) Motor met running overload protection test of this clause when:   |  | N/A     |
|             | 1) it is intended to be remotely or automatically controlled by a single control device with no redundant protection, or   |  | N/A     |
|             | 2) it is likely to be subjected to CONTINUOUS OPERATION while unattended   |  | N/A     |
|             | Motor winding temperature determined during each steady period and maximum value did not exceed Table 27 (Insulation Class, Maximum temperature measured °C) .....   |  | N/A     |
|             | Motor removed from ME EQUIPMENT and tested separately when load could not be changed in appropriate steps  |  | N/A     |
|             | Running overload test for motors operating at 42.4 V peak a.c./60 V d.c. or less performed only when examination and review of design indicated possibility of an overload   |  | N/A     |
|             | Test not conducted where electronic drive circuits maintained a substantially constant drive current   |  | N/A     |
|             | Test not conducted based on other justifications (justification).....  |  | N/A     |
|             | c) ME EQUIPMENT with 3-phase motors operated with normal load, connected to a 3-phase SUPPLY MAINS with one phase disconnected, and periods of operation per 13.2.10   |  | N/A     |
| 13.2.13.4   | ME EQUIPMENT RATED FOR NON-CONTINUOUS OPERATION  |  | N/A     |
|             | ME EQUIPMENT (other than HAND-HELD) operated under normal load and at RATED voltage or at upper limit of RATED voltage range until increase in temperature was ≤ 5 °C in one hour, or a protective device operated | Equipment is continuous use. See summary of testing. | N/A     |
|             | When a load-reducing device operated in NORMAL USE, test continued with ME EQUIPMENT running idle  |  | N/A     |
|             | Motor winding temperatures did not exceed values in 13.2.10 .....  |  | N/A     |
|             | Insulation Class .....   |  | —       |
|             | Maximum temperature measured (°C) .....  |  | —       |

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| Clause      | Requirement + Test   | Result - Remark  | Verdict    |
| <b>15</b>   | <b>CONSTRUCTION OF ME EQUIPMENT</b>  |  | <b>P</b>   |
| 15.1        | Risks associated with arrangement of controls and indicators of ME EQUIPMENT addressed through the application of a USABILITY ENGINEERING PROCESS .....  |  | <b>NE</b>  |
| 15.2        | Parts of ME EQUIPMENT subject to mechanical wear, electrical, environmental degradation or ageing resulting in unacceptable RISK when unchecked for a long period, are accessible for inspection, replacement, and maintenance |  | <b>N/A</b> |
|             | Inspection, servicing, replacement, and adjustment of parts of ME EQUIPMENT can easily be done without damage to or interference with adjacent parts or wiring   | Service only by manufacturer or approved representative. | <b>N/A</b> |
| 15.3        | Mechanical strength  |  | <b>P</b>   |
| 15.3.1      | Mould stress relief, push, impact, drop, and rough handling tests did not result in loss of BASIC SAFETY OF ESSENTIAL PERFORMANCE  |  | <b>N/A</b> |
| 15.3.2      | Push test conducted.....   | See Appended Table 15.3                                  | <b>P</b>   |
|             | No damage resulting in an unacceptable RISK sustained  | No RMF consideration necessary.                          | <b>N/A</b> |
| 15.3.3      | Impact test conducted .....  | See Appended Table 15.3                                  | <b>P</b>   |
|             | No damage resulting in an unacceptable RISK sustained  | No RMF consideration necessary.                          | <b>N/A</b> |
| 15.3.4      | Drop test  |  | <b>P</b>   |
| 15.3.4.1    | Sample of HAND-HELD ME EQUIPMENT, ACCESSORIES and HAND-HELD part with SAFE WORKING LOAD tested.....  | See Appended Table 15.3                                  | <b>P</b>   |
|             | No unacceptable RISK resulted  | No RMF consideration necessary.                          | <b>N/A</b> |
| 15.3.4.2    | Sample of PORTABLE ME EQUIPMENT, ACCESSORIES and PORTABLE part with SAFE WORKING LOAD withstood stress as demonstrated by test .....   |  | <b>N/A</b> |
|             | No damage resulting in an unacceptable RISK sustained  | No RMF consideration necessary.                          | <b>N/A</b> |
| 15.3.5      | MOBILE ME EQUIPMENT and MOBILE part with SAFE WORKING LOAD and in most adverse condition in NORMAL USE passed Rough Handling tests.....  |  | <b>N/A</b> |
|             | No damage resulting in an unacceptable RISK sustained  |  | <b>N/A</b> |
| 15.3.6      | Examination of ENCLOSURE made from moulded or formed thermoplastic material indicated that material distortion due to release of internal stresses by moulding or forming operations will not result in an unacceptable RISK   | No such material relied upon.                            | <b>N/A</b> |

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| Clause          | Requirement + Test   | Result - Remark   | Verdict    |
|                 | <b>Mould-stress relief test conducted by placing one sample of complete ME EQUIPMENT, ENCLOSURE or a portion of larger ENCLOSURE, for 7 hours in a circulating air oven at 10°C over the max temperature measured on ENCLOSURE in 11.1.3, but no less than 70 °C..... :</b>  |   | <b>N/A</b> |
|                 | <b>No damage resulting in an unacceptable RISK</b>   |   | <b>N/A</b> |
| <b>15.3.7</b>   | <b>INTENDED USE, EXPECTED SERVICE LIFE, and conditions for transport and storage were taken into consideration for selection and treatment of materials used in construction of ME EQUIPMENT</b>   | Considered.   | <b>P</b>   |
|                 | <b>Based on review of EQUIPMENT, ACCOMPANYING DOCUMENTS, specifications and processing of materials, and MANUFACTURER'S relevant tests or calculations, corrosion, ageing, mechanical wear, degradation of biological materials due to bacteria, plants, animals and the like, will not result in an unacceptable RISK</b> | According to manufacturer, selection and treatment of materials used in the construction of ME equipment taking into consideration. Compliance is documented by manufacturer. | <b>P</b>   |
| <b>15.4</b>     | <b>ME EQUIPMENT components and general assembly</b>  |   | <b>N/A</b> |
| <b>15.4.1</b>   | <b>Incorrect connection of accessible connectors, removable without a TOOL, prevented where an unacceptable RISK exists, ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)</b>   |   | <b>NE</b>  |
|                 | <b>a) Plugs for connection of PATIENT leads or PATIENT cables cannot be connected to outlets on same ME EQUIPMENT intended for other functions, ..... :</b>  | No such patient leads.  | <b>N/A</b> |
|                 | <b>b) Medical gas connections on ME EQUIPMENT for different gases to be operated in NORMAL USE are not interchangeable inspection ..... :</b>  | No external gas connections.  | <b>N/A</b> |
| <b>15.4.2</b>   | <b>Temperature and overload control devices</b>  |   | <b>N/A</b> |
| <b>15.4.2.1</b> | <b>a) THERMAL CUT-OUTS and OVER-CURRENT RELEASES with automatic resetting not used in ME EQUIPMENT when their use could lead to a HAZARDOUS SITUATION ..... : (ISO 14971 Cl. 4.2-4.4, 5)</b>   | Equipment does not use automatic resetting thermal cut-outs. No RMF consideration necessary.  | <b>N/A</b> |
|                 | <b>b) THERMAL CUT-OUTS with a safety function with reset by a soldering not fitted in ME EQUIPMENT</b>   | No thermal cut-out in the equipment.  | <b>N/A</b> |
|                 | <b>c) An additional independent non-SELF-RESETTING THERMAL CUT-OUT is provided..... : (ISO 14971 Cl. 4.2-4.4)</b>  | No thermostats used. No RMF consideration necessary.  | <b>N/A</b> |
|                 | <b>d) Operation of THERMAL CUT-OUT or OVER CURRENT RELEASE doesn't result in a HAZARDOUS SITUATION or loss of ESSENTIAL PERFORMANCE .... : (ISO 14971 Cl. 4.2-4.4)</b>   | Loss of function does not cause a hazard. No RMF consideration necessary.   | <b>N/A</b> |

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| Clause      | Requirement + Test  | Result - Remark  | Verdict |
|             | <b>e) Capacitors or other spark-suppression devices not connected between contacts of THERMAL CUT-OUTS</b>  | No thermal cut-out in the equipment.                         | N/A     |
|             | <b>f) Use of THERMAL CUT-OUTS or OVER-CURRENT RELEASES do not affect safety as verified by following tests</b>  |  | N/A     |
|             | - Positive temperature coefficient devices) complied with IEC 60730-1: 2010, Clauses 15, 17, J.15, and J.17   |  | N/A     |
|             | - ME EQUIPMENT containing THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated under the conditions of Clause 13..... :  |  | N/A     |
|             | - SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions Certified according to appropriate standards .....                                   |  | N/A     |
|             | - In the absence of Certification in accordance with IEC standards, SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions operated 200 times |  | N/A     |
|             | Manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES Certified in accordance with appropriate IEC standards  |  | N/A     |
|             | manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated 10 times   |  | N/A     |
|             | Thermal protective devices tested separately from ME EQUIPMENT when engineering judgment indicated test results would not be impacted   |  | N/A     |
|             | <b>g) Protective device incorporating a fluid filled container with heating means, operated when heater switched on with container empty and prevented an unacceptable RISK due to overheating</b>  | No such protective device.                                   | N/A     |
|             | <b>h) ME EQUIPMENT with tubular heating elements provided with protection against overheating. : (ISO 14971 Cl. 4.2-4.4)</b>  | No tubular heating elements. No RMF consideration necessary. | N/A     |
| 15.4.2.2    | Temperature settings clearly indicated when means provided to vary setting of THERMOSTATS   |  | N/A     |
| 15.4.3      | <b>Batteries</b>  |  | N/A     |
| 15.4.3.1    | Battery housings provided with ventilation..... : (ISO 14971 Cl. 4.2-4.4)   | No batteries provided.                                       | N/A     |
|             | Battery compartments designed to prevent accidental short circuiting  |  | N/A     |
| 15.4.3.2    | Means provided to prevent incorrect connection of polarity..... :   |  | N/A     |



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| Clause      | Requirement + Test  | Result - Remark                             | Verdict |
|             | RISK MANAGEMENT FILE includes an assessment of RISKS associated with incorrect connection or replacement of batteries ..... : (ISO 14971 Cl. 4.2-4.4)                               |   | N/A     |
| 15.4.3.3    | Overcharging of battery prevented by virtue of design..... :  |   | N/A     |
|             | RISK MANAGEMENT FILE includes an assessment of RISKS associated with overcharging of batteries ..... : (ISO 14971 Cl. 4.2-4.4)  |   | NE      |
| 15.4.3.4    | Primary lithium batteries comply with IEC 80086-4   | None provided.                              | N/A     |
|             | Secondary lithium batteries comply with IEC 62133   |   | N/A     |
| 15.4.3.5    | A properly RATED protective device provided within INTERNAL ELECTRICAL POWER SOURCE to protect against fire..... :  | No batteries provided.                      | N/A     |
|             | Protective device has adequate breaking capacity  |   | N/A     |
|             | Justification for OVER-CURRENT RELEASES OR FUSE exclusion is documented   |   | N/A     |
|             | Short circuit test between the positive and negative poles of an INTERNAL ELECTRICAL POWER SOURCE between the output and protective device(s) omitted where 2 MOOPs provided, or    |   | N/A     |
|             | Short circuit between the positive and negative poles of an INTERNAL ELECTRICAL POWER SOURCE between the output and protective device(s) does not result in any HAZARDOUS SITUATION |   | N/A     |
| 15.4.4      | Indicator lights provided to indicate ME EQUIPMENT is ready for..... :  | Amplifier is provided with indicator light. | P       |
|             | An additional indicator light provided on ME EQUIPMENT with a stand-by state or a warm-up state exceeding 15 s,   | No warm up state required.                  | N/A     |
|             | Indicator lights provided on ME EQUIPMENT incorporating non-luminous heaters to indicate heaters are operational  | No heaters.                                 | N/A     |
|             | RISK MANAGEMENT FILE includes an assessment of RISKS associated with the use of indicator lights for EQUIPMENT incorporating non-luminous heaters ..... : (ISO 14971 Cl. 4.2-4.4)   | No RMF consideration necessary.             | N/A     |
|             | Requirement not applied to heated stylus-pens for recording purposes  |   | N/A     |
|             | Indicator lights provided on ME EQUIPMENT to indicate an output exists  |   | N/A     |
|             | Colours of indicator lights complied with 7.8.1   | Indicator light is blue                     | P       |

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| Clause      | Requirement + Test  | Result - Remark                                     | Verdict    |
|             | <b>Charging mode visibly indicated</b>  |   | <b>N/A</b> |
| 15.4.5      | <b>Risks associated with pre-set controls addressed in RISK MANAGEMENT PROCESS ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)</b>                      | No pre-set controls. No RMF consideration necessary | <b>N/A</b> |
| 15.4.6      | <b>Actuating parts of controls of ME EQUIPMENT</b>  |   | <b>N/A</b> |
| 15.4.6.1    | <b>a) Actuating parts cannot be pulled off or loosened during NORMAL USE</b>  | No actuating parts of controls.                     | <b>N/A</b> |
|             | <b>b) Controls secured so that the indication of any scale always corresponds to the position of the control</b>                                    | No actuating parts of controls.                     | <b>N/A</b> |
|             | <b>c) Incorrect connection prevented by adequate construction when it could be separated without use of a TOOL</b>                                  |   | <b>N/A</b> |
|             | <b>When torque values per Table 30 applied knobs did not rotate ..... :</b>   |   | <b>N/A</b> |
|             | <b>Tests conducted with no unacceptable RISK . :</b>  |   | <b>N/A</b> |
| 15.4.6.2    | <b>Stops on rotating/ movable parts of controls are of adequate mechanical strength ..... :</b>   |   | <b>N/A</b> |
|             | <b>Torque values in Table 30 applied ..... :</b>  |   | <b>N/A</b> |
|             | <b>No unexpected change of the controlled parameter when tested ..... :</b>   |   | <b>N/A</b> |
| 15.4.7      | <b>Cord-connected HAND-HELD and foot-operated control devices</b>   |   | <b>N/A</b> |
| 15.4.7.1    | <b>a) HAND-HELD control devices of ME EQUIPMENT complied with 15.3.4.1</b>  | No such parts.                                      | <b>N/A</b> |
|             | <b>b) Foot-operated control device supported an actuating force of 1350 N in its position of NORMAL USE with no damage ..... :</b>                  |   | <b>N/A</b> |
| 15.4.7.2    | <b>Control device of HAND-HELD and foot-operated control devices turned in all possible abnormal positions and placed on a flat surface ..... :</b> |   | <b>N/A</b> |
|             | <b>No unacceptable RISK caused by changing control setting when accidentally placed in an abnormal position</b>                                     |   | <b>N/A</b> |
| 15.4.7.3    | <b>a) Foot-operated control device is at least rated IPX1 ..... :</b>   |   | <b>N/A</b> |
|             | <b>b) ENCLOSURE of foot operated control devices containing electrical circuits is at least IPX6.... :</b>  |   | <b>N/A</b> |
| 15.4.8      | <b>Aluminium wires less than 16 mm<sup>2</sup> in cross-sectional area are not used</b>   |   | <b>N/A</b> |
| 15.4.9      | <b>a) Oil container in PORTABLE ME EQUIPMENT allows for expansion of oil and is adequately sealed</b>   | No oil containers.                                  | <b>N/A</b> |
|             | <b>b) Oil containers in MOBILE ME EQUIPMENT sealed to prevent loss of oil during transport</b>  |   | <b>N/A</b> |

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| Clause          | Requirement + Test  | Result - Remark  | Verdict    |
|                 | <b>A pressure-release device operating during NORMAL USE is provided</b>  |  | <b>N/A</b> |
|                 | <b>c) Partially sealed oil-filled ME EQUIPMENT and its parts provided with means for checking the oil level to detect leakage</b>                   |  | <b>N/A</b> |
|                 | <b>ME EQUIPMENT and technical description examined, and manual tests conducted to confirm compliance with above requirements</b>                    |  | <b>N/A</b> |
| <b>15.5</b>     | <b>MAINS SUPPLY TRANSFORMERS OF ME EQUIPMENT and transformers providing separation in accordance with 8.5</b>                                       |  | <b>N/A</b> |
| <b>15.5.1</b>   | <b>Overheating</b>  |  | <b>P</b>   |
| <b>15.5.1.1</b> | <b>Transformers of ME EQUIPMENT are protected against overheating .....</b> :   | Evaluated as part of the certified external power supply unit. | <b>P</b>   |
|                 | <b>During tests, windings did not open, no HAZARDOUS SITUATION occurred, and maximum temperatures of windings did not exceed values in Table 31</b> |  | <b>P</b>   |
|                 | <b>Dielectric strength test conducted after short circuit and overload tests .....</b> :  |  | <b>P</b>   |
| <b>15.5.1.2</b> | <b>Transformer output winding short circuited, and test continued until protective device operated or THERMAL STABILITY achieved .....</b> :        | Evaluated as part of the certified external power supply unit. | <b>P</b>   |
|                 | <b>Short circuit applied directly across output windings</b>  |  | <b>P</b>   |
| <b>15.5.1.3</b> | <b>Multiple overload tests conducted on windings .....</b> :  | Evaluated as part of the certified external power supply unit. | <b>P</b>   |
| <b>15.5.2</b>   | <b>Transformers operating at a frequency above 1kHz tested according to clause 8.8.3 .....</b> :  |  | <b>P</b>   |
|                 | <b>Transformer windings provided with adequate insulation</b>   |  | <b>P</b>   |
|                 | <b>Dielectric strength tests were conducted .....</b> :   |  | <b>P</b>   |
| <b>15.5.3</b>   | <b>Transformers forming MEANS OF PROTECTION as required by 8.5 comply with .....</b> :  | Evaluated as part of the certified external power supply unit. | <b>P</b>   |
|                 | <b>- Means provided to prevent displacement of end turns</b>  |  | <b>P</b>   |
|                 | <b>- protective earth screens with a single turn have insulated overlap</b>   |  | <b>P</b>   |
|                 | <b>- Exit of wires form internal windings of toroid transformers protected with double sleeving</b>   |  | <b>P</b>   |
|                 | <b>- insulation between primary and secondary windings complies with 8.8.2</b>  |  | <b>P</b>   |

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| Clause      | Requirement + Test   | Result - Remark   | Verdict   |
|             | - CREEPAGE DISTANCES and AIR CLEARANCE comply with 8.9.4   |   | <b>P</b>  |
| <b>16</b>   | <b>ME SYSTEMS</b>  |   | <b>P</b>  |
| <b>16.1</b> | <b>After installation or subsequent modification, ME SYSTEM didn't result in an unacceptable RISK</b>  | The equipment was evaluated as a medical device.  | <b>P</b>  |
|             | RISK MANAGEMENT FILE includes an assessment of RISKS associated with installation and modification of an ME SYSTEM.....: (ISO 14971 Cl. 4.2-4.4, 5)      |   | <b>NE</b> |
|             | Only HAZARDS arising from combining various equipment to form a ME SYSTEM considered   |   | <b>P</b>  |
|             | – ME SYSTEM provides the level of safety within the PATIENT ENVIRONMENT equivalent to ME EQUIPMENT complying with this standard                          | Only headphones are considered to be within the patient environment.  | <b>P</b>  |
|             | – ME SYSTEM provides the level of safety outside PATIENT ENVIRONMENT equivalent to equipment complying with their respective IEC or ISO safety standards | Transducer is considered to be outside the patient environment and evaluated to the requirements of IEC 60601-1 in this test report.<br><br>All other system components are considered to comply with the requirements of IEC60950-1. | <b>P</b>  |
|             | – tests performed in NORMAL CONDITION, except as specified   |   | <b>P</b>  |
|             | – tests performed under operating conditions specified by MANUFACTURER of ME SYSTEM  |   | <b>P</b>  |
|             | Safety tests previously conducted on individual equipment of ME SYSTEM according to relevant standards not repeated                                      |   | <b>P</b>  |
|             | RISK MANAGEMENT methods used by MANUFACTURER of an ME SYSTEM reconfigurable by RESPONSIBLE ORGANIZATION or OPERATOR                                      |   | <b>NE</b> |
|             | Non-ME EQUIPMENT used in ME SYSTEM complied with applicable IEC or ISO safety standards  | Transducer is considered to be outside the patient environment and evaluated to the requirements of IEC 60601-1 in this test report.<br><br>All other system components are considered to comply with the requirements of IEC60950-1. | <b>P</b>  |

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| Clause      | Requirement + Test  | Result - Remark  | Verdict   |
|             | <b>Equipment relying only on BASIC INSULATION for protection against electric shock not used in ME SYSTEM</b>   | External PSU's provide 2MOOP for system components.<br>Headphones are provided with 2MOPP by nonconductive connection to Transducer. | <b>P</b>  |
| <b>16.2</b> | <b>ACCOMPANYING DOCUMENTS of an ME SYSTEM</b>   |  | <b>NE</b> |
|             | <b>Documents containing all data necessary for ME SYSTEM to be used as intended by MANUFACTURER including a contact address accompany ME SYSTEM or modified ME SYSTEM</b> | Documentation was not evaluated as part of this evaluation.  | <b>NE</b> |
|             | <b>ACCOMPANYING DOCUMENTS regarded as a part of ME SYSTEM</b>   |  | <b>NE</b> |
|             | <b>a) ACCOMPANYING DOCUMENTS provided for each item of ME EQUIPMENT supplied by MANUFACTURER</b>  |  | <b>NE</b> |
|             | <b>b) ACCOMPANYING DOCUMENTS provided for each item of non-ME EQUIPMENT supplied by MANUFACTURER</b>  |  | <b>NE</b> |
|             | <b>c) the required information is provided:</b>   |  | <b>NE</b> |
|             | <b>– specifications, instructions for use as intended by MANUFACTURER, and a list of all items forming the ME SYSTEM</b>  |  | <b>NE</b> |
|             | <b>– instructions for installation, assembly, and modification of ME SYSTEM to ensure continued compliance with this standard</b>   |  | <b>NE</b> |
|             | <b>– instructions for cleaning and, when applicable, disinfecting and sterilizing each item of equipment or equipment part forming part of the ME SYSTEM</b>              |  | <b>NE</b> |
|             | <b>– additional safety measures to be applied during installation of ME SYSTEM</b>  |  | <b>NE</b> |
|             | <b>– identification of parts of ME SYSTEM suitable for use within the PATIENT ENVIRONMENT</b>   |  | <b>NE</b> |
|             | <b>– additional measures to be applied during preventive maintenance</b>  |  | <b>NE</b> |
|             | <b>– a warning forbidding placement of MULTIPLE SOCKET-OUTLET, when provided and it is a separate item, on the floor</b>  |  | <b>NE</b> |
|             | <b>– a warning indicating an additional MULTIPLE SOCKET-OUTLET or extension cord not to be connected to ME SYSTEM</b>   |  | <b>NE</b> |
|             | <b>– a warning to connect only items that have been specified as part of ME SYSTEM or specified as being compatible with ME SYSTEM</b>                                    |  | <b>NE</b> |
|             | <b>– maximum permissible load for any MULTIPLE SOCKET-OUTLET(s) used with ME SYSTEM</b>   |  | <b>NE</b> |

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| Clause      | Requirement + Test   | Result - Remark   | Verdict |
|             | – instructions indicating MULTIPLE SOCKET-OUTLETS provided with the ME SYSTEM to be used only for supplying power to equipment intended to form part of ME SYSTEM  |   | NE      |
|             | – an explanation indicating RISKS of connecting non-ME EQUIPMENT supplied as a part of ME SYSTEM directly to wall outlet when non-ME EQUIPMENT is intended to be supplied via a MULTIPLE SOCKET-OUTLET with a separating transformer |   | NE      |
|             | – an explanation indicating RISKS of connecting any equipment supplied as a part of ME SYSTEM to MULTIPLE SOCKET-OUTLET  |   | NE      |
|             | – permissible environmental conditions of use for ME SYSTEM including conditions for transport and storage   |   | NE      |
|             | – instructions to OPERATOR not to, simultaneously, touch parts referred to in 16.4 and PATIENT   |   | NE      |
|             | d) the following instructions provided for use by RESPONSIBLE ORGANIZATION:  |   | NE      |
|             | – adjustment, cleaning, sterilization, and disinfection PROCEDURES   |   | NE      |
|             | – assembly of ME SYSTEMS and modifications during actual service life shall be evaluated based on the requirements of this standard  |   | NE      |
| 16.3        | Instructions for use of ME EQUIPMENT intended to receive its power from other equipment in an ME SYSTEM, describe the other equipment to ensure compliance with these requirements   |   | NE      |
|             | Transient currents restricted to allowable levels for the specified IPS or UPS..... :  |   | NE      |
|             | Technical description and installation instructions specify the actual transient currents where an IPS or UPS is not specified   |   | NE      |
| 16.4        | Parts of non-ME EQUIPMENT in PATIENT ENVIRONMENT subject to contact by OPERATOR during maintenance, calibration, after removal of covers, connectors operated at a voltage ≤ voltage in 8.4.2 c)                                     | No nonmedical equipment located in the patient environment. | N/A     |
| 16.5        | Safety measures incorporating a SEPARATION DEVICE applied when FUNCTIONAL CONNECTION between ME EQUIPMENT and other items of an ME SYSTEM or other systems can cause allowable values of LEAKAGE CURRENT to exceed                   | No separation device relied upon.                           | N/A     |
|             | SEPARATION DEVICE has dielectric strength, CREEPAGE and CLEARANCES required for one MEANS OF OPERATOR PROTECTION   |   | N/A     |

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| Clause          | Requirement + Test   | Result - Remark  | Verdict    |
|                 | <b>WORKING VOLTAGE was highest voltage across SEPARATION DEVICE during a fault condition, but not less than MAXIMUM MAINS VOLTAGE (V)..... :</b>   |  | <b>N/A</b> |
| <b>16.6</b>     | <b>LEAKAGE CURRENTS</b>  |  | <b>P</b>   |
| <b>16.6.1</b>   | <b>TOUCH CURRENT in NORMAL CONDITION did not exceed 100 µA..... :</b>  | See appended Table 8.7   | <b>P</b>   |
|                 | <b>TOUCH CURRENT did not exceed 500 µA in event of interruption of any non-PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR..... :</b>   | See appended Table 8.7   | <b>P</b>   |
| <b>16.6.2</b>   | <b>Current in PROTECTIVE EARTH CONDUCTOR of MULTIPLE SOCKET-OUTLET didn't exceed 5 mA..... :</b>   | No MSO provided.   | <b>N/A</b> |
| <b>16.6.3</b>   | <b>PATIENT LEAKAGE CURRENT and total PATIENT LEAKAGE CURRENT of ME SYSTEM in NORMAL CONDITION did not exceed values..... :</b>   | See appended Table 8.7   | <b>P</b>   |
| <b>16.7</b>     | <b>ME SYSTEM complied with applicable requirements of Clause 9 ..... :</b>   | Transducer evaluated to stability requirements.  | <b>P</b>   |
| <b>16.8</b>     | <b>Interruption and restoration power to the ME SYSTEM or any part of the ME SYSTEM did not result in a loss of BASIC SAFETY or ESSENTIAL PERFORMANCE</b>  | Interruption of power evaluated during Leakage measurements.                             | <b>P</b>   |
| <b>16.9</b>     | <b>ME SYSTEM connections and wiring</b>  |  | <b>P</b>   |
| <b>16.9.1</b>   | <b>Incorrect connection of accessible connectors, removable without a TOOL, prevented where unacceptable RISK can result..... :</b>  |  | <b>P</b>   |
|                 | <b>RISK MANAGEMENT FILE includes an assessment of RISKS associated with plugs for connection of PATIENT leads or cables likely to be located in the PATIENT ENVIRONMENT ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)</b>  |  | <b>NE</b>  |
|                 | <b>– Plugs for connection of PATIENT leads or PATIENT cables could not be connected to other outlets of the same ME SYSTEM likely to be located in PATIENT ENVIRONMENT, except when examination of connectors and interchanging them proved no unacceptable RISK results</b> | Headphones provided with nonconductive connection.<br>No possibility of miss connection. | <b>P</b>   |
|                 | <b>Medical gas connections on the ME SYSTEM for different gasses operated in NORMAL USE are not interchangeable</b>  |  | <b>N/A</b> |
| <b>16.9.2</b>   | <b>MAINS PARTS, components and layout</b>  |  | <b>N/A</b> |
| <b>16.9.2.1</b> | <b>a) – MULTIPLE SOCKET-OUTLET only allows connection using a TOOL, or</b>   | No MSO provided.   | <b>N/A</b> |
|                 | <b>– MULTIPLE SOCKET-OUTLET is of a type that cannot accept MAINS PLUGS of any of the kinds specified in IEC/TR 60083, or</b>  |  | <b>N/A</b> |
|                 | <b>– MULTIPLE SOCKET-OUTLET is supplied via a separating transformer</b>   |  | <b>N/A</b> |

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| Clause      | Requirement + Test  | Result - Remark  | Verdict    |
|             | <b>b) – MULTIPLE SOCKET-OUTLET marked with safety sign 2 of Table D.2 visible in NORMAL USE, and</b>  |                  | <b>N/A</b> |
|             | – marked either individually or in combinations, with the maximum allowed continuous output in amperes or volt-amperes, or  |                  | <b>N/A</b> |
|             | – marked to indicate the equipment or equipment parts it may safely be attached to  |                  | <b>N/A</b> |
|             | – MULTIPLE SOCKET-OUTLET is a separate item or an integral part of ME EQUIPMENT or non-ME EQUIPMENT   | No MSO provided. | <b>N/A</b> |
|             | <b>c) MULTIPLE SOCKET-OUTLET complied with IEC 60884-1 and the following requirements:</b>  |                  | <b>N/A</b> |
|             | – CREEPAGE and CLEARANCES complied with 8.9   |                  | <b>N/A</b> |
|             | – It is CLASS I, and PROTECTIVE EARTH CONDUCTOR is connected to earthing contacts in socket-outlets   |                  | <b>N/A</b> |
|             | – PROTECTIVE EARTH TERMINALS and PROTECTIVE EARTH CONNECTIONS comply with 8.6:  |                  | <b>N/A</b> |
|             | – ENCLOSURE complied with 8.4.2 d)  |                  | <b>N/A</b> |
|             | – MAINS TERMINAL DEVICES and wiring complied with 8.11.4, when applicable   |                  | <b>N/A</b> |
|             | – RATINGS of components are not in conflict with conditions of use .....  |                  | <b>N/A</b> |
|             | – Electrical terminals and connectors of MULTIPLE SOCKET-OUTLETS prevent incorrect connection of accessible connectors removable without a TOOL                                       |                  | <b>N/A</b> |
|             | – POWER SUPPLY CORD complied with 8.11.3  |                  | <b>N/A</b> |
|             | <b>d) Additional requirements applied when MULTIPLE SOCKET-OUTLET combined with a separating transformer:</b>   |                  | <b>N/A</b> |
|             | – Separating transformer complied with this standard or IEC 61558-2-1, .....  |                  | <b>N/A</b> |
|             | – Separating transformer is CLASS I   |                  | <b>N/A</b> |
|             | – Degree of protection against ingress of water specified as in IEC 60529   |                  | <b>N/A</b> |
|             | – Separating transformer assembly marked according to 7.2 and 7.3   |                  | <b>N/A</b> |
|             | – MULTIPLE SOCKET-OUTLET permanently connected to separating transformer, or socket-outlet of separating transformer assembly cannot accept MAINS PLUGS as identified in IEC/TR 60083 |                  | <b>N/A</b> |



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| Clause      | Requirement + Test   | Result - Remark  | Verdict |
| 16.9.2.2    | The impedance between the protective earth pin in the MAINS PLUG and any part that is PROTECTIVELY EARTHED did not exceed 200 mΩ   | No MSO provided. | N/A     |
|             | Removal of any single item of equipment in ME SYSTEM will not interrupt the protective earthing of any other part without simultaneous disconnection of electrical supply to that part |                  | N/A     |
|             | Additional PROTECTIVE EARTH CONDUCTORS can be detachable only by use of a TOOL   |                  | N/A     |
| 16.9.2.3    | Conductors connecting different items within an ME SYSTEM protected against mechanical damage  |                  | N/A     |

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| <b>ANNEX G</b> | <b>PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANESTHETIC MIXTURES</b>  |  | <b>N/A</b> |
| <b>G.2</b>     | <b>Locations and basic requirements</b>   |  | <b>N/A</b> |
| <b>G.2.1</b>   | Parts of CATEGORY APG ME EQUIPMENT in which a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR OCCURS are CATEGORY AP or APG ME EQUIPMENT and complied with G.3, G.4, and G.5 | Not intended for use in such environments. | <b>N/A</b> |
| <b>G.2.2</b>   | FLAMMABLE AESTHETIC MIXTURE WITH  |  | <b>N/A</b> |
| <b>G.2.3</b>   | A FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE  |  | <b>N/A</b> |
| <b>G.2.4</b>   | ME EQUIPMENT specified for use with FLAMMABLE AESTHETIC MIXTURE WITH AIR complied with G.4 and G.5  |  | <b>N/A</b> |
| <b>G.2.5</b>   | ME EQUIPMENT or parts thereof for use with FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE comply with G.4 and G.6   |  | <b>N/A</b> |
|                | ME EQUIPMENT in G.2.4 to G.2.5 met appropriate tests of G.3-G.5 conducted after tests of 11.6.6 and 11.6.7  |  | <b>N/A</b> |
| <b>G.3</b>     | <b>Marking, ACCOMPANYING DOCUMENTS</b>  |  | <b>N/A</b> |
| <b>G.3.1</b>   | CATEGORY APG ME EQUIPMENT prominently marked "APG" (symbol 23 in Table D.1) .....   |  | <b>N/A</b> |
|                | Length of green-coloured band is ≥ 4 cm, and size of marking is as large as possible for particular case  |  | <b>N/A</b> |
|                | When above marking not possible, relevant information included in instructions for use... :   |  | <b>N/A</b> |
|                | Marking complied with tests and criteria of 7.1.2 and 7.1.3   |  | <b>N/A</b> |
| <b>G.3.2</b>   | CATEGORY AP ME EQUIPMENT prominently marked, with a green-coloured circle "AP" (symbol 22 in Table D.1) .....   |  | <b>N/A</b> |

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|-------------|--|-----------------|---------|
| Clause      | Requirement + Test   | Result - Remark | Verdict |
|             | Marking is as large as possible for the particular case  |                 | N/A     |
|             | When above marking not possible, the relevant information included in instructions for use... :  |                 | N/A     |
|             | Marking complied with tests and criteria of 7.1.2 and 7.1.3  |                 | N/A     |
| G.3.3       | The marking placed on major part of ME EQUIPMENT for CATEGORY AP or APG parts  |                 | N/A     |
| G.3.4       | ACCOMPANYING DOCUMENTS contain an indication enabling the RESPONSIBLE ORGANIZATION to distinguish between CATEGORY AP and APG parts  |                 | N/A     |
| G.3.5       | Marking clearly indicates which parts are CATEGORY AP or APG when only certain ME EQUIPMENT parts are CATEGORY AP or APG   |                 | N/A     |
| G.4         | Common requirements for CATEGORY AP and CATEGORY APG ME EQUIPMENT  |                 | N/A     |
| G.4.1       | a) CREEPAGE and CLEARANCES are according to Table 12 for one MEANS OF PATIENT PROTECTION   |                 | N/A     |
|             | b) Connections protected against accidental disconnection  |                 | N/A     |
|             | c) CATEGORY AP and APG not provided with a DETACHABLE POWER SUPPLY CORD,   |                 | N/A     |
| G.4.2       | Construction details   |                 | N/A     |
|             | a) Opening of an ENCLOSURE protecting against penetration of gases or vapours into ME EQUIPMENT or its parts possible only with a TOOL   |                 | N/A     |
|             | b) ENCLOSURE complies with..... :  |                 | N/A     |
|             | – no openings on top covers of ENCLOSURE,  |                 | N/A     |
|             | – openings in side-covers prevented penetration of a solid cylindrical test rod  |                 | N/A     |
|             | – openings in base plates prevented penetration of a solid cylindrical test  |                 | N/A     |
|             | c) Short circuiting conductor(s) to a conductive part (when no explosive gasses) did not result in loss of integrity of the part, an unacceptable temperature, or any HAZARDOUS SITUATION  |                 | N/A     |
| G.4.3       | a) Electrostatic charges prevented on CATEGORY AP and APG ME EQUIPMENT by a combination of appropriate measures  |                 | N/A     |
|             | – Use of antistatic materials with a limited electrical resistance..... :  |                 | N/A     |
|             | – Provision of electrically conductive paths from ME EQUIPMENT or its parts to a conductive floor, protective earth or potential equalization system, or via wheels to an antistatic floor |                 | N/A     |

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|--------------|---|---|------------|
| Clause       | Requirement + Test  | Result - Remark   | Verdict    |
|              | <b>b) Electrical resistance limits of aesthetic tubing, mattresses/ pads, castor tires &amp; other antistatic material comply with ISO 2882..... :</b>  |   | <b>N/A</b> |
| <b>G.4.4</b> | <b>Corona cannot be produced by components or parts of ME EQUIPMENT operating at more than 2000 V a.c. or 2400 V d.c. and not included in ENCLOSURES complying with G.5.4 or G.5.5</b>  |   | <b>N/A</b> |
| <b>G.5</b>   | <b>Requirements and tests for CATEGORY AP ME EQUIPMENT, parts and components</b>  |   | <b>N/A</b> |
| <b>G.5.1</b> | <b>ME EQUIPMENT, its parts or components do not ignite FLAMMABLE AESTHETIC MIXTURES WITH AIR under NORMAL USE and CONDITIONS based on compliance with G.5.2 to G.5.5</b>  |   | <b>N/A</b> |
|              | <b>Alternatively, ME EQUIPMENT, its parts, and components complied with requirements of IEC 60079-0 for pressurized ENCLOSURES (IEC 60079-2); for sand-filled ENCLOSURES, IEC 60079-5; or for oil immersed equipment, IEC 60079-6; and with this standard excluding G.5.2 to G.5.5..... :</b> |   | <b>N/A</b> |
| <b>G.5.2</b> | <b>Temperature limits..... :</b>  |   | <b>N/A</b> |
| <b>G.5.3</b> | <b>ME EQUIPMENT, its parts, and components producing sparks in NORMAL USE and CONDITION complied with temperature requirements of G.5.2, and <math>U_{max}</math> and <math>I_{max}</math> occurring in their circuits, and complied as follows:</b>  |   | <b>N/A</b> |
|              | <b>Measured <math>U_{max} \leq U_{zR}</math> with <math>I_{zR}</math> as in Fig. G.1 ..... :</b>  | $U_{max} = \_ \_ V$<br>$U_{zR} = \_ \_ V$<br>$I_{zR} = \_ \_ A$   | <b>N/A</b> |
|              | <b>Measured <math>U_{max} \leq U_c</math> with <math>C_{max}</math> as in Fig. G.2 ... :</b>  | $U_{max} = \_ \_ V$<br>$U_c = \_ \_ V$<br>$C_{max} = \_ \_ \mu F$ | <b>N/A</b> |
|              | <b>Measured <math>I_{max} \leq I_{zR}</math> with <math>U_{zR}</math> as in Fig G.1 ..... :</b>   | $I_{max} = \_ \_ A$<br>$I_{zR} = \_ \_ A$<br>$U_{zR} = \_ \_ V$   | <b>N/A</b> |
|              | <b>Measured <math>I_{max} \leq I_{zL}</math> with <math>L_{max}</math> and a <math>U_{max} \leq 24 V</math> as in Fig G.3..... :</b>  | $I_{max} = \_ \_ A$<br>$I_{zL} = \_ \_ A$<br>$L_{max} = \_ \_ mH$ | <b>N/A</b> |
|              | <b>– Combinations of currents and corresponding voltages within the limitations <math>I_{zR}.U_{zR} \leq 50 W</math> extrapolated from Fig G.1</b>  |   | <b>N/A</b> |
|              | <b>No extrapolation made for voltages above 42 V</b>  |   | <b>N/A</b> |
|              | <b>– Combinations of capacitances and corresponding voltages within limitations of <math>C/2U^2 \leq 1.2 mJ</math> extrapolated from Fig G.2</b>  |   | <b>N/A</b> |
|              | <b>No extrapolation made for voltages above 242V</b>  |   | <b>N/A</b> |
|              | <b><math>U_{max}</math> determined using actual resistance R</b>  |   | <b>N/A</b> |

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| Clause       | Requirement + Test  | Result - Remark | Verdict    |
|              | – Combinations of currents and corresponding inductances within limitations $L/2I^2 \leq 0.3 \text{ mJ}$ extrapolated from Fig G.3  |                 | N/A        |
|              | No extrapolation made for inductances larger than 900 mH  |                 | N/A        |
|              | – $U_{\text{max}}$ was the highest supply voltage occurring in circuit under investigation with sparking contact open   |                 | N/A        |
|              | – $I_{\text{max}}$ was the highest current flowing in circuit under investigation with sparking contact closed  |                 | N/A        |
|              | – $C_{\text{max}}$ and $L_{\text{max}}$ taken as values occurring at the component under investigation producing sparks   |                 | N/A        |
|              | – Peak value considered when a.c. supplied  |                 | N/A        |
|              | – An equivalent circuit calculated to determine equivalent max capacitance, inductance, and equivalent $U_{\text{max}}$ and $I_{\text{max}}$ , either as d.c. or a.c. peak values in case of a complicated circuit... : |                 | N/A        |
|              | Temperature measurements made according to 11.1, and $U_{\text{max}}$ , $I_{\text{max}}$ , R, $L_{\text{max}}$ , and $C_{\text{max}}$ determined with application of Figs G.1-G.3 .. :                                  |                 | N/A        |
|              | Alternatively, compliance was verified by examination of design data.....:  |                 | N/A        |
| <b>G.5.4</b> | <b>External ventilation with internal overpressure</b>  |                 | <b>N/A</b> |
|              | ME EQUIPMENT, its parts, and components enclosed in an ENCLOSURE with external ventilation by means of internal overpressure complied with the following requirements:  |                 | N/A        |
|              | a) FLAMMABLE AESTHETIC MIXTURES WITH AIR removed by ventilation before EQUIPMENT energized,   |                 | N/A        |
|              | b) Overpressure inside ENCLOSURE was 75 Pa, min., in NORMAL CONDITION (Pa)..... :   |                 | N/A        |
|              | Overpressure maintained at the site of potential ignition   |                 | N/A        |
|              | ME EQUIPMENT could be energized only after the required minimum overpressure was present long enough to ventilate the ENCLOSURE   |                 | N/A        |
|              | ME EQUIPMENT energized at will or repeatedly when overpressure was continuously present   |                 | N/A        |
|              | c) Ignition sources de-energized automatically when during operation overpressure dropped below 50 Pa (Pa) .....  |                 | N/A        |
|              | d) External surface of ENCLOSURE did not exceed 150 °C in 25 °C..... :  |                 | N/A        |

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|--------------|--|-----------------|------------|
| Clause       | Requirement + Test   | Result - Remark | Verdict    |
| <b>G.5.5</b> | <b>ENCLOSURES with restricted breathing</b>  |                 | <b>N/A</b> |
|              | <b>ME EQUIPMENT, its parts, and components enclosed in an ENCLOSURE with restricted breathing complied with the following:</b>   |                 | <b>N/A</b> |
|              | <b>a) A FLAMMABLE AESTHETIC MIXTURE WITH AIR did not form inside ENCLOSURE with restricted breathing</b>   |                 | <b>N/A</b> |
|              | <b>b) Gasket or sealing material used to maintain tightness complied with aging test B-b of IEC 60068-2-2, Clause 15, at 70 °C ± 2 °C and 96 h :</b>   |                 | <b>N/A</b> |
|              | <b>c) Gas-tightness of ENCLOSURE containing inlets for flexible cords maintained</b>   |                 | <b>N/A</b> |
|              | <b>Cords are fitted with adequate anchorages to limit stresses as determined by test</b>   |                 | <b>N/A</b> |
|              | <b>Overpressure not reduced below 200 Pa</b>   |                 | <b>N/A</b> |
|              | <b>Tests waived when examination of ENCLOSURE indicated it is completely sealed or gas-tight without a doubt (100 % degree of certainty)</b>   |                 | <b>N/A</b> |
|              | <b>Operating temperature of external surface of ENCLOSURE was ≤ 150 °C in 25 °C (°C)..... :</b>  |                 | <b>N/A</b> |
|              | <b>Steady state operating temperature of ENCLOSURE also measured (°C)..... :</b>   |                 | <b>N/A</b> |
| <b>G.6</b>   | <b>CATEGORY APG ME EQUIPMENT, parts and components thereof</b>   |                 | <b>N/A</b> |
| <b>G.6.1</b> | <b>ME EQUIPMENT, its parts, and components did not ignite FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE under NORMAL USE and SINGLE FAULT CONDITION</b>   |                 | <b>N/A</b> |
|              | <b>ME EQUIPMENT, its parts, and components not complying with G.6.3 subjected to a CONTINUOUS OPERATION test</b>   |                 | <b>N/A</b> |
| <b>G.6.2</b> | <b>Parts and components of CATEGORY APG ME EQUIPMENT operating in a FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE supplied from a source isolated from earth by insulation equal to one MEANS OF PATIENT PROTECTION and from electrical parts by insulation twice the MEANS OF PATIENT PROTECTION .....</b> |                 | <b>N/A</b> |
| <b>G.6.3</b> | <b>Test of G.6.1 waived when the following requirements were met in NORMAL USE and under NORMAL and SINGLE FAULT CONDITIONS..... :</b>   |                 | <b>N/A</b> |
|              | <b>a) no sparks produced and temperatures did not exceed 90 °C, or</b>   |                 | <b>N/A</b> |
|              | <b>b) a temperature limit of 90 °C not exceeded, sparks produced in NORMAL USE, and SINGLE FAULT CONDITIONS, except U<sub>max</sub> and I<sub>max</sub> occurring in their circuits complied with requirements, taking C<sub>max</sub> and L<sub>max</sub> into consideration:</b>                                     |                 | <b>N/A</b> |

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|-------------|---|---|---------|
| Clause      | Requirement + Test  | Result - Remark   | Verdict |
|             | Measured $U_{max} \leq U_{zR}$ with $I_{zR}$ as in Fig. G.4 .... :  | $U_{max} = \_\_V$<br>$U_{zR} = \_\_V$<br>$I_{zR} = \_\_A$   | N/A     |
|             | Measured $U_{max} \leq U_{zC}$ with $C_{max}$ as in Fig. G.5... :   | $U_{max} = \_\_V$<br>$U_c = \_\_V$<br>$C_{max} = \_\_\mu F$ | N/A     |
|             | Measured $I_{max} \leq I_{zR}$ with $U_{zR}$ as in Fig G.4 ..... :  | $I_{max} = \_\_A$<br>$I_{zR} = \_\_A$<br>$U_{zR} = \_\_V$   | N/A     |
|             | Measured $I_{max} \leq I_{zL}$ with $L_{max}$ and a $U_{max} \leq 24 V$ as in Fig G.6 ..... :   | $I_{max} = \_\_A$<br>$I_{zL} = \_\_A$<br>$L_{max} = \_\_mH$ | N/A     |
|             | - Extrapolation from Figs G.4, G.5, and G.6 was limited to areas indicated  |   | N/A     |
|             | - $U_{max}$ was the highest no-load voltage occurring in the circuit under investigation, taking into consideration mains voltage variations as in 4.10   |   | N/A     |
|             | - $I_{max}$ was the highest current flowing in the circuit under investigation, taking into account MAINS VOLTAGE variations as in 4.10   |   | N/A     |
|             | - $C_{max}$ and $L_{max}$ are values occurring in relevant circuit  |   | N/A     |
|             | - $U_{max}$ additionally determined with actual resistance R when equivalent resistance R in Fig G.5 was less than 8000 $\Omega$  |   | N/A     |
|             | - Peak value considered when a.c. supplied  |   | N/A     |
|             | - An equivalent circuit calculated to determine max capacitance, inductance, and $U_{max}$ and $I_{max}$ , either as d.c. or a.c. peak values in case of a complicated circuit ..... :  |   | N/A     |
|             | - When energy produced in an inductance or capacitance in a circuit is limited by voltage or current-limiting devices, two independent components applied, to obtain the required limitation even when a first fault (short or open circuit) in one of these components |   | N/A     |
|             | - requirement not applied to transformers complying with this standard  |   | N/A     |
|             | - requirement not applied to wire-wound current-limiting resistors provided with a protection against unwinding of the wire in case of rupture  |   | N/A     |
|             | Compliance verified by examination of CATEGORY APG ME EQUIPMENT, parts, and components , or   |   | N/A     |
|             | Temperature measurements made in accordance with 11.1..... :  |   | N/A     |

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|-------------|--|---|---------|
| Clause      | Requirement + Test   | Result - Remark   | Verdict |
|             | - or $U_{max}$ , $I_{max}$ , $R$ , $L_{max}$ and $C_{max}$ determined together with application of Figs G.4-G.6..... :   | $U_{max} = \_ \_ V$<br>$I_{max} = \_ \_ A$<br>$R = \_ \_ \Omega$<br>$L_{max} = \_ \_ mH$<br>$C_{max} = \_ \_ \mu F$ | N/A     |
|             | Alternatively, compliance verified by comparison with design data.....:  |   | N/A     |
| G.6.4       | ME EQUIPMENT, its parts, and components heating a FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE provided with a non-SELF-RESETTING THERMAL CUT-OUT and complied with 15.4.2.1 ..... |   | N/A     |
|             | Current-carrying part of heating element is not in direct contact with FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE  |   | N/A     |
| G.7         | Test apparatus for flammable mixtures according to this Clause and Fig G.7   |   | N/A     |

|         |   |  |     |
|---------|---|--|-----|
| ANNEX L | INSULATED WINDING WIRES FOR USE WITHOUT INTERLEAVED INSULATION  |  | N/A |
| L.1     | BASIC, SUPPLEMENTARY, DOUBLE, and REINFORCED INSULATION in wound components without interleaved insulation complied with this Annex                                     | Evaluated separately as part of certified power supply. Certified wire used. | N/A |
| L.2     | Wire construction   |  | N/A |
|         | Overlap of layers when wire is insulated with two or more spirally wrapped layers of tape is adequate to ensure continued overlap during manufacture of wound component |  | N/A |
|         | Layers of spirally wrapped wire insulation are sufficiently secured to maintain the overlap   |  | N/A |
| L.3     | Type Test   |  | N/A |
|         | The wire subjected to tests of L.3.1 to L.3.4 at a temperature and a relative humidity specified  |  | N/A |
|         | Temperature (°C)..... :   |  | —   |
|         | Humidity (%)..... :   |  | —   |
| L.3.1   | Dielectric strength   |  | N/A |
|         | Dielectric strength test of Clause 8.8.3 for the appropriate type and number of MOP(s) conducted with no breakdown:   |  | N/A |
|         | – 3000 V for BASIC and SUPPLEMENTARY INSULATION (V) .....   |  | N/A |
|         | – 6000 V for REINFORCED INSULATION (V)..... :   |  | N/A |
| L.3.2   | Flexibility and adherence   |  |     |
|         | Sample subjected to flexibility and adherence   |  | N/A |

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|-------------|---|-----------------|---------|
| Clause      | Requirement + Test  | Result - Remark | Verdict |
|             | Sample examined per IEC 60851-3: 1997, cl. 5.1.1.4, followed by dielectric test of cl. 8.8.3, with no breakdown             |                 | N/A     |
|             | Test voltage was at least the voltage in Tables 6 and 7 but not less than the following:                                    |                 | N/A     |
|             | – 1500 V for BASIC and SUPPLEMENTARY INSULATION (V) .....   |                 | N/A     |
|             | – 3000 V for REINFORCED INSULATION (V).....   |                 | N/A     |
|             | Tension applied to wire during winding on mandrel calculated from the wire diameter equivalent to 118 MPa ± 11.8 MPa .....  |                 | N/A     |
| L.3.3       | Heat Shock  |                 | N/A     |
|             | Sample subjected to heat shock test 9 of IEC 60851-6:1996, followed by dielectric strength test of clause 8.8.3             |                 | N/A     |
|             | Test voltage was at least the voltage in Tables 6 and 7, but not less than the following:                                   |                 | N/A     |
|             | – 1500 V for BASIC and SUPPLEMENTARY INSULATION (V) .....   |                 | N/A     |
|             | – 3000 V for REINFORCED INSULATION (V).....   |                 | N/A     |
|             | Oven temperature based on Table L.2 (°C).....   |                 | —       |
|             | Mandrel diameter and tension applied as in clause L.3.2, (MPa; N/mm <sup>2</sup> ).....                                     |                 | N/A     |
|             | Dielectric strength test conducted at room temperature after removal from the oven  |                 | N/A     |
| L.3.4       | Retention of electric strength after bending  |                 | N/A     |
|             | Five samples prepared as in L.3.2 subjected to dielectric strength and bending tests  |                 | N/A     |
|             | Test voltage was at least the voltage in Tables 6 and 7, but not less than the following:                                   |                 | N/A     |
|             | – 1500 V for BASIC and SUPPLEMENTARY INSULATION (V) .....   |                 | N/A     |
|             | – 3000 V for REINFORCED INSULATION (V).....   |                 | N/A     |
|             | Test voltage applied between the shot and conductor   |                 | N/A     |
|             | Mandrel diameter and tension applied as in L.3.2, (MPa; N/mm <sup>2</sup> ) .....   |                 | N/A     |
| L.4         | Tests during manufacture  |                 | N/A     |
| L.4.1       | Production line dielectric strength tests done by the manufacture per L.4.2 and L.4.3.....                                  |                 | N/A     |
| L.4.2       | Test voltage for routine testing (100 % testing) is at least the voltage in Tables 6 and 7 but not less than the following: |                 | N/A     |



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|-------------|--|-----------------|---------|
| Clause      | Requirement + Test   | Result - Remark | Verdict |
|             | – 1500 V r.m.s. or 2100 V peak for BASIC and SUPPLEMENTARY INSULATION (V).....:                |                 | N/A     |
|             | – 3000 V r.m.s. or 4200 V peak for REINFORCED INSULATION (V) .....                             |                 | N/A     |
| L.4.3       | Sampling tests conducted using twisted pair samples (IEC 60851-5:1996, clause 4.4.1).....:     |                 | N/A     |
|             | Minimum breakdown test voltage at least twice the voltage in Tables 6 and 7 but not less than: |                 | N/A     |
|             | – 3000 V r.m.s. or 4200 V peak for BASIC and SUPPLEMENTARY INSULATION .....                    |                 | N/A     |
|             | – 6000 V r.m.s. or 8400 V peak for REINFORCED INSULATION.....:                                 |                 | N/A     |

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|-------------|--------------------|-----------------|---------|
| Clause      | Requirement + Test | Result - Remark | Verdict |

|   |   |                |           |
|---|---|----------------|-----------|
| <b>4.3</b>  | <b>TABLE: ESSENTIAL PERFORMANCE</b>   |                | <b>NE</b> |
| <b>List of ESSENTIAL PERFORMANCE functions</b>  | <b>MANUFACTURER'S document number reference or reference from this standard or collateral or particular standard(s)</b> | <b>Remarks</b> |           |
|   |   |                |           |
| <b>Supplementary Information:</b><br>ESSENTIAL PERFORMANCE is performance, the absence or degradation of which, would result in an unacceptable risk. |   |                |           |

|  |                           |                       |                    |                        |                             |          |
|--|---------------------------|-----------------------|--------------------|------------------------|-----------------------------|----------|
| <b>4.11</b>                                | <b>TABLE: Power Input</b> |                       |                    |                        |                             | <b>P</b> |
| <b>Operating Conditions / Ratings</b>      | <b>Voltage (V)</b>        | <b>Frequency (Hz)</b> | <b>Current (A)</b> | <b>Power (W or VA)</b> | <b>Power factor (cos φ)</b> |          |
| Amplifier playing audio file at max volume | 90                        | 60                    | 0.52               | 17.5                   | 0.41                        |          |
|  | 100                       | 60                    | 0.48               | 17.9                   | 0.40                        |          |
|  | 120                       | 60                    | 0.44               | 17.0                   | 0.37                        |          |
|  | 132                       | 60                    | 0.40               | 17.8                   | 0.36                        |          |
|  | 180                       | 60                    | 0.31               | 17.4                   | 0.30                        |          |
|  | 200                       | 60                    | 0.30               | 17.4                   | 0.29                        |          |
|  | 220                       | 60                    | 0.28               | 17.1                   | 0.27                        |          |
|  | 230                       | 60                    | 0.28               | 17.2                   | 0.27                        |          |
|  | 240                       | 60                    | 0.27               | 17.8                   | 0.26                        |          |
|  | 264                       | 60                    | 0.26               | 17.4                   | 0.26                        |          |

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|--|---------------------------|-----------------|-------------|-----------------|----------------------|
| Clause                                     | Requirement + Test        | Result - Remark |             |                 | Verdict              |
| 4.11                                       | <b>TABLE: Power Input</b> |                 |             |                 | <b>P</b>             |
| Operating Conditions / Ratings             | Voltage (V)               | Frequency (Hz)  | Current (A) | Power (W or VA) | Power factor (cos φ) |
| Amplifier playing audio file at max volume | 90                        | 50              | 0.51        | 19.8            | 0.41                 |
|  | 100                       | 50              | 0.48        | 18.9            | 0.39                 |
|  | 120                       | 50              | 0.42        | 17.6            | 0.36                 |
|  | 132                       | 50              | 0.40        | 18.4            | 0.36                 |
|  | 180                       | 50              | 0.34        | 18.8            | 0.30                 |
|  | 200                       | 50              | 0.32        | 18.6            | 0.29                 |
|  | 220                       | 50              | 0.31        | 18.5            | 0.28                 |
|  | 230                       | 50              | 0.29        | 18.6            | 0.28                 |
|  | 240                       | 50              | 0.24        | 18.9            | 0.26                 |
|  | 264                       | 50              | 0.25        | 18.1            | 0.26                 |
| <b>Supplementary Information:</b>          |                           |                 |             |                 |                      |

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|-------------|--------------------|-----------------|---------|
| Clause      | Requirement + Test | Result - Remark | Verdict |

| 5.9.2   | TABLE: Determination of ACCESSIBLE parts        |                               | P |
|---|---|-------------------------------|---|
| Location  | Determination method (NOTE1)                    | Comments                      |   |
| Transducer  | Visual, Test finger, 30N with rigid test finger | No access to hazardous parts. |   |
| Over ear headphones   | Visual, Test finger, 30N with rigid test finger | No access to hazardous parts. |   |
| In ear headphones   | Visual, Test finger, 30N with rigid test finger | No access to hazardous parts. |   |
| <b>Supplementary information:</b><br><sup>1)</sup> NOTE: The determination methods are: visual; rigid test finger; jointed test finger. |   |                               |   |

| 8.4.2   | TABLE: TABLE: Working Voltage / Power Measurement |            |                                   |            |            | N/A     |
|---|---|------------|-----------------------------------|------------|------------|---------|
| Test supply voltage/frequency (V/Hz) <sup>1)</sup> ..... :  |   |            |                                   |            |            |         |
| Location From/To  | Measured values                                   |            |                                   |            |            | Remarks |
|   | Vrms  | Vpk or Vdc | Peak-to-peak ripple <sup>2)</sup> | Power W/VA | Energy (J) |         |
| -   | -   | -          | -                                 | -          | -          | -       |
| <b>Supplementary Information:</b><br><sup>1)</sup> The input supply voltage to the ME EQUIPMENT was the RATED voltage or the voltage within the RATED voltage range which results in the highest measured value. See clause 8.5.4.<br><sup>2)</sup> . If the d.c peak-to-peak ripple >10%, waveform considered as a.c. See clause 8.4.2.2 |   |            |                                   |            |            |         |

| 8.4.3   | TABLE: ME EQUIPMENT for connection to a power source by a plug - measurement of voltage or calculation of stored charge 1 s after disconnection of plug from mains supply |   |   |   |   |   |   |   |   |    | N/A |
|---|---|---|---|---|---|---|---|---|---|----|-----|
| Maximum allowable voltage (V)..... :  |   |   |   |   |   |   |   |   |   |    | 60  |
| Voltage measured (V)  |   |   |   |   |   |   |   |   |   |    |     |
| Voltage Measured Between:   | 1   | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |     |
| Plug pins 1 and 2   |   |   |   |   |   |   |   |   |   |    |     |
| Plug pin 1 and plug earth pin   |   |   |   |   |   |   |   |   |   |    |     |
| Plug pin 2 and plug earth pin   |   |   |   |   |   |   |   |   |   |    |     |
| Plug pin 1 and enclosure  |   |   |   |   |   |   |   |   |   |    |     |
| Plug pin 2 and enclosure  |   |   |   |   |   |   |   |   |   |    |     |
| Maximum allowable stored charge when measured voltage exceeded 60 v (µc)..... : |   |   |   |   |   |   |   |   |   |    | 45  |
| Calculated stored charge (µc)   |   |   |   |   |   |   |   |   |   |    |     |
| Voltage Measured Between:   | 1   | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |     |

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|--|--------------------|----|----|----|----|-----------------|----|----|----|----|---------|
| Clause   | Requirement + Test |    |    |    |    | Result - Remark |    |    |    |    | Verdict |
| Plug pins 1 and 2  | --                 | -- | -- | -- | -- | --              | -- | -- | -- | -- | --      |
| Plug pin 1 and plug earth pin  | --                 | -- | -- | -- | -- | --              | -- | -- | -- | -- | --      |
| Plug pin 2 and plug earth pin  | --                 | -- | -- | -- | -- | --              | -- | -- | -- | -- | --      |
| Plug pin 1 and enclosure   | --                 | -- | -- | -- | -- | --              | -- | -- | -- | -- | --      |
| Plug pin 2 and enclosure   | --                 | -- | -- | -- | -- | --              | -- | -- | -- | -- | --      |
| Supplementary information:<br>PSU accepted based on current UL Listing to UL 60950-1 |                    |    |    |    |    |                 |    |    |    |    |         |

| 8.4.4   | TABLE: Internal capacitive circuits – measurement of residual voltage or calculation of the stored charge in capacitive circuits (i.e., accessible capacitors or circuit parts) after de-energizing ME EQUIPMENT |                               |  |                               |  | N/A     |  |  |  |       |  |
|---|--|-------------------------------|--|-------------------------------|--|---------|--|--|--|-------|--|
| Maximum allowable residual voltage (V) .....  |  |                               |  |                               |  |         |  |  |  | 60 V  |  |
| Maximum allowable stored charge when residual voltage exceeded 60 V ....            |  |                               |  |                               |  |         |  |  |  | 45 µC |  |
| Description of the capacitive circuit (i.e., accessible capacitor or circuit parts) |  | Measured residual voltage (V) |  | Calculated stored charge (µC) |  | Remarks |  |  |  |       |  |
| -   |  | -                             |  | -                             |  | -       |  |  |  |       |  |
| Supplementary information:  |  |                               |  |                               |  |         |  |  |  |       |  |

| 8.5.5.1a                     | TABLE: defibrillation-proof applied parts – measurement of hazardous electrical energies |                                |                       |   |         | N/A |  |  |  |  |  |
|------------------------------|--|--------------------------------|-----------------------|---|---------|-----|--|--|--|--|--|
| Test Condition: Figs. 9 & 10 | Measurement made on accessible part  | Applied part with test voltage | Test voltage polarity | Measured voltage between Y1 and Y2 (mV) | Remarks |     |  |  |  |  |  |
| -                            | -  | -                              | -                     | -                                       | -       |     |  |  |  |  |  |
| Supplementary information:   |  |                                |                       |   |         |     |  |  |  |  |  |

| 8.5.5.1b                       | TABLE: defibrillation-proof applied parts – verification of recovery time |                                  |                            |         |  | N/A |  |  |  |  |  |
|--------------------------------|---|----------------------------------|----------------------------|---------|--|-----|--|--|--|--|--|
| Applied part with test voltage | Test voltage polarity   | Recovery time from documents (s) | Measured recovery time (s) | Remarks |  |     |  |  |  |  |  |
| -                              | -   | -                                | -                          | -       |  |     |  |  |  |  |  |
| Supplementary information:     |   |                                  |                            |         |  |     |  |  |  |  |  |

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|-------------|--------------------|-----------------|---------|
| Clause      | Requirement + Test | Result - Remark | Verdict |

| 8.5.5.2   | TABLE: DEFIBRILLATION-PROOF APPLIED PARTS OR PATIENT CONNECTIONS OF DEFIBRILLATION-PROOF APPLIED PARTS - Energy reduction test –measurement of Energy delivered to a 100 Ω load |                         |                          | N/A |
|---|---|-------------------------|--------------------------|-----|
| Test Voltage applied to   | Measured Energy E1 (mJ)   | Measured Energy E2 (mJ) | Energy E1 as % of E2 (%) |     |
| PATIENT CONNECTION 1 or APPLIED PART with PATIENT CONNECTIONS 2, 3, and 4 of the same APPLIED PART connected to earth   | –   | –                       | –                        |     |
| PATIENT CONNECTION 2 or APPLIED PART with PATIENT CONNECTIONS 1, 3, and 4 of the same APPLIED PART connected to earth   | –   | –                       | –                        |     |
| PATIENT CONNECTION 3 or APPLIED PART with PATIENT CONNECTIONS 1, 2, and 4 of the same APPLIED PART connected to earth   | –   | –                       | –                        |     |
| PATIENT CONNECTION 4 or APPLIED PART with PATIENT CONNECTIONS 1, 2, and 3 of the same APPLIED PART connected to earth   | –   | –                       | –                        |     |
| <b>Supplementary information:</b> For compliance: E1 must at least 90% of E2<br>E1= Measured energy delivered to 100 Ω with ME Equipment connected;<br>E2= Measured energy delivered to 100 Ω without ME equipment connected. |   |                         |                          |     |

| 8.6.4   | TABLE: Impedance and current-carrying capability of PROTECTIVE EARTH CONNECTIONS |   |                                   |                                  | N/A |
|---|--|---|-----------------------------------|----------------------------------|-----|
| Type of ME EQUIPMENT & impedance measured between parts   | Test current (A) /Duration (s)   | Voltage drop measured between parts (V) | Maximum calculated impedance (mΩ) | Maximum allowable impedance (mΩ) |     |
|   |  |   |                                   |                                  |     |
|   |  |   |                                   |                                  |     |
| <b>Supplementary information:</b><br>PERMANENTLY INSTALLED ME EQUIPMENT, impedance between PROTECTIVE EARTH TERMINAL and a PROTECTIVELY EARTHED part - Limit 100 mΩ<br>ME EQUIPMENT with an APPLIANCE INLET, impedance between earth pin in the APPLIANCE INLET and a PROTECTIVELY EARTHED part - Limit 100 mΩ<br>ME EQUIPMENT with an APPLIANCE INLET, impedance between earth pin in the protective earth pin on the DETACHABLE POWER SUPPLY CORD and a PROTECTIVELY EARTHED part - Limit 200 mΩ<br>ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD, impedance between the protective earth pin in the MAINS PLUG and a PROTECTIVELY EARTHED part - Limit 200 mΩ |  |   |                                   |                                  |     |

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|---|-------------------------------|-----------------------|--------------------------|---|
| Clause  | Requirement + Test            | Result - Remark       |                          | Verdict   |
| <b>8.7</b>  | <b>TABLE: leakage current</b> |                       |                          | <b>P</b>  |
| Type of leakage current and test condition (including single faults)                          | Supply voltage (V)            | Supply frequency (Hz) | Measured max. value (µA) | Remarks   |
| Fig. 13 - Earth Leakage (ER)  | —                             | —                     | —                        | Maximum allowed values:<br>5 mA NC; 10 mA SFC   |
| A, NC, S1=1, S5= 1, S12=0   | 264                           | 60                    | 152.6 ac /<br>0.1 dc     | Pass  |
| A, SFC, S1=0, S5= 1, S12=0  | 264                           | 60                    | 231.9 ac /<br>0.2 dc     | Pass  |
| A, NC, S1=1, S5= 0, S12=0 (NW)  | 264                           | 60                    | 162.0 ac /<br>0.1 dc     | Pass  |
| A, SFC, S1=0, S5= 1, S12=1 (NW)   | 264                           | 60                    | 233.4 ac /<br>0.2 dc     | Pass  |
| Fig. 14 - Touch Current (TC)  | —                             | —                     | —                        | Maximum allowed values:<br>100 µA NC; 500 µA SFC  |
| Foil on body or of Transducer   |                               |                       |                          |   |
| A, NC, S1=1, S5=0, S7=1, S12=1  | 264                           | 60                    | 0.8 ac / 0.1<br>dc       | Pass  |
| A, SFC, S1=1, S5=0, S7=0, S12=1   | 264                           | 60                    | 3.6 ac / 0.1<br>dc       | Pass  |
| A, NC, S1=1, S5=0, S7=1, S12=0 (NW)   | 264                           | 60                    | 0.3 ac / 0.1<br>dc       | Pass  |
| A, SFC, S1=1, S5=0, S7=0, S12=0 (NW)  | 264                           | 60                    | 3.6 ac / 0.1<br>dc       | Pass  |
| Fig. 15 - Patient Leakage Current (P)   | —                             | —                     | —                        | Maximum allowed values:<br>Type B or BF AP: 10 µA NC; 50 µA SFC (d.c. current);<br>100 µA NC; 500 µA SFC (a.c.)<br>Type CF AP: 10 µA NC; 50 µA SFC (d.c. or a.c. current) |
| A, NC, S1=1, S5=1, S7=1, S13=1  | 264                           | 60                    | 0.9 ac / 0.0<br>dc       | Pass  |
| A, SFC, S1=1, S5=0, S7=1, S13=1   | 264                           | 60                    | 0.8 ac / 0.0<br>dc       | Pass  |
| A, NC, S1=1, S5=1, S7=1, S13=1 (NW)   | 264                           | 60                    | 0.1 ac / 0.0<br>dc       | Pass  |
| A, SFC, S1=1, S5=1, S7=0, S13=1 (NW)  | 264                           | 60                    | 0.0 ac / 0.1<br>dc       | Pass  |
| Fig. 16 - Patient leakage current with mains on the F-type applied parts (PM)                 | —                             | —                     | —                        | Maximum allowed values:<br>Type B: N/A<br>Type BF AP: 5000 µA<br>Type CF AP: 50 µA  |
| Type B applied part   |                               |                       |                          | N/A   |
| Fig. 17 - Patient leakage current with external voltage on Signal Input/Output part (SIP/SOP) | —                             | —                     | —                        | Maximum allowed values:<br>Type B or BF AP: 10 µA NC; 50 µA SFC(d.c. current);  |

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|---|--------------------|-----------------------|--------------------------|---|---------|
| Clause  | Requirement + Test |                       |                          | Result - Remark   | Verdict |
| Type of leakage current and test condition (including single faults)  | Supply voltage (V) | Supply frequency (Hz) | Measured max. value (µA) | Remarks   |         |
|   |                    |                       |                          | 100 µA NC; 500 µA SFC (a.c.) ;<br>Type CF AP: 10 µA NC; 50 µA SFC (d.c. or a.c. current)  |         |
| Type B applied part   |                    |                       |                          | N/A   |         |
| Fig. 18 - Patient leakage current with external voltage on metal Accessible Part that is not Protectively Earthed   | —                  | —                     | —                        | Maximum allowed values:<br>Type B or BF AP: 500 µA<br>Type CF: N/A  |         |
| No test considered necessary  | —                  | —                     | —                        | N/A   |         |
| Fig. 19 – Patient Auxiliary Current   | —                  | —                     | —                        | Maximum allowed values:<br>Type B or BF AP: 10 µA NC; 50 µA SFC (d.c. current);<br>100 µA NC; 500 µA SFC (a.c.) ;<br>Type CF AP: 10 µA NC; 50 µA SFC (d.c. or a.c. current)     |         |
| Single applied part   | —                  | —                     | —                        | N/A   |         |
| Fig. 15 and 20 – Total Patient Leakage Current with all AP of same type connected together  | —                  | —                     | —                        | Maximum allowed values:<br>Type B or BF AP: 50 µA NC;<br>100µA SFC (d.c. current);<br>500 µA NC; 1000 µA SFC (a.c.);<br>Type CF AP: 50 µA NC; 100 µA SFC (d.c. or a.c. current) |         |
| Single applied part   | —                  | —                     | —                        | N/A   |         |
| Fig. 17 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on SIP/SOP   | —                  | —                     | —                        | Maximum allowed values:<br>Type B or BF AP: 50 µA NC;<br>100µA SFC (d.c. current);<br>500 µA NC; 1000 µA SFC (a.c.);<br>Type CF AP: 50 µA NC; 100 µA SFC (d.c. or a.c. current) |         |
| Single applied part   | —                  | —                     | —                        | N/A   |         |
| Fig. 16 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on F-type AP   | —                  | —                     | —                        | Maximum allowed values:<br>Type B: NA<br>Type BF: 5000 µA<br>Type CF: 100 µA  |         |
| Single applied part   | —                  | —                     | —                        | N/A   |         |
| Fig. 18 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on metal Accessible Part not Protectively Earthed  | —                  | —                     | —                        | Maximum allowed values:<br>Type B & BF: 1000 µA<br>Type CF: N/A   |         |
| Single applied part   | —                  | —                     | —                        | N/A   |         |
| Function Earth Conductor Leakage Current (FECLC)  | —                  | —                     | —                        | Maximum allowed values:<br>5 mA NC; 10 mA SFC   |         |
| Test not conducted.   | —                  | —                     | —                        | —   |         |
| <b>Supplementary information:</b>   |                    |                       |                          |   |         |
| Note 1: For EARTH LEAKAGE CURRENT see 8.7.3 d) and 8.7.4.5;   |                    |                       |                          |   |         |
| Note 2: For TOUCH CURRENT see 8.7.3 c) and 8.7.4.6;   |                    |                       |                          |   |         |
| Note 3: For PATIENT LEAKAGE CURRENT SEE 8.7.3.b) and 8.7.4.7  |                    |                       |                          |   |         |
| Note 4: Total PATIENT LEAKAGE CURRENT values are only relative to equipment with multiple APPLIED PARTS of the same type. See 8.7.4.7 h). The individual APPLIED PARTS complied with the PATIENT LEAKAGE CURRENT values.                          |                    |                       |                          |   |         |
| Note 5: In addition to conditions indicated in the Table, tests conducted at operating temperature and after humidity preconditioning of 5.7, EQUIPMENT energized in stand-by condition and fully operating, max rated supply frequency, at 110 % |                    |                       |                          |   |         |



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|-------------|--------------------|-----------------|---------|
| Clause      | Requirement + Test | Result - Remark | Verdict |

| Type of leakage current and test condition (including single faults)   | Supply voltage (V) | Supply frequency (Hz) | Measured max. value (µA)   | Remarks |
|--|--------------------|-----------------------|--|---------|
| of the max RATED MAINS VOLTAGE, and after relevant tests of Clause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate matter, cleaning & disinfection, & sterilization).  |                    |                       |  |         |
| <b>(NW) – Non Weighted measurement</b>   |                    |                       |  |         |
| ER - Earth leakage current<br>TC – Touch current<br>P - Patient leakage current<br>PA – Patient auxiliary current<br>TP – Total Patient current<br>PM - Patient leakage current with mains on the applied parts<br>MD - Measuring device |                    |                       | A - After humidity conditioning<br>B - Before humidity conditioning<br>1 - Switch closed or set to normal polarity<br>0 - Switch open or set to reversed polarity<br>NC - Normal condition<br>SFC - Single fault condition |         |

| Insulation under test (area from insulation diagram) | Insulation Type (1 or 2 MOOP/MOPP) | Reference Voltage                          |                                 | A.C. test voltages in V r.m.s <sup>1)</sup> | Dielectric breakdown after 1 minute Yes/No <sup>2)</sup> |
|--|------------------------------------|--|---------------------------------|---|--|
|  |                                    | PEAK WORKING VOLTAGE (U) V <sub>peak</sub> | PEAK WORKING VOLTAGE (U) V d.c. |   |  |
| A  | 2 MOOP                             | 240  | 340                             | --  | No 1)  |
| B  | 2 MOOP                             | 240  | 340                             | --  | No 1)  |
| C  | 2 MOPP                             | 240  | 340                             | 3000  | No 2)  |
| c  | 2 MOPP                             | --   | --                              | 500   | No 3)  |

**Supplementary information:**

<sup>1</sup> Alternatively, per the Table (i.e., \_\_dc), a d.c. test voltage equal to the peak value of the a.c. test voltage used.

<sup>2</sup> A) Immediately after humidity treatment of 5.7, ME EQUIPMENT de-energized, B) after required sterilization PROCEDURE, ME EQUIPMENT de-energized, C) after reaching steady state operating temperature as during heating test of 11.1.1, and D) after relevant tests of 11.6 (i.e., overflow, spillage, leakage, ingress of water, cleaning, disinfection, and sterilization).

1) Accepted based on power supply certification.

2) Tested from output of the Transducer to headphones.

3) Tested from input of Transducer to accessible enclosure of Transducer. Not relied upon for insulation. Test performed for informational purposes.

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|---|--|------------------------------|---------------------------------|
| Clause  | Requirement + Test   | Result - Remark              | Verdict                         |
| 8.8.4.1   | <b>TABLE: Resistance to heat - Ball pressure test of thermoplastic parts</b> |                              | <b>N/A</b>                      |
|   | Allowed impression diameter (mm) .....                                       | ≤ 2 mm                       | —                               |
|   | Force (N).....   | 20                           | —                               |
| <b>Part/material</b>                                    |  | <b>Test temperature (°C)</b> | <b>Impression diameter (mm)</b> |
| Enclosure/External insulating parts                     |  |                              |                                 |
| Insulating material supporting un-insulated Mains Parts |  |                              |                                 |
| Supplementary information:                              |  |                              |                                 |

|   |   |  |  |                |
|---|---|--|--|----------------|
| 8.9.2   | <b>TABLE: Short circuiting of each single one of the CREEPAGE DISTANCES and AIR CLEARANCES for insulation in the MAINS PART between parts of opposite polarity in lieu of complying with the required measurements in 8.9.4</b> |  |  | <b>N/A</b>     |
|   | <b>Specific areas of circuits short-circuited and test conditions</b>   | <b>Test in lieu of CREEPAGE DISTANCE or AIR CLEARANCE<sup>1)</sup></b> | <b>HAZARDOUS SITUATION observed (i.e., fire hazard, shock hazard, explosion, discharge of parts, etc.)? Yes/No</b> | <b>Remarks</b> |
|   | —   | —  | —  | —              |
| <b>Supplementary information:</b>                             |   |  |  |                |
| <sup>1)</sup> Note: AC - AIR CLEARANCE CD - CREEPAGE DISTANCE |   |  |  |                |

|   |   |                                |  |  |
|---|---|--------------------------------|--|--|
| 8.9.3.2   | <b>Table: Thermal cycling tests on one sample of insulating compound forming solid insulation between conductive parts</b>                |                                |  | <b>N/A</b>   |
| <b>Part Test</b>  | <b>8.9.3.4 - Test duration and temperature for 10 cycles after which the sample was subjected to Humidity Preconditioning per Cl. 5.7</b> | <b>Dielectric test voltage</b> | <b>Dielectric strength test after humidity preconditioning per cl. 5.7 except for 48 h only, Breakdown: Yes/No</b> | <b>Crack or voids in the insulating compound: Yes/No</b> |
| —   | 68 h at T1 ± 2 °C = ___ °C <sup>1)</sup>  | —                              | —  | —  |
|   | 1 h at 25 °C ± 2 °C   |                                |  |  |
|   | 2 h at 0 °C ± 2 °C  |                                |  |  |
|   | 1 or more h at 25 °C ± 2 °C   |                                |  |  |
| <b>Supplementary information:</b>   |   |                                |  |  |
| <sup>1)</sup> T1 = 10 °C above the maximum temperature of relevant part determined per 11.1.1, or 85 °C, the higher of the two. 10 °C not added to T1 when temperature measured by an embedded thermocouple. Used gradual transition from one temperature to another. |   |                                |  |  |

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|-------------|--------------------|-----------------|---------|
| Clause      | Requirement + Test | Result - Remark | Verdict |

| 8.9.3.3   | Table: Thermal cycling tests on one sample of cemented joint with other insulating parts (see 8.9.3.3) |   |                         | N/A  |
|---|--|---|-------------------------|--|
| Part tested   | Sample   | Each test duration and temperature  | Dielectric test voltage | Dielectric strength test Breakdown: Yes/No |
|   | 1  | 10 Cycles conducted of the following:                                       | -                       | -  |
|   |  | 1 - 68 h at $T1 \pm 2 \text{ }^\circ\text{C} = \text{___ }^\circ\text{C}^1$ |                         |  |
|   |  | 2 - 1 h at $25 \text{ }^\circ\text{C} \pm 2 \text{ }^\circ\text{C}$         |                         |  |
|   |  | 3 - 2 h at $0 \text{ }^\circ\text{C} \pm 2 \text{ }^\circ\text{C}$          |                         |  |
|   |  | 4 - 1 or more h at $25 \text{ }^\circ\text{C} \pm 2 \text{ }^\circ\text{C}$ |                         |  |
|   | 2  | Humidity Conditioning per 5.7   |                         | -  |
|   | 3  | Humidity Conditioning per 5.7   |                         | -  |
| <b>Supplementary information:</b><br>1) T1 = 10 °C above the maximum temperature of relevant part determined per 11.1.1, or 85 °C, the higher of the two. 10 °C not added to T1 when temperature measured by an embedded thermocouple. Used gradual transition from one temperature to another. |  |   |                         |  |

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|-------------|--------------------|-----------------|---------|
| Clause      | Requirement + Test | Result - Remark | Verdict |

| 8.10 b                 | TABLE: List of identified components with HIGH INTEGRITY CHARACTERISTICS |                        |                |                           |  | N/A |
|------------------------|--|------------------------|----------------|---------------------------|--|-----|
| Component/<br>Part No. | Manufacturer/<br>Trademark   | Type No./model<br>No./ | Technical data | Standard No./,<br>Edition | Mark(s) &<br>Certificates of<br>conformity <sup>1)</sup> |     |
| -                      | -  | -                      | -              | -                         | -  |     |

**Supplementary information:**  
1) Indicates a mark which assures the agreed level of surveillance. See Licenses and Certificates of Conformity for verification.

| 8.11.3.5        | TABLE: Cord anchorages    |          |            |         |  | N/A |
|-----------------|---------------------------|----------|------------|---------|--|-----|
| Cord under test | Mass of<br>equipment (kg) | Pull (N) | Torque Nm) | Remarks |  |     |
| -               | -                         | -        | -          | -       |  |     |

**Supplementary information:**

| 8.11.3.6        | TABLE: Cord guard |                    |         |  | N/A |
|-----------------|-------------------|--------------------|---------|--|-----|
| Cord under test | Test mass         | Measured curvature | Remarks |  |     |
| -               | -                 | -                  | -       |  |     |

**Supplementary information:**

| 9.2.2.2           | TABLE: Measurement of gap “a” according to Table 20 (ISO 13852: 1996) |                           |  |                              | N/A |
|-------------------|---|---------------------------|--|------------------------------|-----|
| Part of body      | Allowable adult<br>gap <sup>1)</sup> , mm                             | Measured adult<br>gap, mm | Allowable children<br>gap <sup>1)</sup> , mm | Measured children<br>gap, mm |     |
| Body              | > 500   | -                         | > 500  | -                            |     |
| Head              | > 300 or < 120  | -                         | > 300 or < 60                                | -                            |     |
| Leg               | > 180   | -                         | > 180  | -                            |     |
| Foot              | > 120 or < 35   | -                         | > 120 or < 25                                | -                            |     |
| Toes              | > 50  | -                         | > 50   | -                            |     |
| Arm               | > 120   | -                         | > 120  | -                            |     |
| Hand, wrist, fist | > 100   | -                         | > 100  | -                            |     |
| Finger            | > 25 or < 8   | -                         | > 25 or < 4                                  | -                            |     |

**Supplementary information:** <sup>1)</sup> In general, gaps for adults used, except when the device is specifically

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|-------------|--------------------|-----------------|---------|
| Clause      | Requirement + Test | Result - Remark | Verdict |

designed for use with children, values for children applied.

| 9.2.3.2                    | TABLE: Over-travel End Stop Test     |  | N/A     |
|----------------------------|--------------------------------------|--|---------|
| ME EQUIPMENT end stop      | Test Condition (cycles, load, speed) |  | Remarks |
| –                          | –                                    |  | –       |
| Supplementary information: |                                      |  |         |

| 9.4.2.1                    | TABLE: Instability—overbalance in transport position |           | P |
|----------------------------|--|-----------|---|
| ME EQUIPMENT preparation   | Test Condition (transport position)                  | Remarks   |   |
| Transducer                 | 10° tilt   | No hazard |   |
| Supplementary information: |  |           |   |

| 9.4.2.2                    | TABLE: Instability—overbalance excluding transport position   |         | N/A |
|----------------------------|---|---------|-----|
| ME EQUIPMENT preparation   | Test Condition (excluding transport position) Test either 5 ° incline and verify Warning marking or 10 ° incline) | Remarks |     |
|                            |   |         |     |
| Supplementary information: |   |         |     |

| 9.4.2.3                    | TABLE: Instability—overbalance from horizontal and vertical forces                      |         | N/A |
|----------------------------|---|---------|-----|
| ME EQUIPMENT preparation   | Test Condition (force used, direction of force, weight of equipment, location of force) | Remarks |     |
|                            |   |         |     |
| Supplementary information: |   |         |     |

| 9.4.2.4.2                  | TABLE: Castors and wheels – Force for propulsion |         | N/A |
|----------------------------|--|---------|-----|
| ME EQUIPMENT preparation   | Test Condition (force location and height)       | Remarks |     |
|                            |  |         |     |
| Supplementary information: |  |         |     |

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|----------------------------|---|-----------------|---------|
| Clause                     | Requirement + Test                                    | Result - Remark | Verdict |
| 9.4.2.4.3                  | TABLE: Castors and wheels – Movement over a threshold |                 | N/A     |
| ME EQUIPMENT preparation   | Test Condition (speed of movement)                    | Remarks         |         |
|                            |   |                 |         |
| Supplementary information: |   |                 |         |

| 9.4.3.1                    | TABLE: Instability from unwanted lateral movement (including sliding) in transport position |         | N/A |
|----------------------------|---|---------|-----|
| ME EQUIPMENT preparation   | Test Condition (speed of movement)  | Remarks |     |
|                            |   |         |     |
| Supplementary information: |   |         |     |

| 9.4.3.2                    | TABLE: Instability from unwanted lateral movement (including sliding) excluding transport position        |         | N/A |
|----------------------------|---|---------|-----|
| ME EQUIPMENT Preparation   | Test Condition (working load, locking device(s), caster position, force, force location, force direction) | Remarks |     |
|                            |   |         |     |
| Supplementary information: |   |         |     |

| 9.4.4                      | TABLE: Grips and other handling devices |         | N/A |
|----------------------------|---|---------|-----|
| Clause and Name of Test    | Test Condition                          | Remarks |     |
|                            |   |         |     |
| Supplementary information: |   |         |     |

| 9.7.5  | TABLE: Pressure vessels |                       |       |                        | N/A     |
|--|-------------------------|-----------------------|-------|------------------------|---------|
| Hydraulic, Pneumatic or Suitable Media and Test Pressure | Vessel Burst            | Permanent Deformation | Leaks | Vessel fluid substance | Remarks |
| –  | –                       | –                     | –     | –                      | –       |
| Supplementary Information:                               |                         |                       |       |                        |         |

|         |  |  |     |
|---------|--|--|-----|
| 9.8.3.2 | TABLE: PATIENT support/suspension system - Static forces |  | N/A |
|---------|--|--|-----|

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|-----------------------------------|---|------|------|-----------------|------------|
| Clause                            | Requirement + Test  |      |      | Result - Remark | Verdict    |
| 9.8.3.2                           | <b>TABLE: PATIENT support/suspension system - Static forces</b> |      |      |                 | <b>N/A</b> |
| ME EQUIPMENT part or area         | Position  | Load | Area | Remarks         |            |
| -                                 | -   | -    | -    | -               |            |
| <b>Supplementary Information:</b> |   |      |      |                 |            |

| 9.8.3.3   |          |                   |      |         |  |
|---|----------|-------------------|------|---------|--|
| TABLE: Support/Suspension System – Dynamic forces due to loading from persons |          |                   |      | Verdict |  |
| ME EQUIPMENT part or area   | Position | Safe Working Load | Area | Remarks |  |
| -   | -        | -                 | -    | -       |  |
| <b>Supplementary Information:</b>   |          |                   |      |         |  |

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|-------------|--------------------|-----------------|---------|
| Clause      | Requirement + Test | Result - Remark | Verdict |

| 10.1.1  | TABLE: Measurement of X - radiation |   | N/A     |
|---|-------------------------------------|---|---------|
| Maximum allowable radiation pA/kg ( μSv/h) (mR/h)                 |                                     | 36 (5 μSv/h) (0.5 mR/h)                     |         |
| Surface area under test<br>Surface no./ Description <sup>1)</sup> |                                     | Measured Radiation,<br>pA/kg (μSv/h) (mR/h) | Remarks |
| 1/  | /                                   | –   | –       |
| 2/  | /                                   | –   | –       |
| 3/  | /                                   | –   | –       |
| 4/  | /                                   | –   | –       |
| 5/  | /                                   | –   | –       |
| 6/  | /                                   | –   | –       |
| 7/  | /                                   | –   | –       |
| 8/  | /                                   | –   | –       |
| 9/  | /                                   | –   | –       |
| 10/   | /                                   | –   | –       |

**Supplementary information:**  
<sup>1)</sup> Measurements made at a distance of 5 cm from any surface to which OPERATOR (other than SERVICE PERSONNEL) can gain access without a TOOL, is deliberately provided with means of access, or is instructed to enter regardless of whether or not a TOOL is needed to gain access



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|-------------|--------------------|-----------------|---------|
| Clause      | Requirement + Test | Result - Remark | Verdict |

| 11.1.1   | <b>TABLE: Excessive temperatures in ME EQUIPMENT</b> |  |  |   |      | <b>P</b>          |
|--|--|--|--|---|------|-------------------|
| Model No..... :  |  |  |  |   |      |                   |
| Test ambient (°C) .....                                |  | See below  |  |   |      |                   |
| Test supply voltage/frequency (V/Hz) <sup>4)</sup> . : |  | 90V, 60Hz  |  |   |      |                   |
| Model No.  | Thermo-couple No.                                    | Thermocouple location <sup>3)</sup>                  | Max allowable temperature <sup>1)</sup> from Table 22, 23 or 24 or RM file for AP <sup>5)</sup> (°C) | Max measured temperature <sup>2)</sup> , (°C)<br>Measured / corrected |      | Remarks           |
|  | 1  | PSU enclosure  | 60, Table 22   | 32.5  | 49.9 | 10 sec > t > 1min |
|  | 2  | Amplifier enclosure Top                              | 48, Table 22   | 27.0  | 44.4 | t > 1min          |
|  | 3  | Amplifier enclosure Front                            | 48, Table 22   | 28.8  | 46.2 | t > 1min          |
|  | 4  | Transducer enclosure Top adjacent to input connector | 48, Table 22   | 29.0  | 46.4 | t > 1min          |
|  | 5  | Transducer enclosure Front                           | 48, Table 22   | 28.3  | 45.7 | t > 1min          |
|  | 6  | Headphone pad  | 43, Table 23   | 22.9  | 40.3 | t > 10min         |
|  | 7  | Headphone External enclosure                         | 43, Table 23   | 23.2  | 40.6 | t > 10min         |
|  | 8  | Ambient  | 85, Table 22   | 22.6  | 40.0 | ---               |

**Supplementary information:**

- 1) Maximum allowable temperature on surfaces of test corner is 90 °C
- 2) Max temperature determined in accordance with 11.1.3e)
- 3) When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C.
- 4) Supply voltage:
  - ME EQUIPMENT with heating elements - 110 % of the maximum RATED voltage;
  - Motor operated ME EQUIPMENT - least favourable voltage between 90 % of the minimum RATED and 110 % of the maximum RATED voltage. ME EQUIPMENT operated under normal load and normal DUTY CYCLE.
  - Combined heating and motor operated and other ME EQUIPMENT - tested both at 110 % of the maximum RATED voltage and at 90 % of the minimum RATED voltage.
- 5) **APPLIED PARTS** intended to supply heat to a **PATIENT** - See RISK MANAGEMENT FILE containing temperatures and clinical effects. Also, see instructions for use.

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|-------------|--------------------|-----------------|---------|
| Clause      | Requirement + Test | Result - Remark | Verdict |

| 11.1.1   | <b>TABLE: Excessive temperatures in ME EQUIPMENT</b> |  |  |   |      | <b>P</b>          |
|--|--|--|--|---|------|-------------------|
| <b>Model No..... :</b>                                       |  |  |  |   |      |                   |
| <b>Test ambient (°C) .....</b>                               |  | See below  |  |   |      |                   |
| <b>Test supply voltage/frequency (V/Hz)<sup>4)</sup> . :</b> |  | 264V, 50Hz   |  |   |      |                   |
| Model No.  | Thermo-couple No.                                    | Thermocouple location <sup>3)</sup>                  | Max allowable temperature <sup>1)</sup> from Table 22, 23 or 24 or RM file for AP <sup>5)</sup> (°C) | Max measured temperature <sup>2)</sup> , (°C)<br>Measured / corrected |      | Remarks           |
|  | 1  | PSU enclosure  | 60, Table 22   | 31.7  | 48.6 | 10 sec > t > 1min |
|  | 2  | Amplifier enclosure Top                              | 48, Table 22   | 26.4  | 43.3 | t > 1min          |
|  | 3  | Amplifier enclosure Front                            | 48, Table 22   | 28.0  | 44.9 | t > 1min          |
|  | 4  | Transducer enclosure Top adjacent to input connector | 48, Table 22   | 28.1  | 45.0 | t > 1min          |
|  | 5  | Transducer enclosure Front                           | 48, Table 22   | 27.2  | 44.1 | t > 1min          |
|  | 6  | Headphone pad  | 43, Table 23   | 22.9  | 39.8 | t > 10min         |
|  | 7  | Headphone External enclosure                         | 43, Table 23   | 22.9  | 39.8 | t > 10min         |
|  | 8  | Ambient  | 85, Table 22   | 23.1  | 40.0 | ---               |

**Supplementary information:**

- 1) Maximum allowable temperature on surfaces of test corner is 90 °C
- 2) Max temperature determined in accordance with 11.1.3e)
- 3) When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C.
- 4) Supply voltage:
  - ME EQUIPMENT with heating elements - 110 % of the maximum RATED voltage;
  - Motor operated ME EQUIPMENT - least favourable voltage between 90 % of the minimum RATED and 110 % of the maximum RATED voltage. ME EQUIPMENT operated under normal load and normal DUTY CYCLE.
  - Combined heating and motor operated and other ME EQUIPMENT - tested both at 110 % of the maximum RATED voltage and at 90 % of the minimum RATED voltage.
- 5) **APPLIED PARTS** intended to supply heat to a **PATIENT** - See RISK MANAGEMENT FILE containing temperatures and clinical effects. Also, see instructions for use.

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|----------------------------|---|--------------------|---------------------|--------------------|--------|-------------------------------|------------------|
| Clause                     | Requirement + Test  |                    |                     |                    |        | Result - Remark               | Verdict          |
| 11.1.3d                    | TABLE: Temperature of windings by change-of-resistance method |                    |                     |                    |        |                               | N/A              |
| Temperature T of winding:  | t <sub>1</sub> (°C)   | R <sub>1</sub> (Ω) | t <sub>2</sub> (°C) | R <sub>2</sub> (Ω) | T (°C) | Allowed T <sub>max</sub> (°C) | Insulation class |
| -                          | -   | -                  | -                   | -                  | -      | -                             | -                |
| Supplementary information: |   |                    |                     |                    |        |                               |                  |

| 11.2.2.1  | TABLE: Alternative method to 11.2.2.1 a) 5) to determine existence of an ignition source |  |  |   |         | N/A |
|---|--|--|--|---|---------|-----|
| Areas where sparking might cause ignition:  |  |  |  |   | Remarks |     |
| 1.  |  |  |  |   | -       |     |
| 2.  |  |  |  |   | -       |     |
| 3.  |  |  |  |   | -       |     |
| 4.  |  |  |  |   | -       |     |
| 5.  |  |  |  |   | -       |     |
| 6.  |  |  |  |   | -       |     |
| Materials of the parts between which sparks could occur (Composition, Grade Designation, Manufacturer): |  |  |  |   | Remarks |     |
| 1.  |  |  |  |   | -       |     |
| 2.  |  |  |  |   | -       |     |
| 3.  |  |  |  |   | -       |     |
| 4.  |  |  |  |   | -       |     |
| 5.  |  |  |  |   | -       |     |
| 6.  |  |  |  |   | -       |     |
| Test parameters selected representing worst case conditions for ME EQUIPMENT:                           |  |  |  |   | Remarks |     |
| Oxygen concentration (%)..... :   |  |  |  | - | -       |     |
| Fuel..... :   |  |  |  | - | -       |     |
| Current (A)..... :  |  |  |  | - | -       |     |
| Voltage (V)..... :  |  |  |  | - | -       |     |
| Capacitance (µF)..... :   |  |  |  | - | -       |     |
| Inductance or resistance (h or Ω).... :   |  |  |  | - | -       |     |
| No. of trials (300 Min)..... :  |  |  |  | - | -       |     |
| Sparks resulted in ignition (Yes/No) :  |  |  |  | - | -       |     |

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|-------------|--------------------|-----------------|---------|
| Clause      | Requirement + Test | Result - Remark | Verdict |

**Supplementary information:** Test procedure of 11.2.2.1 a) 5) & Figs 35-37 used for tests. For circuits not in Figs 35-37, test voltage or current set at 3 times the worst case values with other parameters set at worst case values to determine if ignition can occur.  
**Information from Risk Management, as applicable:**

| 11.6.1                     | TABLE: overflow, spillage, leakage, ingress of water, cleaning, disinfection, sterilization, compatibility with substances |                 |         | N/A |
|----------------------------|--|-----------------|---------|-----|
| Clause / Test Name         | Test Condition   | Part under test | Remarks |     |
|                            |  |                 |         |     |
| Supplementary information: |  |                 |         |     |

| 13.1.2                                 | TABLE: measurement of power or energy dissipation in parts & components to waive SINGLE FAULT CONDITIONS in 4.7, 8.1 b), 8.7.2, and 13.2.2 relative to emission of flames, molten metal, or ignitable substances |                                  |   | N/A     |
|--|--|----------------------------------|---|---------|
| Power dissipated less than (W)..... :  |  | 15                               |   |         |
| Energy dissipated less than (J)..... : |  | 900                              |   |         |
| Part or component tested               | Measured power dissipated (W)  | Calculated energy dissipated (J) | SINGLE FAULT CONDITIONS waived (Yes/No) | Remarks |
|  |  |                                  |   |         |
| Supplementary information:             |  |                                  |   |         |

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|-------------|---|------------------|------------------------------|
| Clause      | Requirement + Test  | Result - Remark  | Verdict                      |
| <b>13.2</b> | <b>TABLE: SINGLE FAULT CONDITIONS in accordance with 13.2.2 to 13.2.13, inclusive</b>   |                  | <b>N/A</b>                   |
| Clause No.  | Description of SINGLE FAULT CONDITION   | Results observed | HAZARDOUS SITUATION (Yes/No) |
| 13.2.2      | Electrical SINGLE FAULT CONDITIONS per Cl. 8.1:   | —                | —                            |
|             | PSU accepted based on active UL Listing.  |                  | N/A                          |
| 13.2.3      | Overheating of transformers per Clause 15.5:  | —                | —                            |
|             | No transformer.   | —                | N/A                          |
| 13.2.4      | Failure of THERMOSTATS according to 13.2.13 & 15.4.2, overloading - THERMOSTATS short circuited or interrupted, the less favourable of the two:                 | —                | —                            |
|             | No thermostats.   | —                | N/A                          |
| 13.2.5      | Failure of temperature limiting devices according to 13.2.13 & 15.4.2, overloading, THERMOSTATS short circuited or interrupted, the less favourable of the two: | —                | —                            |
|             | No temperature limiting devices.  | —                | N/A                          |
| 13.2.6      | Leakage of liquid - RISK MANAGEMENT FILE examined to determine the appropriate test conditions (sealed rechargeable batteries exempted)                         | —                | —                            |
|             | No liquid.  | —                | N/A                          |
| 13.2.7      | Impairment of cooling that could result in a HAZARD using test method of 11.1:  | —                | —                            |
|             | No fans of vents  |                  |                              |
|             | Single ventilation fans locked consecutively  |                  | N/A                          |
|             | Ventilation openings on top and sides impaired by covering openings on top of ENCLOSURE or positioning of ME EQUIPMENT against walls                            |                  | N/A                          |
|             | Simulated blocking of filters   |                  | N/A                          |
|             | Flow of a cooling agent interrupted   |                  | N/A                          |
| 13.2.8      | Locking of moving parts – Only one part locked at a time – Also see 13.2.10 below:  | —                | —                            |
|             | No motors   |                  | N/A                          |
| 13.2.9      | Interruption and short circuiting of motor capacitors – Motor capacitors short & open circuited <sup>1)</sup> – Also see 13.10                                  | —                | —                            |
|             | No such capacitors.   | —                | N/A                          |
| 13.2.10     | Additional test criteria for motor operated ME EQUIPMENT in 13.2.8 & 13.2.9:  | —                | —                            |
|             | No motors.  |                  |                              |

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|---|--|------------------|------------------------------|
| Clause  | Requirement + Test   | Result - Remark  | Verdict                      |
| Clause No.  | Description of SINGLE FAULT CONDITION  | Results observed | HAZARDOUS SITUATION (Yes/No) |
|   | For every test in SINGLE FAULT CONDITION of 13.2.8 and 13.2.9, motor-operated EQUIPMENT started from COLD CONDITION at RATED voltage or upper limit of RATED voltage range for specified time: |                  | No                           |
|   | Temperatures of windings determined at the end of specified test periods or at the instant of operation of fuses, THERMAL CUT-OUTS, motor protective devices                                   |                  | No                           |
|   | Temperatures measured as specified in 11.1.3 d)  |                  | No                           |
|   | Temperatures did not exceed limits of Table 26   |                  | No                           |
| 13.2.11   | Failures of components in ME EQUIPMENT used in conjunction with OXYGEN RICH ENVIRONMENTS:  | —                | —                            |
|   | Not applicable.  | —                | N/A                          |
| 13.2.12   | Failure of parts that might result in a MECHANICAL HAZARD (See 9 & 15.3):  | —                | —                            |
|   | Not applicable.  | —                | N/A                          |
| <b>Supplementary information:</b><br><sup>1)</sup> Test with short-circuited capacitor not performed when motor provided with a capacitor complying with IEC 60252-1 and the ME EQUIPMENT not intended for unattended use including automatic or remote control. See Attachment # and appended Table 8.10.<br><b>Information from Risk Management, as applicable:</b> |  |                  |                              |

| 15.3  | TABLE: Mechanical Strength tests <sup>1)</sup> |   |   | P |
|---|--|---|---|---|
| Clause  | Name of Test                                   | Test conditions   | Observed results/Remarks                                      |   |
| 15.3.2  | Push Test                                      | Force = 250 N ± 10 N for 5 s                                  | For both Transducer and Headphones, no damage or hazard. Pass |   |
| 15.3.3  | Impact Test                                    | Steel ball (50 mm in dia., 500 g ± 25 g) falling from a 1.3 m | For both Transducer and Headphones, no damage or hazard. Pass |   |
| 15.3.4.1  | Drop Test (hand-held)                          | Free fall height (m) = 1                                      | For Headphones, no damage or hazard. Pass                     |   |
| 15.3.4.2  | Drop Test (portable)                           | Drop height (cm) = 5  | For Transducer only, no damage or hazard. Pass                |   |
| <b>Supplementary information:</b> <sup>1)</sup> As applicable, Push, Impact, Drop, Mould Stress Relief and Rough Handling Tests (delete not applicable rows or state N/A in Remarks field). |  |   |   |   |

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|-------------|--------------------|-----------------|---------|
| Clause      | Requirement + Test | Result - Remark | Verdict |

| 15.4.6                      | TABLE: actuating parts of controls of ME EQUIPMENT – torque & axial pull tests |                           |                         |                                   |         | N/A |
|-----------------------------|--|---------------------------|-------------------------|-----------------------------------|---------|-----|
| Rotating control under test | Gripping diameter “d” of control knob (mm) <sup>1)</sup>                       | Torque from Table 30 (Nm) | Axial force applied (N) | Unacceptable RISK occurred Yes/No | Remarks |     |
| –                           | –  | –                         | –                       | –                                 | –       |     |

**Supplementary information:** <sup>1)</sup> Gripping diameter (d) is the maximum width of a control knob regardless of its shape (e.g. control knob with pointer)

| 15.5.1.2  | TABLE: transformer short circuit test short-circuit applied at end of windings or at the first point that could be short circuited under SINGLE FAULT CONDITION |  |                                   |   |   |                                    |              | N/A |
|---|---|--|-----------------------------------|---|---|------------------------------------|--------------|-----|
| Primary voltage (most adverse value from 90 % to 110 % of RATED voltage)(V) <sup>1)</sup> ... : |   |  |                                   | –   |   | –                                  |              | –   |
| RATED input frequency (Hz) .....  |   |  |                                   | –   |   | –                                  |              | –   |
| Winding tested  | Class of insulation (A, B, E, F, or H)  | Type of protective device (fuse, circuit breaker) /Ratings | Protective device operated Yes/No | Time to THERMAL STABILITY (when protective device did not operate)(Min) | Maximum allowed temp from Table 31 (°C) | Maximum winding temp measured (°C) | Ambient (°C) |     |
| –   | –   | –  | –                                 | –   | –                                       | –                                  | –            |     |

**Supplementary information:**  
<sup>1)</sup> Loads on other windings between no load and their NORMAL USE load. Short-circuit applied at end of windings or at the first point that could be short circuited under SINGLE FAULT CONDITION.

| 15.5.1.3  | TABLE: transformer overload test – conducted only when protective device under short-circuit test operated |  |   |                                    |              |   | N/A |
|---|--|--|---|------------------------------------|--------------|---|-----|
| Primary voltage, most adverse value between 90 % to 110 % of RATED voltage (V) <sup>1)</sup> ..... :  |  |  |   |                                    |              | – |     |
| RATED input frequency (Hz) .....  |  |  |   |                                    |              | – |     |
| Test current just below minimum current that would activate protective device and achieve THERMAL STABILITY under method a) (A)..... :        |  |  |   |                                    |              | – |     |
| Test current based on Table 32 when protective device that operated under method a) is external to transformer, and it was shunted (A)..... : |  |  |   |                                    |              | – |     |
| Winding tested  | Class of insulation (A, B, E, F, H)  | Type of protective device used (fuse, circuit breaker)/Ratings | Maximum allowed temp from Table 31 (°C) | Maximum winding temp measured (°C) | Ambient (°C) |   |     |
| –   | –  | –  | –                                       | –                                  | –            |   |     |

**Supplementary information:**  
<sup>1)</sup> Loads on other windings between no load and their NORMAL USE load.  
 Time durations: - IEC 60127-1 fuse: 30 min at current from Table 32.  
 Non IEC 60127-1 fuse: 30 min at the current based on characteristics supplied by fuse manufacturer, specifically, 30 min clearing-time current. When no 30 min clearing-time current data available, test current from Table 32 used until THERMAL STABILITY achieved.  
 - Other types of protective devices: until THERMAL STABILITY achieved at a current just below minimum current operating the protective device in a). This portion concluded at specified time or when a second protective device opened.

| IEC 60601-1   |   |                   |                     |                  |                      |
|---|---|-------------------|---------------------|------------------|----------------------|
| Clause  | Requirement + Test  |                   |                     | Result - Remark  | Verdict              |
| 15.5.2  | <b>TABLE: Transformer dielectric strength after humidity preconditioning of 5.7</b> |                   |                     |                  | <b>N/A</b>           |
| Transformer Model/Type/ Part No   | Test voltage applied between  | Test voltage, (V) | Test frequency (Hz) | Breakdown Yes/No | Deterioration Yes/No |
| -   | Primary & secondary windings  | -                 | -                   | -                | -                    |
| -   | Primary winding & frame   | -                 | -                   | -                | -                    |
| -   | Secondary winding & frame   | -                 | -                   | -                | -                    |
| <b>Supplementary information:</b> Tests conducted under the conditions of 11.1, in ME EQUIPMENT or under simulated conditions on the bench. See Clause 15.5.2 for test parameters & other details |   |                   |                     |                  |                      |

| 16.6.1   | <b>TABLE: LEAKAGE CURRENTS in ME SYSTEM _ TOUCH CURRENT MEASUREMENTS</b> |   |  |   | <b>N/A</b> |
|--|--|---|--|---|------------|
| Specific area where TOUCH CURRENT measured (i.e., from or between parts of ME SYSTEM within PATIENT ENVIRONMENT) | Allowable TOUCH CURRENT in NORMAL CONDITION (µA)                         | Measured TOUCH CURRENT in NORMAL CONDITION (µA) | Allowable TOUCH CURRENT in event of interruption of PROTECTIVE EARTH CONDUCTOR, (µA) | Measured TOUCH CURRENT in event of interruption of PROTECTIVE EARTH CONDUCTOR, (µA) |            |
| -  | 100  | -   | 500  | -   |            |
| <b>Supplementary information:</b>  |  |   |  |   |            |

| SP                                | <b>TABLE: Additional or special tests conducted</b> |                  | <b>N/A</b> |
|-----------------------------------|---|------------------|------------|
| Clause and Name of Test           | Test type and condition                             | Observed results |            |
| -                                 | -   | -                |            |
| <b>Supplementary information:</b> |   |                  |            |



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| Clause      | Requirement + Test | Result - Remark | Verdict |

**Photographs: Medical equipment**



Transducer Front, Left



Transducer Rear, Right



Transducer output aperture

| IEC 60601-1 |                    |                 |         |
|-------------|--------------------|-----------------|---------|
| Clause      | Requirement + Test | Result - Remark | Verdict |

**Photographs: Medical equipment**



Over ear headphones Front



Over ear headphones Rear

| IEC 60601-1 |                    |                 |         |
|-------------|--------------------|-----------------|---------|
| Clause      | Requirement + Test | Result - Remark | Verdict |

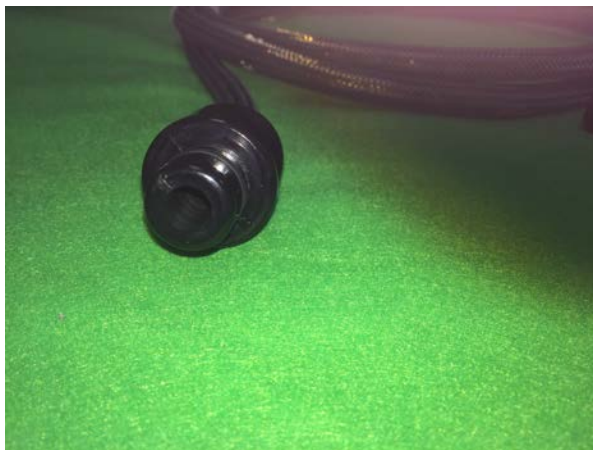
**Photographs: Medical equipment**



In ear headphones



Pneumatic Tubing



Pneumatic Tubing, Transducer interface

| IEC 60601-1 |                    |                 |         |
|-------------|--------------------|-----------------|---------|
| Clause      | Requirement + Test | Result - Remark | Verdict |

**System Components (non-medical equipment)**



Amplifier Front, Left



Amplifier Rear, Right



Amplifier rear panel connections

| IEC 60601-1 |                    |                 |         |
|-------------|--------------------|-----------------|---------|
| Clause      | Requirement + Test | Result - Remark | Verdict |

**System Components (non-medical equipment)**



Amplifier external power supply



Microphone Front Left



Microphone Rear Right