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Test report

340891-1TRFEMC

Date of issue: November 30, 2017

Applicant: MRI Audio

Product: MRI Audio System

Models: MRIaudioPREM-1000(tested) & MRIaudioPREM-1001

Specification: IEC 60601-1-2: 2014 Medical electrical equipment —

PART 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests



Nemko USA Inc., a testing laboratory, is accredited by NVLAP. The tests included in this report are within the scope of this accreditation.

EN 60601-1-2 (2014) .docx - Date: December 23, 2015

NVLAP Code 200116-0 www.nemko.com



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Tested by	Rodel Resolme, EMC Test Engineer
Reviewed by	Mark Phillips, Sr. EMC Test Engineer
Review date	November 30, 2017
Reviewer signature	Mark Pally

Limits of responsibility

Note that the results contained in this report relate only to the items tested and were obtained in the period between the date of initial receipt of samples and the date of issue of the report.

This test report has been completed in accordance with the requirements of ISO/IEC 17025. All results contain in this report are within Nemko USA ISO/IEC

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Section 1 Report summary

1.1 Test specifications

155 50501 1 2: 2014	Madical electrical environment
IEC 60601-1-2: 2014	Medical electrical equipment —
	PART 1-2: General requirements for basic safety and essential performance —
	Collateral standard: Electromagnetic compatibility — Requirements and tests

1.2 Statement of compliance

In the configuration tested, the EUT was found compliant.

Testing was completed against all relevant requirements of the test standard. Results obtained indicate that the product under test complies in full with the requirements tested. The test results relate only to the items tested.

See "Summary of test results" for full details.

1.3 Exclusions

None

1.4 Test report revision history

Table 1.4-1: Test report revision history

Revision #	Details of changes made to test report
TRF	Original report issued



Section 2 Summary of test results

2.1 Test results

Table 2.1-1: EM Environments **EM Environments** Physician offices, dental offices, clinics, limited care facilities, freestanding surgical centers, freestanding birthing centers, \boxtimes Professional healthcare facility environment multiple treatment facilities, hospitals (emergency rooms, patient rooms, intensive care, surgery rooms except near HF SURGICAL EQUIPMENT, outside the RF shielded room of an ME SYSTEM for magnetic resonance imaging) HOME HEALTHCARE ENVIRONMENT Restaurants, cafes, shops, stores, markets, schools, churches, libraries, outdoors (streets, sidewalks, parks), domiciles (residences, homes, nursing homes), vehicles (cars, buses, trains, boats, planes, helicopters), train stations, bus stations, airports, hotels, hostels, pensions, museums, theatres Special environment Military areas (submarines, near radar installations, near weapons control systems), heavy industrial areas (power plants, steel and paper mills, foundries, automotive and appliance manufacturing, smelting and mining operations, oil and gas refineries), medical treatment areas with high-powered ME EQUIPMENT (HF SURGICAL EQUIPMENT, SHORT-WAVE THERAPY EQUIPMENT, inside the RF shielded room of an ME SYSTEM for magnetic resonance imaging) Notes: Although healthcare professionals are present in the EMERGENCY MEDICAL SERVICES ENVIRONMENT, the ELECTROMAGNETIC ENVIRONMENT is similar to that of the HOME HEALTHCARE ENVIRONMENT. Therefore, for the purposes of this collateral standard, the EMISSIONS and IMMUNITY requirements of the HOME HEALTHCARE ENVIRONMENT apply to ME EQUIPMENT and ME SYSTEMS intended for use in the EMERGENCY MEDICAL SERVICES ENVIRONMENT. An example of such a location is an ambulance.

Table 2.1-2: Emission results

Phenomenon	Professional healthcare facility environment	HOME HEALTHCARE ENVIRONMENT	Verdict
Radiated RF EMISSIONS	CISPR 11	CISPR 11 ^{b), c)}	Pass
Conducted RF EMISSIONS	CISPR 11	CISPR 11 ^{b), c)}	Pass
Harmonic distortion	IEC 61000-3-2 ^{a)}	IEC 61000-3-2	Pass
Voltage fluctuations and flicker	IEC 61000-3-3 ^{a)}	IEC 61000-3-3	Pass

Notes: ^{a)} This test is not applicable in this environment unless the ME EQUIPMENT and ME SYSTEMS used there will be connected to the PUBLIC MAINS NETWORK and the power input is otherwise within the scope of the Basic EMC standard.

^{b)} ME EQUIPMENT and ME SYSTEMS intended for use in aircraft shall meet the RF EMISSIONS requirements of ISO 7137. The conducted RF EMISSIONS test is applicable only to ME EQUIPMENT and ME SYSTEMS that are intended to be connected to aircraft power. ISO 7137 is identical to RTCA DO-160C:1989 and EUROCAE ED-14C:1989. The latest editions are RTCA DO-160G: 2010 and EUROCAE ED-14G: 2011. Therefore, use of Section 21 (and category M) of a more recent edition, e.g. [39] or [40], should be considered.

^{c)} Standards applicable to other modes or EM ENVIRONMENTS of transportation for which use is intended shall apply. Examples of standards that might be applicable include CISPR 25 and ISO 7637-2.

¹Group 1 Class A



2.1 Test results, continued

Phenomenon	Basic EMC standard or	Immunity te	est levels	Verdict
	test method	Professional healthcare facility environment	HOME HEALTHCARE ENVIRONMENT	
Electrostatic discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ±4 kV, ±8 kV, ±15 kV air		Pass
Radiated RF EM fields ^{a)}	IEC 61000-4-3	3 V/m ^{f)} 80 MHz – 2.7 GHz ^{b)} 80 % AM at 1 kHz ^{c)}	10 V/m ^{f)} 80 MHz – 2.7 GHz ^{b)} 80 % AM at 1 kHz ^{c)}	Pass
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See Clause 8.10 of IEC 60601-1-2.		Pass
Rated power frequency magnetic fields ^{d) e)}	IEC 61000-4-8	30 A/m ^{g)} 50 Hz or 60 Hz		Pass

^{a)} The interface between the PATIENT physiological signal simulation, if used, and the ME EQUIPMENT or ME SYSTEM shall be located within 0,1 m of the vertical plane of the uniform field area in one orientation of the ME EQUIPMENT or ME SYSTEM. ^{b)} ME EQUIPMENT and ME SYSTEMS that intentionally receive RF electromagnetic energy for the purpose of their operation shall be tested at the frequency of

reception. Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS. This test assesses the BASIC SAFETY and ESSENTIAL PERFORMANCE of an intentional receiver when an ambient signal is in the passband. It is understood that the receiver might not achieve normal reception during the test. ^{c)} Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.

^{d)} Applies only to ME EQUIPMENT and ME SYSTEMS with magnetically sensitive components or circuitry.

e) During the test, the ME EQUIPMENT or ME SYSTEM may be powered at any NOMINAL input voltage, but with the same frequency as the test signal (see Table 1). ^{f)} Before modulation is applied.

^{g)} This test level assumes a minimum distance between the ME EQUIPMENT or ME SYSTEM and sources of power frequency magnetic field of at least 15 cm. If the RISK ANALYSIS shows that the ME EQUIPMENT or ME SYSTEM will be used closer than 15 cm to sources of power frequency magnetic field, the IMMUNITY TEST LEVEL shall be adjusted as appropriate for the minimum expected distance.



2.1 Test results, continued

Table 2.1-4: Input a.c. power port results				
Phenomenon	Basic EMC standard or	Immunity test levels		Verdict
	test method	Professional healthcare facility environment	HOME HEALTHCARE ENVIRONMENT	
Electrical fast transients/bursts ^{a), l), o)}	IEC 61000-4-4	± 2 kV 100 kHz repetition frequency		Pass
Surges ^{a), b), j), o)} Line-to-line	IEC 61000-4-5	± 0.5 kV, ±1 kV		Pass
Surges ^{a), b), j), k), o) Line-to-ground}	IEC 61000-4-5	± 0.5 kV, ±1 kV, ±2 kV		Pass
		3 V ^{m)} 0,15 – 80 MHz	3 V ^{m)} 0,15 – 80 MHz	
Conducted disturbances induced by RF fields ^{c), d), o)}	IEC 61000-4-6	6 V $^{\text{m})}$ in ISM bands between 0.15 MHz and 80 MHz $^{\text{n})}$	6 V ^{m)} in ISM and amateur radio bands between 0.15 MHz and 80 MHz ⁿ⁾	Pass
		80 % AM at 1 kHz	80 % AM at 1 kHz	
Voltage dips ^{f), p), r)}	IEC 61000-4-11	0 % U _T ; 0,5 cycle ^{g)} , @ 0°, 45°, 90°, 135°, 1 0% U _T ; 1 cycle and 70% U _T ; 25/30 cycles ^b		Pass
Voltage interruptions ^{f), i), o), r)}	IEC 61000-4-11	0 % U _T ; 250/300 cycle ^{h)}		Pass

Notes: ¹ The test may be performed at any one power input voltage within the ME EQUIPMENT or ME SYSTEM RATED voltage range. If the ME EQUIPMENT or ME SYSTEM is tested at one power input voltage, it is not necessary to re-test at additional voltages.

^{b)} All ME EQUIPMENT and ME SYSTEM cables are attached during the test.

 $^{\text{c}\text{i}}$ Calibration for current injection clamps shall be performed in a 150 Ω system.

^{d)} If the frequency stepping skips over an ISM or amateur band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range. ^{a)} Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.

¹ ME EQUIPMENT and ME SYSTEMS with a d.c. power input intended for use with a.c.-to-d.c. converters shall be tested using a converter that meets the specifications of the MANUFACTURER of the ME EQUIPMENT or ME SYSTEM. The IMMUNITY TEST LEVELS are applied to the a.c. power input of the converter. Applicable only to ME EQUIPMENT and ME SYSTEMS connected to single-phase a.c. mains.

^{h)} E.g. 10/12 means 10 periods at 50 Hz or 12 periods at 60 Hz.

¹⁾ ME EQUIPMENT and ME SYSTEMS with RATED input current greater than 16 A / phase shall be interrupted once for 250/300 cycles at any angle and at all phases at the same time (if applicable). ME EQUIPMENT and ME SYSTEMS with battery backup shall resume line power operation after the test. For ME EQUIPMENT and ME SYSTEMS with RATED input current not exceeding 16 A, all phases shall be interrupted simultaneously. ^{J)} ME EQUIPMENT and ME SYSTEMS that do not have a surge protection device in the primary power circuit may be tested only at ± 2 kV line(s) to earth and ± 1 kV

line(s) to line(s).

^{k)} Not applicable to CLASS II ME EQUIPMENT and ME SYSTEMS.

¹⁾ Direct coupling shall be used.

^{m)} r.m.s., before modulation is applied.

ⁿ⁾ The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

input current greater than 16 A / phase.

^{p)} Applicable to ME EQUIPMENT and ME SYSTEMS with RATED input current less than or equal to 16 A / phase.

^{q)} At some phase angles, applying this test to ME EQUIPMENT with transformer mains power input might cause an overcurrent protection device to open. This can occur due to magnetic flux saturation of the transformer core after the voltage dip. If this occurs, the ME EQUIPMENT or ME SYSTEM shall provide BASIC SAFETY during and after the test.

r) For ME EQUIPMENT and ME SYSTEMS that have multiple voltage settings or auto ranging voltage capability, the test shall be performed at the minimum and maximum RATED input voltage. ME EQUIPMENT and ME SYSTEMS with a RATED input voltage range of less than 25 % of the highest RATED input voltage shall be tested at one RATED input voltage within the range. See Table 1 Note c) for examples calculations.



2.1 Test results, continued

Phenomenon	Basic EMC standard or	r Immunity test levels		Verdict
	test method	Professional healthcare facility environment	HOME HEALTHCARE ENVIRONMENT	
ELECTROSTATIC DISCHARGE ^{c)}	IEC 61000-4-2	± 8 kV contact ± 2 kV, ±4 kV, ±8 kV, ±15 kV air		Not applicable
Conducted disturbances induced by RF fields a)	IEC 61000-4-6	3 V ^{b)} 0,15 – 80 MHz	3 V ^{b)} 0,15 – 80 MHz	
		6 V $^{\rm b)}$ in ISM bands between 0.15 MHz and 80 MHz	6 V ^{b)} in ISM and amateur radio bands between 0.15 MHz and 80 MHz	Not applicable
		80 % AM at 1 kHz	80 % AM at 1 kHz	

Table 2.1-5: PATIENT coupling PORT results

Notes: ^{a)} The following apply:

All PATIENT-COUPLED cables shall be tested, either individually or bundled

 PATIENT-COUPLED cables shall be tested using a current clamp unless a current clamp is not suitable. In cases were a current clamp is not suitable, an EM clamp shall be used.

- No intentional decoupling device shall be used between the injection point and the PATIENT COUPLING POINT in any case.

Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.

Tubes that are intentionally filled with conductive liquids and intended to be connected to a PATIENT shall be considered to be PATIENT-COUPLED cables.

 If the frequency stepping skips over an ISM or amateur radio band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.

The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

^{b)} r.m.s., before modulation is applied

^{el} Discharges shall be applied with no connection to an artificial hand and no connection to PATIENT simulation. PATIENT simulation may be connected after the test as needed in order to verify BASIC SAFETY and ESSENTIAL PERFORMANCE.



Test results, continued 2.1

Phenomenon	Basic EMC standard or	Immunity test levels		Verdict
	test method	Professional healthcare facility environment	HOME HEALTHCARE ENVIRONMENT	
ELECTROSTATIC DISCHARGE ^{e)}	IEC 61000-4-2	± 8 kV contact ± 2 kV, ±4 kV, ±8 kV, ±15 kV air		Pass
Electrical fast transients/bursts ^{b), f)}	IEC 61000-4-4	± 1 kV 100 kHz repetition frequency		Pass
Surges Line-to-ground ^{a)}	IEC 61000-4-5	± 2 kV		Pass
		3 V ^{h)} 0,15 – 80 MHz	3 V ^{h)} 0,15 – 80 MHz	
Conducted disturbances induced by RF fields ^{b), d), g)}	IEC 61000-4-6	6 V $^{\mathfrak{b})}$ in ISM bands between 0.15 MHz and 80 MHz $^{\mathfrak{i})}$	6 V ^{h)} in ISM and amateur radio bands between 0.15 MHz and 80 MHz ⁱ⁾	Pass
		80 % AM at 1 kHz ^{c)}	80 % AM at 1 kHz °	

^{a)} This test applies only to output lines intended to connect directly to outdoor cables.

^{b)} SIP/SOPS whose maximum cable length is less than 3 m in length are excluded.

^{c)} Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.

 $^{\text{d})}$ Calibration for current injection clamps shall be performed in a 150 Ω system.

e) Connectors shall be tested per 8.3.2 and Table 4 of IEC 61000-4-2:2008. For insulated connector shells, perform air discharge testing to the connector shell and the pins using the rounded tip finger of the ESD generator, with the exception that the only connector pins that are tested are those that can be contacted or touched, under conditions of INTENDED USE, by the standard test finger shown in Figure 6 of the general standard, applied in a bent or straight position.

(b) If the frequency stepping skips over an ISM or amateur radio band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and a mateur radio band within the specified frequency range. $^{h)}$ r.m.s., before modulation is applied.

¹⁾ The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.



Section 3 Equipment under test (EUT) details

3.1 Applicant

Company name	MRI Audio
Address	2720 Loker Avenue West, Suite N
City	Carlsbad
Province/State	California
Postal/Zip code	92008
Country	United States of America

3.2 Manufacturer

Company name	MRI Audio
Address	2720 Loker Avenue West, Suite N
City	Carlsbad
Province/State	California
Postal/Zip code	92008
Country	United States of America

3.3 Sample information

Receipt date	November 13, 2017
Nemko sample ID number	340891

3.4 EUT information

Product name	MRI Audio System
Model	PREM-100X
Serial number	NA
Part number	NA
Power requirements	100-240 50/60 Hz
Description/theory of operation	The MRIaudioPREM system is an MRI conditional audio solution that provides MRI patients with music, direct communication, and hearing protection.
Operational frequencies	50-60Hz
Software details	N/A
Intended use	The MRIaudioPREM-1000 & 1001 system is will produce high quality audio for patients undergoing MRI scans.
Intended environments	Professional healthcare

3.5 EUT exercise and monitoring details

The MRIaudioPREM system is an MRI conditional audio solution that provides MRI patients with music, direct communication, and hearing protection. The EUT was exercised by playing audio during the tests.



3.6 EUT setup details

Description	Brand name	Model/Part number	Serial number	Rev.	
Premium MRIaudio music system	MRIaudio Prem 1000	1000	N/A	А	
Premium MRIaudio music system	MRIaudio Prem 1001	1001	N/A	A	
	Table 3.6-2: EUT :	interface ports			
Description				Qty.	
BNC port on Transducer				1	
Two proper (1/) omplifier out (to Tr	anadu aar)			1	
Two-prong (+/-) amplifier out (to Tra		ort equipment			
	Table 3.6-3: Supp Brand name	ort equipment Model/Part number	Serial number	Rev.	
Description Amplifier	Table 3.6-3: Supp		Serial number N/A		
Description	Table 3.6-3: Supp Brand name	Model/Part number 600		Rev.	
Description Amplifier	Table 3.6-3: Supp Brand name MRIaudio Amplifier	Model/Part number 600		Rev.	
Description	Table 3.6-3: Supp Brand name MRIaudio Amplifier Table 3.6-4: Inter-co	Model/Part number 600	N/A	Rev. A	



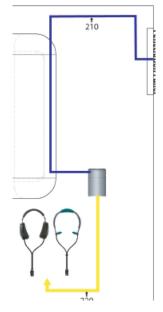


Figure 3.6-1: Setup diagram



Section 4 Engineering considerations

4.1 Modifications incorporated in the EUT

There were no modifications performed to the EUT during this assessment.

4.2 Technical judgment

None

4.3 Deviations from laboratory tests procedures

No deviations were made from laboratory procedures.



Section 5 Test conditions

5.1 Atmospheric conditions

Temperature	15–30 °C
Relative humidity	20-75 %
Air pressure	86–106 kPa

When it is impracticable to carry out tests under these conditions, a note to this effect stating the ambient temperature and relative humidity during the tests shall be recorded and stated.

5.2 Power supply range

The normal test voltage for equipment to be connected to the mains shall be the nominal mains voltage. For the purpose of the present document, the nominal voltage shall be the declared voltage, or any of the declared voltages ±5 %, for which the equipment was designed.



Section 6 Measurement uncertainty

6.1 Uncertainty of measurement

Nemko USA Inc. has calculated measurement uncertainty and is documented in EMC/MUC/001 "Uncertainty in EMC measurements." Measurement uncertainty was calculated using the methods described in CISPR 16-4 Specification for radio disturbance and immunity measuring apparatus and methods – Part 4: Uncertainty in EMC measurements; as well as described in UKAS LAB34: The expression of Uncertainty in EMC Testing. Measurement uncertainty calculations assume a coverage factor of K=2 with 95% certainty.



Section 7 Terms and definitions

7.1 Performance criterion

Immunity Pass fail criterion as provided by client.

Basic safety: No description provided.

Essential performance: No description provided.



Section 8 Testing data

8.1 Radiated RF emissions

8.1.1 References

CISPR 11: 2009 + A1: 2010

8.1.2 Test summary

Verdict	Pass		
Test date	November 13, 2017	Temperature	20 °C
Test engineer	Rodel Resolme, EMC Test Engineer	Air pressure	1003 mbar
Test location	10m semi anechoic chamber	Relative humidity	48 %

8.1.3 Notes

None.

8.1.4 Setup details

EUT setup configuration	Table top
Test facility	10 m Semi anechoic chamber
Measuring distance	10 m
EUT mains voltage	120 V _{AC} 60 Hz
Antenna height variation	1–4 m
Turn table position	0–360°
Measurement details	A preview measurement was generated with receiver in continuous scan or sweep mode while the EUT was rotated
	and antenna adjusted to maximize radiated emission. Emissions detected within 6 dB or above limit were re-
	measured with the appropriate detector against the correlating limit and recorded as the final measurement.

Receiver/spectrum analyzer settings for frequencies below 1 GHz:

Resolution bandwidth	120 kHz
Video bandwidth	300 kHz
Detector mode	Peak (preview measurement); Quasi-peak (final measurement)
Trace mode	Max Hold
Measurement time	100 ms (preview measurement); 1000 ms (final measurement)



8.1.4 Setup details, continued

Table 8.1-1: Radiated RF emissions – equipment list

Equipment	Manufacturer	Model no.	Asset no.	Cal cycle	Next cal.
EMC Test Receiver	Rohde & Schwarz	ESU 40	E1121	4/28/2016	4/28/2018
Antenna, Bilog	Schaffner-Chase	CBL 6111D	1763	11/28/2016	11/28/2017
Antenna, Horn	EMCO	3115	1033	7/27/2016	7/27/2018

Notes: None

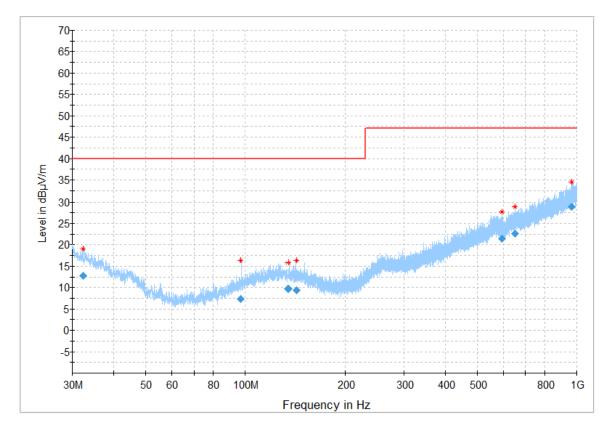
Table 8.1-2: Radiated RF emissions test software details

Manufac	turer of Software	Details
Rhode &	Schwarz	EMC32 V10.0.0
Notes:	None	



8.1.5 Test data

Full Spectrum



The spectral plot is a summation of a vertical and horizontal scan. The spectral scan has been corrected with the associated transducer factors (i.e. antenna factors, cable loss, amplifier gains, and attenuators.

Figure 8.1-1: Radiated RF emissions spectral plot (30 to 1000 MHz)

Frequency (MHz)	QuasiPeak (dBµV/m)	Limit (dBµV/m)	Margin (dB)	Meas. Time (ms)	Bandwidth (kHz)	Height (cm)	Pol	Azimuth (deg)	Corr. (dB)
32.316000	12.76	40.00	27.24	5000.0	120.000	100.0	V	183.0	18.7
97.015000	7.31	40.00	32.69	5000.0	120.000	343.0	V	0.0	11.4
134.782000	9.68	40.00	30.32	5000.0	120.000	231.6	V	0.0	13.6
141.870000	9.38	40.00	30.62	5000.0	120.000	304.0	V	0.0	13.5
594.609000	21.38	47.00	25.62	5000.0	120.000	350.6	Н	102.0	24.8
652.052500	22.67	47.00	24.33	5000.0	120.000	248.2	Н	0.0	26.2
967.413000	28.89	47.00	18.11	5000.0	120.000	247.3	Н	0.0	31.7

Table 8.1-3: Radiated RF emissions (Quasi-Peak) results

Testing data Radiated RF Emissions IEC 60601-1-2: 2014



8.1.6 Setup photos



Figure 8.1-2: Radiated RF emissions setup photo

Testing data Radiated RF Emissions IEC 60601-1-2: 2014



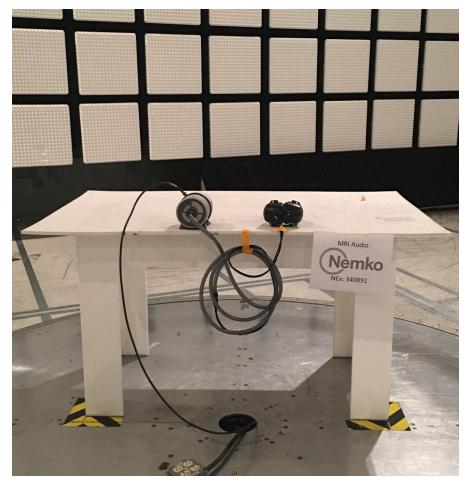


Figure 8.1-3: Radiated RF emissions setup photo



8.2 Conducted RF emissions

8.2.1 References

CISPR 11: 2009 + A1: 2010

8.2.2 Test summary

Verdict	Pass		
Test date	November 13, 2017	Temperature	20 °C
Test engineer	Rodel Resolme, EMC Test Engineer	Air pressure	1003 mbar
Test location	Ground Plane	Relative humidity	48 %

8.2.3 Notes

None

8.2.4 Setup details

Port under test	AC Mains
EUT setup configuration	Table top
EUT mains voltage	230 V _{AC} ; 50 Hz
Measurement details	A preview measurement was generated with the receiver in continuous scan mode. Emissions detected within 6 dB or above limit were re-measured with the appropriate detector against the correlating limit and recorded as the final measurement.

Receiver settings:	
Resolution bandwidth	9 kHz
Video bandwidth	30 kHz
Detector mode	Peak and Average (preview measurement); Quasi-peak and Average (final measurement)
Trace mode	Max Hold
Measurement time	100 ms (preview measurement); 1000 ms (final measurement)

Table 8.2-1: Conducted RF emissions equipment list

Equipment	Manufacturer	Model no.	Asset no.	Cal cycle	Next cal.
LISN	Rohde & Schwarz	ENV216	E1019	6/27/2017	6/27/2018
EMI Receiver	Rohde & Schwarz	ESCI 7	E1026	5/23/2017	5/23/2018

Notes: N/A - not applicable

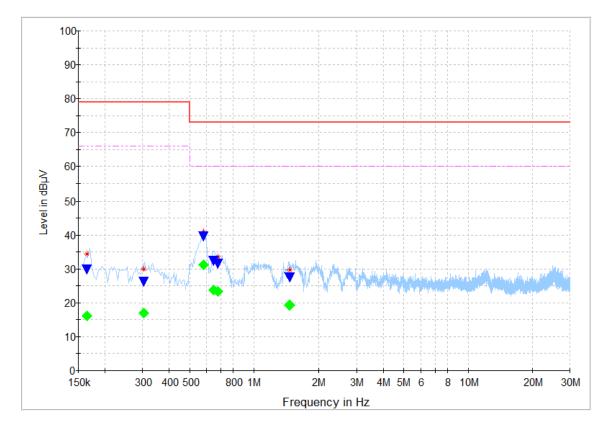
Table 8.2-2: Conducted RF emissions test software details

Manufac	turer of Software	Details
Rohde &	Schwarz	EMC 32 V10.0
Notes:	None	



8.2.5 Test data

Full Spectrum



The spectral plot has been corrected with transducer factors. (i.e. cable loss, LISN factors, and attenuators)

Figure 8.2-1: Conducted RF emissions spectral plot on phase & neutral line



8.2.5 Test data, continued

Table 8.2-3: Conducted RF emissions (Quasi-Peak) results

Frequency	QuasiPeak	Average	Limit	Margin	Meas.	Bandwidth	Line	Filter	Corr.
(MHz)	(dBµV)	(dBµV)	(dBµV)	(dB)	Time	(kHz)			(dB)
					(ms)				
0.164500	29.71		79.00	49.29	5000.0	9.000	N	ON	10.1
0.164500		16.14	66.00	49.86	5000.0	9.000	N	ON	10.1
0.304500		17.05	66.00	48.95	5000.0	9.000	N	ON	10.1
0.304500	26.05		79.00	52.95	5000.0	9.000	N	ON	10.1
0.580500		31.16	60.00	28.84	5000.0	9.000	L1	ON	10.1
0.580500	39.54		73.00	33.46	5000.0	9.000	L1	ON	10.1
0.644500	32.26		73.00	40.74	5000.0	9.000	L1	ON	10.1
0.644500		23.86	60.00	36.14	5000.0	9.000	L1	ON	10.1
0.676500		23.34	60.00	36.66	5000.0	9.000	L1	ON	10.1
0.676500	31.44		73.00	41.56	5000.0	9.000	L1	ON	10.1
1.456500		19.22	60.00	40.78	5000.0	9.000	L1	ON	10.1
1.456500	27.31		73.00	45.69	5000.0	9.000	L1	ON	10.1

Testing data Conducted RF emissions IEC 60601-1-2: 2014



8.2.6 Setup photos

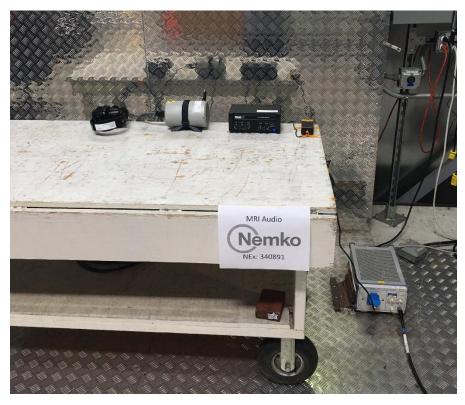


Figure 8.2-2: Conducted RF emissions setup photo



8.3 Harmonic distortion

8.3.1 References

IEC 61000-3-2: 2014

Special Note: A more relevant publication of EN 61000-3-2 has been applied for this assessment.

8.3.2 Test summary

Verdict	Pass		
Test date	November 13, 2017	Temperature	20 °C
Test engineer	Rodel Resolme, EMC Test Engineer	Air pressure	1003 mbar
Test location	Ground Plane	Relative humidity	48 %

8.3.3 Notes

None

8.3.4 Setup details

Port under test	AC Mains
Measurement time	20 min
EUT mains voltage	230 V _{AC} ; 50 Hz

Table 8.3-1: Harmonic distortion equipment list

Equipment	Manufacturer	Model no.	Asset no.	Cal cycle	Next cal.
AC/DC Power Source Analyzer	California Instruments	3001 ix	1851	1 yr.	7/9/2018

Notes: None

Table 8.3-2: Harmonic distortion test software details

Manufactu	urer of Software	Details
California I	nstruments	AC Source CIGui SII Version 3.0.0
Notes:	None	



8.3.5 Test data, continued

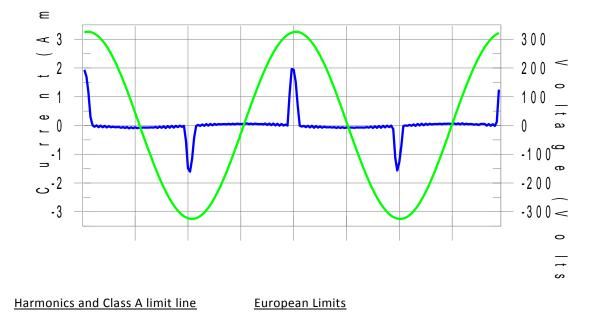
Measurement data

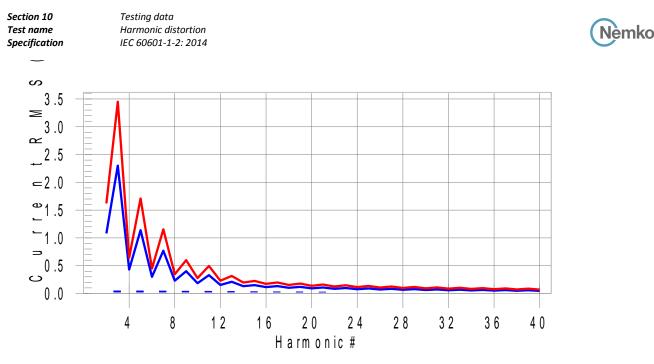
Harmonics - Class-A per Ed. 4.0 (2014)(Run time)

EUT: MRI Audio SystemTested by: R. ResolmeTest category: Class-A per Ed. 4.0 (2014) (European limits)Test Margin: 100Test date: 11/13/2017Start time: 2:03:54 PMEnd time: 2:24:14 PMTest duration (min): 20Data file name: H-000933.cts_dataComment: Nex: 340891Customer: MRI Audio

Test Result: Pass Source qualification: Normal

Current & voltage waveforms







Current Test Result Summary (Run time)

EUT: MRI Audio SystemTested by: R. ResolmeTest category: Class-A per Ed. 4.0 (2014) (European limits)Test Margin: 100Test date: 11/13/2017Start time: 2:03:54 PMEnd time: 2:24:14 PMTest duration (min): 20Data file name: H-000933.cts_dataComment: Nex: 340891Customer: MRI Audio

Test Result: PassSource qualification: NormalTHC(A): 0.135I-THD(%): 195.0POHC(A): 0.046POHC Limit(A): 0.251Highest parameter values during test:

-	-	-					
	V_RMS (Volts):	230.26		Frequency(Hz):	50.00		
	I_Peak (Amps):	2.077		I_RMS (Amps):	0.313		
	I Fund (Amps):	0.086		Crest Factor:	12.276		
	Power (Watts):	16.1		Power Factor:	0.360		
Harm#	Harms(avg)	100%Limit	%of Limit	Harms(max)	150%Limit	%of Limit	Status
2	0.013	1.080	1.2	0.015	1.620	1.0	Pass
3	0.048	2.300	2.1	0.069	3.450	2.0	Pass
4	0.013	0.430	3.0	0.015	0.645	2.3	Pass
5	0.047	1.140	4.1	0.067	1.710	3.9	Pass
6	0.012	0.300	4.2	0.015	0.450	3.3	Pass
7	0.045	0.770	5.9	0.065	1.155	5.6	Pass
8	0.012	0.230	5.2	0.014	0.345	4.0	Pass
9	0.043	0.400	10.8	0.061	0.600	10.2	Pass
10	0.011	0.184	6.1	0.013	0.276	4.7	Pass
11	0.041	0.330	12.5	0.058	0.495	11.7	Pass
12	0.010	0.153	6.8	0.012	0.230	5.2	Pass
13	0.038	0.210	18.3	0.053	0.315	17.0	Pass
14	0.010	0.131	7.3	0.011	0.197	5.5	Pass

Report reference ID: 340891-1TRFEMC

Section 10 Test name Specification		data ic distortion 01-1-2: 2014					Nemko
15	0.035	0.150	23.6	0.049	0.225	21.7	Pass
16	0.009	0.115	7.5	0.010	0.173	5.6	Pass
17	0.032	0.132	24.4	0.044	0.198	22.1	Pass
18	0.008	0.102	7.6	0.009	0.153	5.7	Pass
19	0.029	0.118	24.4	0.039	0.178	21.8	Pass
20	0.007	0.092	7.4	0.008	0.138	5.6	Pass
21	0.026	0.107	23.9	0.034	0.161	20.9	Pass
22	0.006	0.084	7.0	0.007	0.125	5.4	Pass
23	0.022	0.098	22.8	0.028	0.147	19.4	Pass
24	0.005	0.077	6.5	0.006	0.115	5.2	Pass
25	0.019	0.090	21.1	0.024	0.135	17.4	Pass
26	0.004	0.071	N/A	0.005	0.107	N/A	Pass
27	0.016	0.083	19.0	0.019	0.125	15.1	Pass
28	0.004	0.066	N/A	0.005	0.099	N/A	Pass
29	0.013	0.078	16.7	0.015	0.116	12.9	Pass
30	0.003	0.061	N/A	0.004	0.092	N/A	Pass
31	0.010	0.073	14.2	0.012	0.109	10.9	Pass
32	0.003	0.058	N/A	0.004	0.086	N/A	Pass
33	0.008	0.068	11.6	0.009	0.102	9.3	Pass
34	0.002	0.054	N/A	0.003	0.081	N/A	Pass
35	0.006	0.064	9.0	0.008	0.096	7.8	Pass
36	0.002	0.051	N/A	0.003	0.077	N/A	Pass
37	0.004	0.061	N/A	0.006	0.091	N/A	Pass
38	0.002	0.048	N/A	0.003	0.073	N/A	Pass
39	0.003	0.058	N/A	0.005	0.087	N/A	Pass
40	0.002	0.046	N/A	0.003	0.069	N/A	Pass

Voltage Source Verification Data (Run time)

EUT: MRI Audio System		Tested by: R. Resolme
Test category: Class-A per Ed. 4	.0 (2014) (European limits)	Test Margin: 100
Test date: 11/13/2017	Start time: 2:03:54 PM	End time: 2:24:14 PM
Test duration (min): 20	Data file name: H-000933.cts_d	ata
Comment: Nex: 340891		
Customer: MRI Audio		

Test Result: Pass Source qualification: Normal

Highest parameter values during test:

	Voltage (Vrms):	230.26	Frequ	ency(Hz): 50.00	
	I_Peak (Amps):	2.077	I_RM	S (Amps): 0.31	.3
	I_Fund (Amps):	0.086	Crest	Factor: 12.2	76
	Power (Watts):	16.1	Powe	r Factor: 0.36	0
Harm#	Harmoni	cs V-rms	Limit V-rms	% of Limit	Status
2		0.060	0.460	13.11	ОК
3		0.517	2.072	24.97	OK
4		0.037	0.460	7.96	OK
5		0.016	0.921	1.78	ОК
6		0.047	0.460	10.28	ОК
7		0.043	0.691	6.30	OK
8		0.008	0.461	1.67	OK
9		0.101	0.460	22.04	ОК

Report reference ID: 340891-1TRFEMC

Section 10 Test name Specification	Testing data Harmonic distortion IEC 60601-1-2: 2014				Nemko
10	0.004	0.460	0.95	ОК	
11	0.075	0.230	32.61	ОК	
12	0.008	0.230	3.38	OK	
13	0.028	0.230	12.27	OK	
14	0.004	0.230	1.72	OK	
15	0.020	0.230	8.50	OK	
16	0.010	0.230	4.20	OK	
17	0.018	0.230	7.67	OK	
18	0.014	0.230	6.08	OK	
19	0.016	0.230	7.16	OK	
20	0.013	0.230	5.82	OK	
21	0.013	0.230	5.61	OK	
22	0.004	0.230	1.92	OK	
23	0.013	0.230	5.77	OK	
24	0.006	0.230	2.66	OK	
25	0.011	0.230	4.84	OK	
26	0.004	0.230	1.60	OK	
27	0.007	0.230	3.01	OK	
28	0.004	0.230	1.78	OK	
29	0.008	0.230	3.68	OK	
30	0.006	0.230	2.48	OK	
31	0.007	0.230	3.15	OK	
32	0.003	0.230	1.26	OK	
33	0.007	0.230	3.21	OK	
34	0.003	0.230	1.39	OK	
35	0.006	0.230	2.73	OK	
36	0.003	0.230	1.44	OK	
37	0.005	0.230	2.28	ОК	
38	0.004	0.230	1.62	OK	
39	0.005	0.230	2.24	OK	
40	0.007	0.230	3.21	ОК	

Section 10 Test name Specification Testing data Harmonic distortion IEC 60601-1-2: 2014



8.3.6 Setup photos



Figure 8.3-1: Harmonic distortion setup photo



Voltage fluctuations/flicker emissions 8.4

8.4.1 References

IEC 61000-3-3: 2013

Special Note: A more relevant publication of EN 61000-3-3 has been applied for this assessment.

8.4.2 Test summary

Verdict	Pass		
Test date	November 15, 2017	Temperature	20 °C
Test engineer	Rodel Resolme, EMC Test Engineer	Air pressure	1003 mbar
Test location	Ground Plane	Relative humidity	48 %

8.4.3 Notes

None

Setup details 8.4.4

Port under test	AC Mains
Measurement time	20 min
EUT mains voltage	230 V _{AC} ; 50 Hz

Table 8.4-1: Voltage fluctuations/flicker emissions equipment list

Equipment	Manufacturer	Model no.	Asset no.	Cal cycle	Next cal.
Signal Conditioning Unit	Teseq/California	CCN 1000-3-75	961	7/9/2017	7/9/2018
	Instruments				

Notes: NCR - no calibration required

Table 8.4-2: Voltage fluctuations/flicker emissions test software details

Manufacturer of Software	Details
California Instruments	AC Source CIGui SII Version 3.0.0
Notes: None	

Notes:



8.4.5 Test data, continued

Measurement data

Flicker Test Summary per EN/IEC61000-3-3 (Run time)

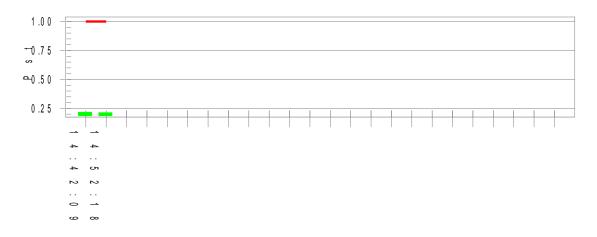
EUT: MRI Audio SystemTested by: R. ResolmeTest category: All parameters (European limits)Test Margin: 100Test date: 11/13/2017Start time: 2:31:39 PMEnd time: 2:52:19 PMTest duration (min): 20Data file name: F-000934.cts_dataComment: Nex: 340891Customer: MRI Audio

Test Result: Pass

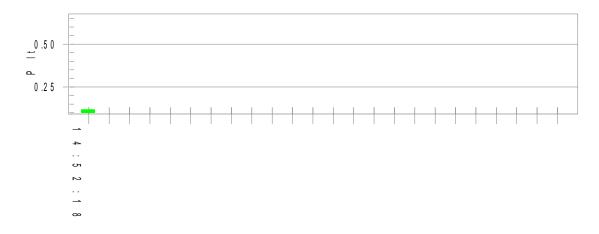
Status: Test Completed

Pst_i and limit line

European Limits



Plt and limit line



Section 10Testing dataTest nameVoltage fluctuations/flicker emissionsSpecificationIEC 60601-1-2: 2014



Parameter values recorded during	; the test:				
Vrms at the end of test (Volt):	230.24				
Highest dt (%):	0.00	Test limit (%):	N/A	N/A	
T-max (mS):	0	Test limit (mS):	500.0	Pass	
Highest dc (%):	0.00	Test limit (%):	3.30	Pass	
Highest dmax (%):	0.06	Test limit (%):	7.00	Pass	
Highest Pst (10 min. period):	0.218	Test limit:	1.000	Pass	
Highest Plt (2 hr. period):	0.119	Test limit:	0.650	Pass	

Testing data Voltage fluctuations/flicker emissions IEC 60601-1-2: 2014



8.4.6 Setup photos

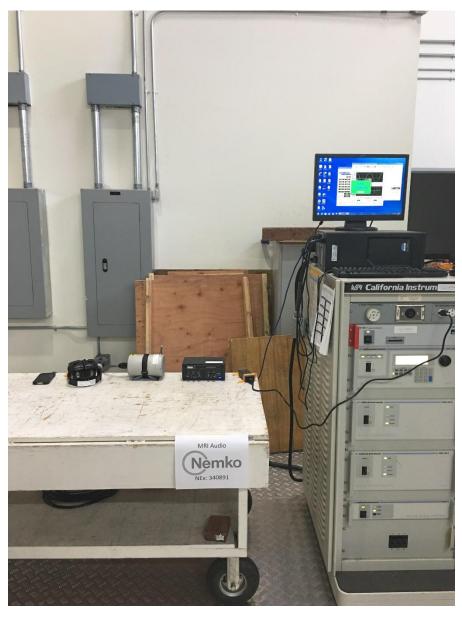


Figure 8.4-1: Voltage fluctuations/flicker emissions setup photo



8.5 Radiated RF EM field

8.5.1 References

IEC 61000-4-3: 2006 + A1: 2007 + A2: 2010

8.5.2 Test summary

Verdict	Pass		
Test date	November 14, 2017	Temperature	20 °C
Test engineer	Rodel Resolme, EMC Test Engineer	Air pressure	1003 mbar
Test location	RFI Chamber	Relative humidity	48 %

8.5.3 Notes

None

8.5.4 Setup details

Table 8.5-1: Radiated RF EM field equipment list

Equipment	Manufacturer	Model no.	Asset no.	Cal cycle	Next cal.
RF Amplifier	Amplifier Research	500W1000M5	740	NCR	NCR
Pulse/Function Generator	HP	8116A	407	1 year	11/17/2017
Signal Generator	Agilent	E8254A	836	1 year	5/17/2018
E-Field Probe	Narda	EF0391	1791	2 year	6/27/2018
Broadband Field Meter	Narda	NBM-520	1789	2 year	6/27/2018
E-Field Probe	Narda	EF5091	1790	2 year	6/27/2018
RF Amplifier	Amplifier Research	200T1G3M3	743	NCR	NCR
RF Amplifier	Amplifier Research	200T2G8	848	NCR	NCR
Antenna, Biconical, high power	TDK RF Solutions	HBA-2030	1818	NCR	NCR
Antenna	Electrometrics	RGA-30	350	1 year	11/29/2017
Microwave Horn Antenna	Amplifier Research	AT4002A	728	NCR	NCR
Antenna, Horn	A.H. Systems	SAS-200/571	993	NCR	NCR

Table 8.5-2: Radiated RF EM field test software details

Manufacturer of Software	Details
ETS Lindgren	Tile 6
Notes: None	



8.5.5 Test data

Table 8.5-3: Radiated RF EM field results

Step size increment	1 %				
Dwell time	3 s				
Antenna polarization	Vertical and Horizo	Vertical and Horizontal			
Modulation	CW signal amplitud	CW signal amplitude modulated (AM) with 80 % depth with a 1 kHz sine wave			
EUT setup configuration	Choose an item.	Choose an item.			
EUT position facing antenna	Front side, back side, left side and right side				
TX antenna distance from EUT	3 m				
EUT mains input voltage	Xxx V _{AC} or V _{DC} ; 50/6	50 Hz			
Frequency range, MH	2	Test level, V/m ¹	Comments		
80 2	700	3	No degradation		

Notes: EUT operational frequencies within specified test band were also assessed.

Nemko

8.5.6 Setup photo

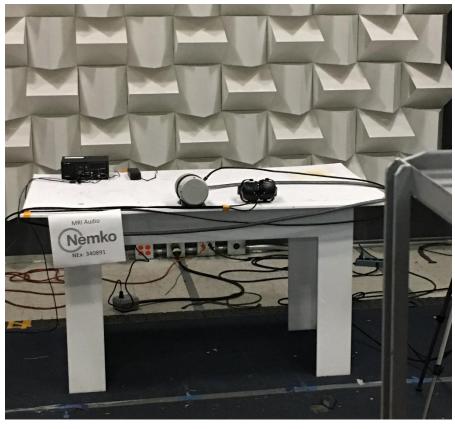


Figure 8.5-1: Radiated RF EM field setup photo



8.6 Proximity fields from RF wireless communications equipment

8.6.1 References

IEC 61000-4-3: 2006 + A1: 2007 + A2: 2010

8.6.2 Test summary

Verdict	Pass		
Test date	November 14, 2017	Temperature	20 °C
Test engineer	Rodel Resolme, EMC Test Engineer	Air pressure	1003 mbar
Test location	RFI Chamber	Relative humidity	48 %

8.6.3 Notes

None

8.6.4 Setup details

Table 8.6-1: Proximity fields from RF wireless communications equipment equipment list

Equipment	Manufacturer	Model no.	Asset no.	Cal cycle	Next cal.
Antenna, Horn	A.H. Systems	SAS-200/571	993	NCR	NCR
RF Amplifier	Amplifier Research	500W1000M5	740	NCR	NCR
Pulse/Function Generator	HP	8116A	407	1 year	11/17/2017
Signal Generator	Agilent	E8254A	836	1 year	5/17/2018
Antenna	Electrometrics	RGA-30	350	1 year	11/29/2017
Microwave Horn Antenna	Amplifier Research	AT4002A	728	NCR	NCR

Notes: None

Table 8.6-2: Proximity fields from RF wireless communications test software details

Manufac	turer of Software	Details
ETS Lindg	ren	Tile 6
Notes:	None	



8.6.5 Test data

Table 8.6-3: Proximity fields from RF wireless communications results

Antenna polarization TX antenna distance from EUT setup configuration EUT position facing anten EUT mains input voltage	EUT 1 m Table top na Front side	nd Horizontal r, back side, left side and right V _{DC} ; 50 Hz	side	
Frequency range, MHz	Dwell time, s	Test level, V/m ¹	Modulation frequency, Hz	Comments
385	60	27	18	No degradation
450	60	28	18	No degradation
710	60	9	217	No degradation
745	60	9	217	No degradation
780	60	9	217	No degradation
810	60	28	18	No degradation
870	60	28	18	No degradation
930	60	28	18	No degradation
1720	60	28	217	No degradation
1845	60	28	217	No degradation
1970	60	28	217	No degradation
2450	60	28	217	No degradation
5240	60	9	217	No degradation
5500	60	9	217	No degradation
5785	60	9	217	No degradation

Notes: None



8.6.6 Setup photo

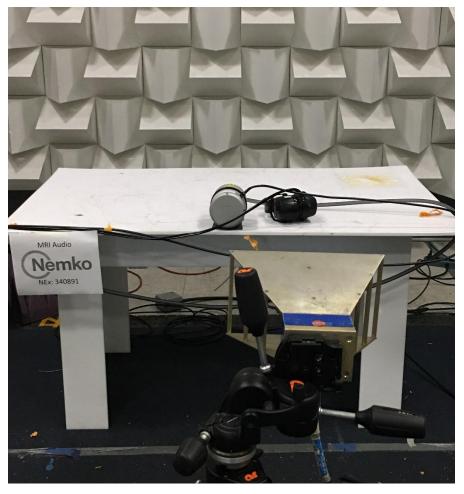


Figure 8.6-1: Proximity fields from RF wireless communications setup photo



Conducted disturbances induced by RF fields 8.7

8.7.1 References

IEC 61000-4-6: 2013

8.7.2 Test summary

Verdict	Pass			
Test date	November 15, 2017	Temperature	20 °C	
Test engineer	Rodel Resolme, EMC Test Engineer	Air pressure	1003 mbar	
Test location	Ground Plane	Relative humidity	48 %	

8.7.3 Notes

```
None
```

8.7.4 Setup details

Table 8.7-1: Conducted disturbances induced by RF fields equipment list

Equipment	Manufacturer	Model no.	Asset no.	Cal cycle	Next cal.
Generator, signal	Hewlett Packard	8656B	D1182	1 year	1/25/2018
CDN	FCC	FCC-801-M3-25A	846	1 year	2/15/2018
Amplifier	IFI	SCCX%))	Rental	1 year	2/10/2018

Notes: None

Table 8.7-2: Conducted disturbances induced by RF fields test software details

Manufacture	er of Software	Details
ETS Lindgren	า	Tile 6
Notes:	None	



8.7.5 Test data

0.15–80 MHz		
1 %		
3 s		
3 V _{RMS}		
CW signal amplitude modulated (AM) w	ith 80 % depth with a 1 kHz sine wave	
230V _{AC} ; 50 Hz		
Coupling method	50 Ω termination point	Comments
CDN		No degradation
Clamp		No degradation
	3 s 3 V _{RMS} CW signal amplitude modulated (AM) w 230V _{AC} ; 50 Hz Coupling method CDN	3 s 3 V _{RMS} CW signal amplitude modulated (AM) with 80 % depth with a 1 kHz sine wave 230V _{AC} ; 50 Hz Coupling method 50 Ω termination point CDN

8.7.6 Setup photo



Figure 8.7-1: Conducted disturbances induced by RF fields setup photo

Section 10 Test name Specification Testing data Conducted disturbances induced by RF fields IEC 60601-1-2: 2014





Figure 8.7-2: Conducted disturbances induced by RF clamp setup photo



8.8 Electrostatic discharge

8.8.1	References

IEC 61000-4-2: 2008

8.8.2 Test summary

Verdict	Pass			
Test date	November 16, 2017	Temperature	20 °C	
Test engineer	Rodel Resolme, EMC Test Engineer	Air pressure	1002 mbar	
Test location	Ground Plane	Relative humidity	48 %	

8.8.3 Notes

None

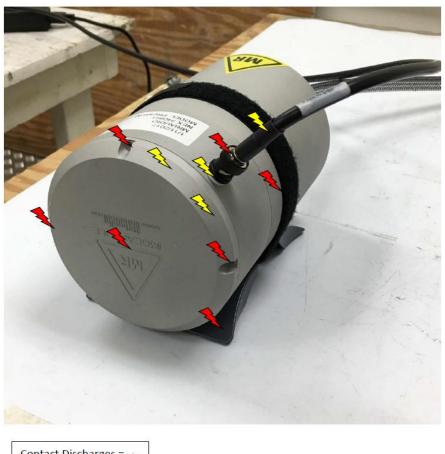
8.8.4 Setup details

Equipment	Manufacturer	Model no.	Asset no.	Cal cycle	Next cal.
ESD Gun	TeseQ	NSG 435	818	1 Year	3/23/2018
Notes: None					
8.8.5 Test data					
	Table 8.8-	2: Electrostatic disch	arge results		
EUT setup configuration:	Table top				
ESD repetition rate:	1 pulse per second				
Discharges:	10 contact discharges and 10 ai	r discharges at each	polarity		
EUT mains input voltage	230Vac; 50 Hz				
Contact discharge		Tes	st voltage (±kV)	Comments	
Please refer to "Electrostatic d this section	lischarge test location points" photos	of	8	No degradatio	on
Indirect discharge		Te	st voltage (±kV)	Comments	
HCP (all sides)			8	No degradatio	on
VCP (all sides)			8	No degradatio	on
Air discharge		Te	st voltage (±kV)	Comments	
Please refer to "Electrostatic d this section	ischarge test location points" photos	of	2, 4, 8, 15	No degradatio	on
Notes: None					

Notes: None



8.8.5 Test data, continued



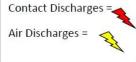
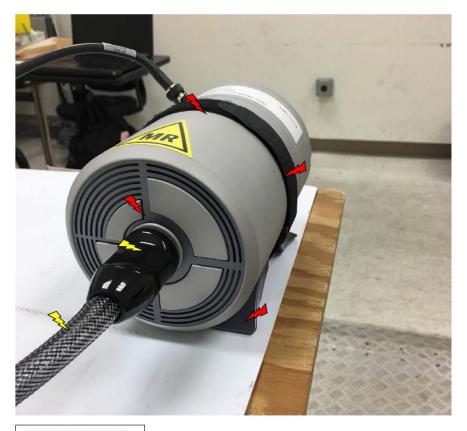


Figure 8.8-1: Electrostatic discharge test location point's photo



8.8.5 Test data, continued



Contact Discharges

Testing data Electrostatic discharge IEC 60601-1-2: 2014





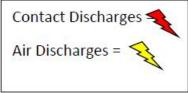


Figure 8.8-2: Electrostatic discharge test location point's photo

Testing data Electrostatic discharge IEC 60601-1-2: 2014





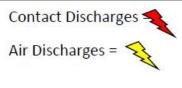


Figure 8.8-3: Electrostatic discharge test location point's photo

Testing data Electrostatic discharge IEC 60601-1-2: 2014



8.8.6 Setup photo



Figure 8.8-4: Electrostatic discharge setup photo



8.9 Surge

8.9.1 References

IEC 61000-4-5: 2005

8.9.2 Test summary

Verdict	Pass		
Test date	November 14, 2017	Temperature	20 °C
Test engineer	Rodel Resolme, EMC Test Engineer	Air pressure	1003 mbar
Test location	Ground Plane	Relative humidity	48 %

8.9.3 Notes

None

8.9.4 Setup details

Table 8.9-1: Surge equipment list Equipment Manufacturer Model no. Asset no. Cal cycle Next cal. Multitest Generator TESEQ NSG 3060 E1124 2 year 5/28/2018 **Coupling Network** TESEQ CDN 3061-C16 E1125 2 year 5/28/2018

Notes: None

Table 8.9-2: Surge test software details

Manufacturer of Software	Details
TESEQ	WIN 3000 V1.3.2
Notes: None	

Notes: None



8.9.5 Test data

	Table 8.9-3: Surge at input a.c. powe	r port results	
Open circuit voltage (T ₁ / T ₂):	$1.2/50 \ \mu s$ (T ₁ = front time, T ₂ = time to half value)		
Short circuit curent (T ₁ / T ₂):	$8/20 \ \mu s$ (T ₁ = front time, T ₂ = time to half value)		
Surge pulse interval:	60 s		
Number of pulses:	5 positive and 5 negative		
EUT mains input voltage:	Xxx V _{AC} or V _{DC} ; 50/60 Hz		
Test port	Coupling	Test voltage (±kV)	Comments
	Phase to Neutral	0.5, 1	No degradation
AC mains	Phase to ground	0.5, 1, 2	No degradation
	Neutral to ground	0.5, 1, 2	No degradation
Notes: – Phase to neutral c	oupling : Surge applied with generator output impedance set to 2	Ω	

_ Phase/neutral to ground coupling : Surge applied with generator output impedance set to 12 Ω

Surge applied synchronous (relation to power supply): 0, 90, 180, and 270° _

Testing data Surge IEC 60601-1-2: 2014



8.9.6 Setup photo

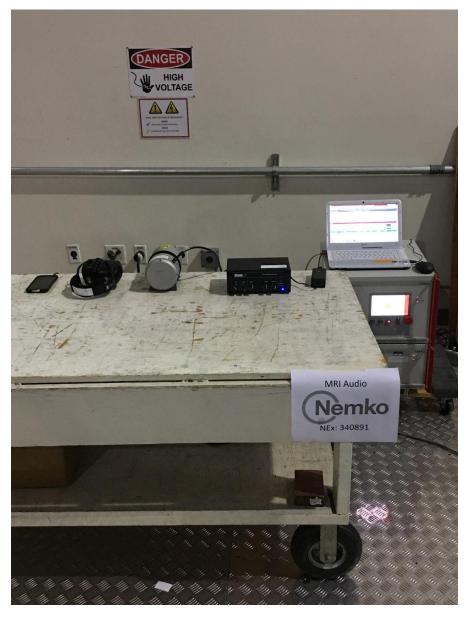


Figure 8.9-1: Surge setup photo



8.10 Electrical fast transients/bursts

8.10.1	References
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IEC 61000-4-4: 2012

8.10.2 Test summary

Verdict	Pass		
Test date	November 14, 2017	Temperature	20 °C
Test engineer	Rodel Resolme, EMC Test Engineer	Air pressure	1002 mbar
Test location	Ground Plane	Relative humidity	49 %

8.10.3 Notes

None

8.10.4 Setup details

Table 8.10-1: Electrical fast transients/bursts equipment list

Equipment	Manufacturer	Model no.	Asset no.	Cal cycle	Next cal.
Multitest Generator	TESEQ	NSG 3060	E1124	2 year	5/28/2018
Coupling Network	TESEQ	CDN 3061-C16	E1125	2 year	5/28/2018

Notes: None

Table 8.10-2: Electrical fast transients/bursts test software details

Manufacturer of Soft	are Details
TESEQ	WIN 3000 V1.3.2
Notes: None	



8.10.5 Test data

Notes:

Notes:

	Table 8.10-3: Electrical fast transients/bursts a	t power supply ports results	
Wave shape (Tr / Td):	5/50 ns (Tr = rise time, Td= duration time)		
Repetition frequency ⁴ :	100 kHz		
Burst duration:	0.75 ms		
Burst period:	300 ms		
Test duration:	60 s		
EUT mains input voltage:	230V _{AC} ; 50 Hz		
Test port		Test voltage (±kV)	Comments
AC mains		2	No degradation

Transient applied asynchronous (relation to power supply)

 The test voltage was applied simultaneously between a ground reference plane and all of the power supply terminals and the protective or functional earth port on the EUT cabinet

Table 8.10-4: Electrical fast transients/bursts at signal input/output parts PORT result
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			.
Coaxial Cable		1	No degradation
Test port		Test voltage (±kV)	Comments
EUT mains input voltage:	230V _{AC} ; 50 Hz		
Test duration:	60 s		
Burst period:	300 ms		
Burst duration:	0.75 ms		
Repetition frequency ⁴ :	100 kHz		
Wave shape (Tr / Td):	5/50 ns (Tr = rise time, Td= duration time)		

The test voltage was applied via capacitive coupling clamp

- SIP/SOPS whose maximum cable length is less than 3 m in length are excluded.

Testing data Electrical fast transients/bursts IEC 60601-1-2: 2014



8.10.6 Setup photos

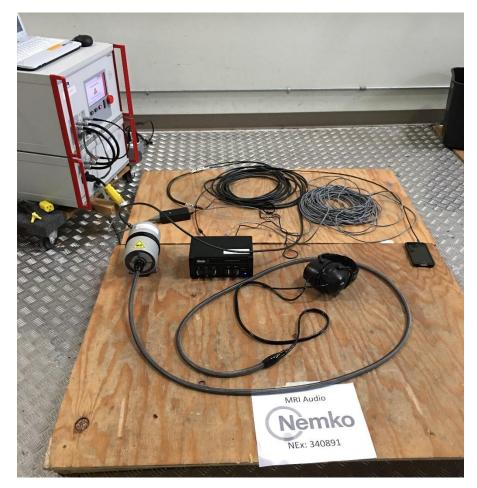


Figure 8.10-1: Electrical fast transients/bursts setup photo



8.11 Voltage dips and interruptions

1.1 References

IEC 61000-4-11: 2004

8.11.2 Test summary

Verdict	Pass		
Test date	November 13, 2017	Temperature	20 °C
Test engineer	Rodel Resolme, EMC Test Engineer	Air pressure	1003 mbar
Test location	Ground Plane	Relative humidity	48 %

8.11.3 Notes

None

8.11.4 Setup details

Table 8.11-1: Voltage dips and interruptions equipment list

Equipment	Manufacturer	Model no.	Asset no.	Cal cycle	Next cal.
Programmable AC & DC Power	California Instruments	3001 ix	1851	1 yr.	7/9/2018
Source Analyzer					
Notes: None					

Table 8.11-2: Voltage dips and interruptions test software details

Manufac	turer of Software	Details
California	Instruments	AC Source CIGui SII Version 3.0.0
Notes:	None	



8.11.5 Test data

	Table 8.11-3: Voltage dips re	sults	
Variation/dip repetition:	Sequence of three dips/interruptions with an interval o	f 10 seconds between ea	ch test
Test port	Voltage reduction (%)	Periods	Comments
AC mains (230 VAC, 50 Hz)	100	0.5	No degradation
AC mains (100 VAC, 60 Hz)	100	0.5	No degradation

Notes: Changes occurred at the 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° crossings of the voltage waveform

Table 8.11-4: Voltage dips results

Variation/dip repetition:	Sequence of thre	three dips/interruptions with an interval of 10 seconds between each test			
Test port		Voltage reduction (%)	Periods	Comments	
AC mains (230 VAC, 50 Hz)		100	1	No degradation	
AC mains (230 VAC, 50 HZ)		30	25	No degradation	
AC mains (100)/AC (C Hz)		100	1	No degradation	
AC mains (100 VAC, 60 Hz)		30	30	No degradation	

Notes: Changes occurred at the 0 crossings of the voltage waveform

Table 8.11-5: Voltage interruptions results

Variation/dip repetition:	Sequence of three dips/interruptions with an interval of 10 seconds between each test			
Test port	Voltage reduction (%)	Periods	Comments	
AC mains (230 VAC, 50 Hz)	100	250	EUT power cycled	
AC mains (100 VAC, 60 Hz)	100	300	EUT power cycled	

Notes: Changes occurred at the 0 crossings of the voltage waveform

Testing data Voltage dips and interruptions IEC 60601-1-2: 2014



8.11.6 Setup photo



Figure 8.11-1: Voltage dips and interruptions setup photo



8.12 Power-frequency magnetic field

8.12.1 References

IEC 61000-4-8: 2009

Special Note: A more relevant publication of EN 61000-4-8 has been applied for this assessment.

8.12.2 Test summary

Verdict	Pass		
Test date	November 15, 2017	Temperature	20 °C
Test engineer	Rodel Resolme, EMC Test Engineer	Air pressure	1002 mbar
Test location	Ground Plane	Relative humidity	48 %

8.12.3 Notes

None

8.12.4 Setup details

Table 8.12-1: Power-frequency magnetic field equipment list

Equipment	Manufacturer	Model no.	Asset no.	Cal cycle	Next cal.
California Instruments	3001 ix	1851	1 yr.	1 yr.	7/9/2018
Small Magnetic Coil	Nemko	NA	821	NCR	NCR

Notes: None



8.12.5 Test data

Table 8.12-2: Power-frequency magnetic field results

Assessment time:	5 minutes at each loop polarizatio	'n	
Signal frequency:	50 Hz		
Magnetic field test level:	30 A/m		
EUT mains input voltage:	230V _{AC} ; 50 Hz		
Loop polarization		Signal frequency (Hz)	Comments
Loop polarization Vertical (aligned with AC powe	r line)	Signal frequency (Hz) 50 or 60	Comments No degradation
	,	• • • • •	

Notes: Applies only to ME EQUIPMENT and ME SYSTEMS with magnetically sensitive components or circuitry.

Testing data Power-frequency magnetic field IEC 60601-1-2: 2014



8.12.6 Setup photo

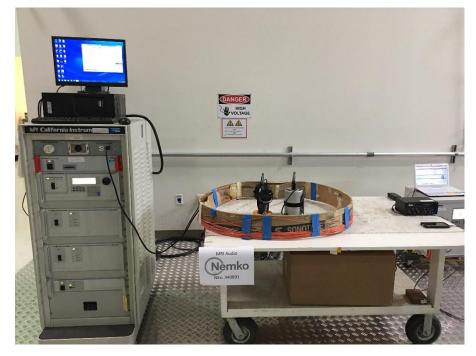


Figure 8.12-1: Power-frequency magnetic field setup photo



Section 9 EUT photos

9.1 External photos



Figure 9.1-1: Front view photo







Figure 9.1-2: Rear view photo







Figure 9.1-3: Side view photo