






Test Report issued under the responsibility of:



<b>TEST REPORT</b> <b>IEC 60601-1-2</b> <b>Medical electrical equipment –</b> <b>Part 1-2: General requirements for basic safety and essential performance –</b> <b>Collateral Standard: Electromagnetic disturbances – Requirements and tests</b>	
Report Number.....	N40P0014
Date of issue.....	Feb 24, 2020
Total number of pages .....	85
Name of Testing Laboratory preparing the Report .....	SGS Germany GmbH, Consumer and Retail Hofmannstrasse 50 81379 Munich, Germany
Applicant's name .....	ADLINK Technology GmbH
Address.....	Ulrichsberger Str. 17 94469 Deggendorf Germany
<b>Test specification:</b>	
Standard.....	IEC 60601-1-2:2014
Test procedure .....	CB
Non-standard test method .....	N/A
Test Report Form No. ....	IEC60601_1_2E_EMC
Test Report Form(s) Originator .....	UL(US)
Master TRF.....	2017-03
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Test item description.....	Medical Panel Computer	
Trade Mark.....		
Manufacturer .....	ADLINK Technology GmbH	
Model/Type reference .....	MLC 8 series: - MLC8-23	
Ratings .....	100 – 240 V ac; 50/60 Hz; Class 1	
Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):		
<input checked="" type="checkbox"/>	CB Testing Laboratory:	SGS Germany GmbH, Consumer and Retail
Testing location/ address.....	Hofmannstrasse 50 81379 Munich, Germany	
Tested by (name, function, signature).....		 Sperling
Approved by (name, function, signature).....		 Wössner
<input type="checkbox"/>	Testing procedure: CTF Stage 1:	
Testing location/ address.....		
Tested by (name, function, signature).....		
Approved by (name, function, signature).....		
<input type="checkbox"/>	Testing procedure: CTF Stage 2:	
Testing location/ address.....		
Tested by (name, function, signature).....		
Witnessed by (name, function, signature).....		
Approved by (name, function, signature).....		

<input type="checkbox"/>	Testing procedure: CTF Stage 3:		
<input type="checkbox"/>	Testing procedure: CTF Stage 4:		
Testing location/ address.....			
Tested by (name, function, signature).....			
Witnessed by (name, function, signature).....			
Approved by (name, function, signature).....			
Supervised by (name, function, signature).....			

<b>List of Attachments (including a total number of pages in each attachment):</b> <b>None</b>	
<b>Summary of testing:</b>	
<b>Tests performed (name of test and subclause):</b> Conducted EMISSIONS (7.3) Radiated EMISSIONS (7.3) Disturbance Power EMISSIONS (7.3) Harmonic Currents (7.2.1) Voltage Fluctuations and Flicker (7.2.3) Electrostatic Discharges (8.9) RF Electromagnetic Fields (8.9) Proximity fields from RF wireless communications EQUIPMENT (8.10) Electrical Fast Transients (8.9) Surge (8.9) Conducted Disturbances Induced by RF Fields (8.9) Voltage Dips and Interruptions (8.9)	<b>Testing location:</b> <b>SGS Germany</b> <b>Consumer and Retail, EMC-Lab</b> <b>81379 Munich, Germany</b>
Note: delete tests not conducted in the list above.	
<b>Summary of compliance with National Differences:</b> <b>List of countries addressed</b> .....  <input checked="" type="checkbox"/> <b>The product fulfils the requirements of IEC 60601-1-2: 2014 (Fourth Edition)</b>	

**Device modifications necessary for compliance:**

(Describe ME EQUIPMENT or ME SYSTEM modifications needed in order to pass any of the EMISSIONS or IMMUNITY tests or delete the whole sentence and state: "not applicable")



Ferrite Würth 742 717 22 on MIC In and Line OUT cables

**A statement that manufacturer will incorporate all changes into production units.**

- ☐ Manufacturer provided declaration statement.
- ☒ Manufacturer did not provide declaration statement.

<b>Test item particulars.....:</b> None	
<b>Classification of installation and use.....:</b> (see IEC 60601-1-2 Annex C for guidance in classification)	
<p><b>Emission limits to be considered:</b></p> <p><input type="checkbox"/> Class A<sup>1</sup></p> <p><input checked="" type="checkbox"/> Class B</p> <p><b>The medical equipment is classified following based on CISPR 11 and IEC 60601-1-2</b></p> <p><input checked="" type="checkbox"/> Group 1</p> <p><input type="checkbox"/> Group 2</p> <p><i><sup>1</sup> If the more stringent class B limits are passed, also the class A limits can be considered as fulfilled</i></p> <p><b>Environments of intended use of medical equipment in practice</b> (see IEC 60601-1-2 chapt 8.9 figure 3 for definition)</p> <p><input checked="" type="checkbox"/> Professional healthcare facility environment</p> <p><input type="checkbox"/> Operated near active RF-surgery</p> <p><input type="checkbox"/> Home healthcare environment</p> <p><input type="checkbox"/> Vehicles</p> <p><input type="checkbox"/> Aircraft</p> <p><input type="checkbox"/> Special environment applicable (see IEC 60601-1-2 chapt 8.9 figure 3)</p> <p><input type="checkbox"/> Determination of special Immunity test levels</p>	
<b>Supply Connection .....</b>	<p><input checked="" type="checkbox"/> PUBLIC MAINS NETWORK (e.g. home care ME equipment and ME equipment for doctor's offices in residential areas, should meet the requirements for CISPR 11 class B)</p> <p><input type="checkbox"/> Dedicated supply Systems (professional ME equipment e.g. in hospitals or doctor's offices, normally fed by separation transformers, also allowed to meet the requirements for CISPR 11 class A)</p>
<b>Possible test case verdicts:</b>	
- test case does not apply to the test object.....: N/A	
- test object does meet the requirement.....: P (Pass)	
- test object does not meet the requirement.....: F (Fail)	
<b>Testing.....:</b>	
<b>Date of receipt of test item .....</b> Mar 12, 2019	
<b>Date (s) of performance of tests .....</b> Mar 12, 2019 to Jul 23,2019	

<b>General remarks:</b>	
"(See Enclosure #)" refers to additional information appended to the report. "(See appended table)" refers to a table appended to the report.  <b>Throughout this report a <input type="checkbox"/> comma / <input checked="" type="checkbox"/> point is used as the decimal separator.</b>	
<b>Manufacturer's Declaration per sub-clause 4.2.5 of IEC60601-1:</b>	
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 ..... :	<input type="checkbox"/> <b>Yes</b> <input checked="" type="checkbox"/> <b>Not applicable</b>
<b>Name and address of factory (ies) .....</b> : ADLINK Technology GmbH Ulrichsberger Str. 17 94469 Deggendorf GERMANY	
<b>General product information:</b>	
For test equipment description refer to item 1.1	
<b>Describe any deviations from the Basic EMC standards or from this collateral standard:</b>	
No deviation	
<b>Complementary Information: Calibration of test equipment</b>	
Some calibration of test equipment ran out during the test period. All equipment was calibrated during the test period of each test	

**IEC 60601-1-2**

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**IEC 60601-1-2****1.1 Equipment Description**

The product is an all-in-one medical panel computer system intended for use in medical environment (hospitals, medical centers, physician's facilities etc.).

The device provides medically relevant information to medical personnel. Patient and / or surgical and medical data are displayed, processed and stored locally or can be exported to external systems.

EUT with basic functionality; the EUT is always at least a combination of the following functions:

CPU (Intel i3 or i5 or i7)  
 2x DDR4 SODIMM sockets  
 LCD panel (21.5" or 23.8" or 27")  
 Internal AC or (optional) external DC PSU  
 PCAP touch or glass front  
 Interfaces as provided by the assembled main board

EUT with basic functionality with add-on (optional) modules; the EUT can have one or more of the following functions:

2.5" SATA HDD/SSD in removable bay  
 M.2 2260 socket for SSD/mPCIe modules  
 M.2 2230 socket for WLAN/Bluetooth modules  
 mPCIe full size socket  
 PCIe raiser card, 16 lanes for PCIe cards  
 Isolated interfaces  
 Backup battery with charger module

Tested configuration: see chapter 1.3



MLC8-23 front view



MLC8-23 rear view

**POTENTIAL EQUALIZATION CONDUCTOR used:** Yes ☒ No ☐

Note: If yes, include information on connection to the terminal for connection of a POTENTIAL EQUALIZATION CONDUCTOR used during testing, if any, below.

**Software and Firmware Version:**

MS Windows 10 Operating system (WIN 10 Enterprise 2016 LTSC x64)  
 Passmark Bitpro test suite (8.1 Pro b1025)  
 Test program for frame grabber module (Streamcatcher 1.1.0.175)

**IEC 60601-1-2**

Test program for RFID reader (Hterm 0.81)  
Ping command to access point IP in an OS CMD window

**Prototype:** ☐ **Production Version:** ☒

Unit(s) Tested (include serial numbers)

MLC8-23  
SN:MLC8-23-0001-19

Rationale for number of samples tested: N/A

**INTENDED USE:**

The product is an all-in-one medical panel computer system intended for use in medical environment (hospitals, medical centers, physician's facilities etc.). The complete wording of the intended purpose is contained in the document ATGD-DMF-MLC8-002\_Intended Purpose [insert link] and in the user manual of the device.

The device provides medically relevant information to medical personnel. Patient and / or surgical and medical data are displayed, processed and stored locally or can be exported to external systems.

The device is intended to be operated within the scope of the intended purpose by medical personnel working in health care facilities. Furthermore, persons functioning as device administrators are intended to use the device and to maintain the device to the extent described in the according device manual.

The device is neither intended to be operated by, nor intended to be connected directly to patients (unless used as part of a medical system, configured by a third party).

The product is a Medical PC intended for stand-alone use or for usage in conjunction with (other) medical electrical equipment.

The maximum operating ambient temperature is +30°C.

The average service life-time of the device used within the limits of the intended purpose ranges from 3 to in max. 7 years.

The device incorporates the LCD panel and computational elements in one enclosure. All operating controls are located on the lower front side. All connectors (I/O interfaces) are provided at the back-bottom side, underneath the cable cover.

Depending from the product variation, the device is available with or without PCAP (projected capacitive) touch screen functionality.

Manufacturer and applicant of the product is ADLINK Technology GmbH, referenced as ATG. Trademark of the computer is provided on the device marking label.

**Intended environments** (Specify environment: Professional healthcare facility, HOME HEALTHCARE or SPECIAL (if SPECIAL please describe):

Professional healthcare facility environment

**Testing of PERMANENTLY INSTALLED LARGE ME EQUIPMENT OR LARGE ME SYSTEM:**

**Yes** ☐ **No** ☒

**If Yes, include the following information**

Frequencies tested	
Power levels of RF test sources	
Modulation of RF test sources	
Test distance used	
Other relevant information related to test	

## IEC 60601-1-2

## 1.1.1 EQUIPMENT Marking Plate



## 1.1.2 EUT and Supporting EQUIPMENT Used During Test:

Use*	Product Type	Manufacturer	Model	Comments
EUT	Panel computer sys.	ADLINK	MLC 8-23	
....	....			

**Note: \* Use one of the following (add more rows if needed):**

**EUT - EQUIPMENT Under Test**

**AE – ACCESSORIES/Auxiliary/Associated EQUIPMENT**

**SIM - Simulator (Not Subjected to Test) \*Note: Use abbreviations:**

**IEC 60601-1-2****1.1.3 SIP/SOP and Input/output Ports:**

<b>PORT No.</b>	<b>Name</b>	<b>Type*</b>	<b>Cable Length</b>	<b>Cable Shielded (Y/N)</b>	<b>Comments (SIP/SOP lines must include description of use) (PATIENT-coupled cable termination must be described) (Interconnecting cables – describe construction details, ferrites, etc.)</b>
0	Enclosure	N/E	—	—	None
1	Mains	AC			1 pcs
2	Ethernet	SIP/SOP	3m	Y	3 pcs
3	COM port RS232	SIP/SOP	3m	Y	2 pcs
4	USB 3.0 port	SIP/SOP	3m	Y	6 pcs
5	DisplayPort	SOP	3m	Y	2 pcs
6	Line out	SOP	3m	Y	1 pcs
7	Mic in	SIP	3m	Y	1 pcs

Supplementary information:

**\*Note**

AC= AC Power PORT

DC = DC Power PORT

Batt=Battery

N/E = Non-Electrical

SIP/SOP= SIGNAL INPUT/OUTPUT PORT

PC – PATIENT-Coupled Cable

TP= Telecommunication Ports IC = Interconnecting cable

**Picture of SIP/SOP and Input/output Ports:**

SOP Display Port



SIP/SOP COM port RS232

**IEC 60601-1-2**

SIP/SOP USB 3.0 Port



SIP Mic in / SOP Line out



SIP/SOP Ethernet

**1.1.4 EUT Internal Operating Frequencies (Optional):**

Frequency (MHz)	Description	Frequency (MHz)	Description
3100	Intel® Core™ i3-8100T CPU	1200	DDR4 DRAM
3500	Intel® Core™ i5-8500T CPU	100	Bus CLK
4000	Intel® Core™ i7-8700T CPU	5000	USB 3.0
6000	SATA 3	480	USB 2.0
25	Base CLK LAN	0.032768	Base CLK RTC
24	Base CLK PCH	8	AT90USB646
2.4	Switching freq. voltage generator	60/72/87.5	21.5" LCD CLK (min/typ/max)
53.7/71.2/90	23.8" LCD CLK (min/typ/max)	53.7/71.2/90	27" LCD CLK (min/typ/max)
13.56	RFID reader	2400/5000	WLAN/Bluetooth®

Supplementary information:

## IEC 60601-1-2

## 1.1.5 Power Interface

Mode No.	Voltage (V)	Current (A)	Power (W)	Frequency (DC/AC-Hz)	Phases (No.)	Comments
Rated	100 - 240	1.5 - 0.75	---	50/60	1	
1	230	0.492	105.2	50	1	
2	100	1.062	105.2	60	1	
3	240	0.473	104.9	50	1	
4	24 VDC	---	---	---	---	Battery operated If not stated otherwise: power cable attached, but supply voltage turned off

Supplementary information:

### Selection of power supply voltage and frequency during tests at equipment

If a test is applicable, it shall be performed using the power input voltages and frequencies specified in the table below. (see IEC 60601-1-2 chap 4.3.3)

Test Power	input voltage	Line frequency
Mains terminal disturbance voltage (conducted EMISSIONS) CISPR 11	Any one voltage a)	Any one frequency b)
Electromagnetic radiation disturbance (radiated EMISSIONS) CISPR 11	Any one voltage a)	Any one frequency b)
Harmonic current EMISSIONS IEC 61000-3-2	For ME EQUIPMENT and ME SYSTEMS RATED 220 V to 240 V or 380 V to 415 V: If RATED at a single voltage, that voltage. If single-phase and a range is specified, 230 V If three-phase and a range is specified, 400 V	50 Hz or 60 Hz
Voltage changes, voltage fluctuations and flicker EMISSIONS IEC 61000-3-3	For ME EQUIPMENT and ME SYSTEMS RATED 220 V to 250 V line to neutral: If RATED at a single voltage, that voltage. If single-phase and a range is specified, 230 V If three-phase and a range is specified, 400 V	50 Hz
ELECTROSTATIC DISCHARGE IMMUNITY IEC 61000-4-2	Any one voltage a)	Any one frequency b)
Radiated RF electromagnetic field IMMUNITY IEC 61000-4-3	Any one voltage a)	Any one frequency b)
IMMUNITY to proximity fields from RF wireless communications equipment IEC 61000-4-3 (interim method)	Any one voltage a)	Any one frequency b)
Electrical fast transient/burst IMMUNITY – a.c. mains IEC 61000-4-4	Any one voltage a)	Any one frequency b)
Electrical fast transient/burst IMMUNITY – I/O SIP/SOP PORTS IEC 61000-4-4	Any one voltage a)	Any one frequency b)
Surge IMMUNITY IEC 61000-4-5	Any one voltage a)	Any one frequency b)
IMMUNITY to conducted DISTURBANCES induced by RF fields (conducted RF DISTURBANCE IMMUNITY) – a.c. mains	Any one voltage a)	Any one frequency b)

**IEC 60601-1-2**

IEC 61000-4-6		
IMMUNITY to conducted DISTURBANCES induced by RF fields (conducted DISTURBANCE IMMUNITY) – SIP/SOP PORTS IEC 61000-4-6	Any one voltage a)	Any one frequency b)
Power frequency magnetic field IMMUNITY IEC 61000-4-8	Any one voltage a)	Either 50 Hz or 60 Hz. During the test, the frequency of the generated magnetic field and the line frequency of the ME EQUIPMENT or ME SYSTEM shall be the same.b)
Voltage dips, short interruptions and voltage variations IMMUNITY IEC 61000-4-11	If the RATED voltage range < 25 % of the lowest RATED input voltage, one RATED input voltage. Otherwise, minimum and maximum RATED voltage c) d)	Any one frequency b)

NOTE "Mains terminal disturbance voltage" is a CISPR 11 term for what is commonly referred to as "mains conducted EMISSIONS".

a) 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) The test may be performed at any one line frequency within the ME EQUIPMENT or ME SYSTEM RATED frequency range. If the ME EQUIPMENT or ME SYSTEM is tested at one line frequency, it is not necessary to retest at additional frequencies.

c) Examples:

- The RATED voltage range is 100 V a.c. to 240 V a.c.  
240 V a.c. – 100 V a.c. = 140 V a.c. (range)  
25 % of 100 V a.c. is 25 V a.c.  
140 V a.c. > 25 V a.c.  
Therefore, the ME EQUIPMENT or ME SYSTEM is tested at the minimum and maximum RATED voltage.
- The RATED voltage range is 220 V a.c. to 240 V a.c.  
240 V a.c. – 220 V a.c. = 20 V a.c. (range)  
25 % of 220 V a.c. is 55 V a.c.  
20 V a.c. < 55 V a.c.  
Therefore, the ME EQUIPMENT or ME SYSTEM is tested at one voltage within the RATED range.

d) ME EQUIPMENT and ME SYSTEMS with power input voltage selection by transformer taps shall be tested at only one tap setting.

**IEC 60601-1-2****1.2 EUT Operation Modes:**

<b>Mode #</b>	<b>Description</b>
1	EUT unpowered, power cable removed (not tested, no emissions expected)
2	EUT power cable attached, standby mode (not tested, no emissions expected)
3	EUT powered and booted, idle/desktop mode (not tested, emissions expected lower than worst case modes)
4	EUT powered and booted, executing system test (not tested, emissions expected lower than worst case modes)
5	EUT powered and booted, power cable attached to provide PE connection, but supply voltage turned off → discharging internal UPS battery, executing system test (worst case mode – discharging)
6	EUT powered and booted, power cable attached, charging internal UPS battery, executing system test (worst case mode – charging)
Supplementary information:	

**1.3 EUT Configuration Modes:**

<b>Configuration #</b>	<b>Description</b>
1	<ul style="list-style-type: none"> <li>• Intel® i7-8700T CPU</li> <li>• 2x8GB DDR4 2400 RAM modules</li> <li>• 23.8" FullHD LCD</li> <li>• AC input for internal SMPS</li> <li>• Glass front</li> <li>• 2.5" SATA SSD 128GB</li> <li>• M.2 2260 SSD 128GB</li> <li>• M.2 2230 frame grabber module</li> <li>• miniPCIe RFID module</li> <li>• PCIe Gigabit LAN card</li> <li>• 2x OptoCom RS232</li> </ul> Backup battery with charger module
Supplementary information (include any special ME EQUIPMENT or ME SYSTEM hardware or software needed to perform the tests).	



**IEC 60601-1-2****1.4 BASIC SAFETY, ESSENTIAL PERFORMANCE and Pass/Fail Criteria as determined by the Manufacturer****Description of BASIC SAFETY and ESSENTIAL PERFORMANCE**

Basic Safety (see IEC 60601-1 and risk analyses)

IEC 60601 clause	Description
	Requirements derived from IEC 60601
8.4	Limitation of voltage, current or energy
8.6	Protective earthing, functional earthing and potential equalization of ME EQUIPMENT
8.7	LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS
8.8	Insulation
11.1	Excessive temperatures in ME EQUIPMENT

MLC8 devices itself do not provide any essential performance, shall be evaluated in the end-use product

**Description how the BASIC SAFETY and ESSENTIAL PERFORMANCE were monitored during each test**

Basic Safety was checked before and after EMC Tests.

Basic Safety requirements are meet.

No excessive temperatures are observed. (smoke, etc).

Basic safety after all immunity tests is evaluated in the report according to IEC 60601-1: N40P0001

**IMMUNITY Pass/Fail Criteria**

Test Description	Pass/Fail Criteria description	Part 2 reference
Electrostatic Discharges	..	NA
Radiated RF EM Fields	..	NA
Proximity Wireless fields	..	NA
Electrical Fast Transients and bursts	..	NA
Surges	..	NA
Conducted Disturbances, induced by RF fields	..	NA
Voltage Dips and Interruptions	..	NA
Rated Power-frequency Magnetic Field	..	NA

Note: Specific, detailed **IMMUNITY** pass/fail criteria, shall be based on applicable part two standards or RISK MANAGEMENT, for **IMMUNITY** with regard to EM DISTURBANCES. These pass/fail criteria shall be included in the RISK MANAGEMENT FILE

**IEC 60601-1-2**

<b>IMMUNITY TEST LEVELS for SPECIAL ENVIRONMENTS</b>		
<b>EM DISTURBANCE levels</b>	<b>Test Level</b>	<b>Justification for SPECIAL ENVIRONMENTS identified</b>
Conducted RF EMISSIONS		NA
Radiated RF EMISSIONS		NA
Harmonic Distortion		NA
Voltage Fluctuations and Flicker		NA
<b>IMMUNITY TEST LEVELS</b>		NA
Electrostatic Discharges		NA
Radiated RF EM Fields		NA
Proximity Wireless fields		NA
Electrical Fast Transients and bursts		NA
Surges		NA
Conducted Disturbances, induced by RF fields		NA
Voltage Dips and Interruptions		NA
Rated Power-frequency Magnetic Field		NA
Supplemental Information: <ul style="list-style-type: none"> <li>The resulting final IMMUNITY TEST LEVELS are to be rounded to the nearest whole number or, if a decimal, to a single significant digit</li> <li>Details of the methods and data sources used in determining the appropriate IMMUNITY TEST LEVELS are to be described in the table below.</li> </ul>		

<b>IMMUNITY</b>	<b>Details of the methods and data sources used in determining the appropriate IMMUNITY TEST LEVELS noted above</b>
Electrostatic Discharges	NA
Radiated RF EM Fields	NA
Proximity Wireless fields	NA
Electrical Fast Transients and bursts	NA
Surges	NA
Conducted Disturbances, induced by RF fields	NA
Voltage Dips and Interruptions	NA
Rated Power-frequency Magnetic Field	NA

**IEC 60601-1-2****1.5 Configuration Block Diagram:**

None

**1.6 Compliance Summary**

List of ACCOMPANYING DOCUMENTS reviewed	Manual_MLC 8_rev 0.7_en, Release date 30.01.2019, Rev 0.7 – Preliminary ATGD-DMF-MLC8-002_Intended Purpose_1.0, Version 1

IEC 60601-1-2			
Clause	Requirement + Test	Result - Remark	Verdict
<b>4</b>	<b>GENERAL REQUIREMENTS</b>		
4.1	RISKS resulting from reasonably foreseeable ELECTROMAGNETIC DISTURBANCES taken into account in the RISK MANAGEMENT PROCESS.	RMF Reference Document: Document ATGD-DMF-MLC8-008, 'product risk analysis', # 29 – # 34	P
4.2	Non-ME EQUIPMENT used in an ME SYSTEM		N/A
	Check 16.1 of general standard, checked by inspection of the RISK MANAGEMENT FILE and OBJECTIVE EVIDENCE of compliance with the respective EMC standards, or by the tests of this collateral standard	RMF Reference Document: ATGD-DMF-MLC8-002 'description of the intended purpose', section 4.2; manual, chapter 4.1.2	N/A
	non-ME EQUIPMENT used in an ME SYSTEM complies with IEC and ISO EMC standards applicable to that EQUIPMENT, checked by inspection of the RISK MANAGEMENT FILE and OBJECTIVE EVIDENCE of compliance with the respective EMC standards, or by the tests of this collateral standard	See above	N/A
	non- ME EQUIPMENT used in an ME SYSTEM for which the intended EM ENVIRONMENT could result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE of the ME SYSTEM due to the non-ME EQUIPMENT tested according to the requirements of this collateral standard, checked by inspection of the RISK MANAGEMENT FILE and OBJECTIVE EVIDENCE of compliance with the respective EMC standards, or by the tests of this collateral standard	See above	N/A
4.3.1	Configurations		P
	ME EQUIPMENT and ME SYSTEMS tested in representative configurations, consistent with INTENDED USE, that are most likely to result in unacceptable RISK as determined by the MANUFACTURER (This was determined using RISK ANALYSIS, experience, engineering analysis, or pretesting). Compliance checked by inspection of the test report and the RISK MANAGEMENT FILE.	See Appended Item Table 1.3 and RMF Reference Document:  Considerations and documentation of the representative configurations are described in ATGD_MLC8_EMC_Testplan_1.2, chapter 3.1  Test plan is part of RMF, see reference document "ATGD-DMF-MLC8-011_internal note EMC test plan_1.0"	P
4.3.3	Power input and frequencies	See appended Table Item 1.1.5	P
<b>5</b>	<b>IDENTIFICATION, MARKING AND DOCUMENTS</b>		
5.1	Additional requirements for marking on the outside of ME EQUIPMENT and ME SYSTEMS specified for use only in a shielded location SPECIAL ENVIRONMENT		N/A

<b>IEC 60601-1-2</b>			
<b>Clause</b>	<b>Requirement + Test</b>	<b>Result - Remark</b>	<b>Verdict</b>
	ME EQUIPMENT and ME SYSTEMS specified for use only in a shielded location SPECIAL ENVIRONMENT labelled with a CLEARLY LEGIBLE warning that they should be used only in the specified type of shielded location		N/A
5.2	<b>ACCOMPANYING DOCUMENTS</b>		
5.2.1	Instructions for use		
5.2.1.1	General		
a)	A statement of the environments for which the ME EQUIPMENT or ME SYSTEM is suitable. Relevant exclusions determined by RISK ANALYSIS, are listed.	RMF Reference Document: See reference document, Manual_MLC 8_rev 0.7_en, Release date 30.01.2019, Rev 0.7 – Preliminary, Chapter 10.1.2. This document will be referred as IFU further in this report	P
b)	The ESSENTIAL PERFORMANCE of ME EQUIPMENT and a description of what the operator can expect if the ESSENTIAL PERFORMANCE is lost or degraded due to EM disturbances.	No essential performance defined by the manufacturer. See reference document, ATGD-DMF-MLC8-008_RA MLC8_draft_0.6, chapter 4.2	N/A
c)	A warning regarding stacking and location close to other EQUIPMENT	See Document “ATGD-DMF-MLC8-002_Intended Purpose_1.0”, Chapter 10.1	P
d)	List of cables, transducers and accessories	See Document “ATGD-DMF-MLC8-002_Intended Purpose_1.0”, Chapter 10.1 The only recommendation is to use shielded cables and observe the vendors bend radius. Therefore a list of cables is not applicable.	N/A
e)	A warning that other cables and accessories may negatively affect EMC performance	No accessories, transducers or cables provided by manufacturer; no restrictions defined	N/A
f)	A statement that portable RF communications EQUIPMENT including antennas, can effect medical electrical EQUIPMENT. The warning includes a use distance such as “...be used no closer than 30 cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by manufacturer”	See IFU, Chapter 10.1	P
5.2.1.2	Requirements applicable to ME EQUIPMENT and ME SYSTEMS classified class A according to CISPR 11		P

IEC 60601-1-2			
Clause	Requirement + Test	Result - Remark	Verdict
	<p>FOR ME EQUIPMENT and ME SYSTEMS that are classified as class A according to CISPR 11, the instructions for use include the following note:</p> <p>NOTE: "The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment."</p>	See IFU, Chapter 10.1	P
5.2.2	Technical description		
5.2.2.1	Requirements applicable to all ME EQUIPMENT and ME SYSTEMS		
	The technical description describes precautions to be taken to prevent adverse events to the PATIENT and Operator due to electromagnetic disturbances	Reference Document: See IFU, Chapter 10, caution passage	P
a)	Compliance for each EMISSIONS and IMMUNITY standard or test specified by this collateral standard, e.g. EMISSIONS class and group and IMMUNITY TEST LEVEL	See IFU, Chapter 10.1	P
b)	Any deviations from this collateral standard and allowances used	Reference Document: No deviations or allowances specified	P
c)	All necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to ELECTROMAGNETIC DISTURBANCES for the EXPECTED SERVICE LIFE	See IFU, Chapter 6.5.1 No maintenance or service intervals required Chapter 10.1 notice	P
5.2.2.2	Requirements applicable to ME EQUIPMENT specified for use only in shielded location SPECIAL ENVIRONMENT		
	The technical description includes the following information:		
a)	A warning to the effect that: WARNING: Failure to use this EQUIPMENT in the specified type of shielded location could result in degradation of performance, interference with other equipment or interference with radio services		N/A
b)	Specifications for shielded location including: – minimum RF shielding effectiveness; – for each cable that enters or exits the shielded location, the minimum RF filter attenuation; and – the frequency range(s) over which the specifications apply		N/A

IEC 60601-1-2			
Clause	Requirement + Test	Result - Remark	Verdict
c)	Test methods for measurement of RF shielding effectiveness and RF filter attenuation		N/A
d)	One or more of the following and a recommendation that a notice containing this information be posted at the entrance(s) to the shielded location: – a specification of the EMISSIONS characteristics of other EQUIPMENT allowed inside the shielded location with the ME EQUIPMENT or ME SYSTEM; – a list of specific EQUIPMENT allowed; – a list of types of EQUIPMENT prohibited.		N/A
5.2.2.3	Requirements applicable to ME EQUIPMENT that intentionally receive RF electromagnetic energy include the following information ..... - each frequency or frequency of reception, - the preferred frequency or frequency band, if applicable, and - the bandwidth of the receiving section of the ME Equipment in those bands	Reference Document: See IFU, Chapter 6.4.2	P
5.2.2.4	Requirements applicable to the ME EQUIPMENT that include RF transmitters the technical description includes the frequency or frequency band of transmission, the type and frequency characteristics of the modulation and the EFFECTIVE RADIATED POWER (ERP).....	Reference Document: See IFU, Chapter 6.4.2	P
5.2.2.5	Requirements applicable to PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS		
	The technical description includes the following information:		
a)	A statement that an exemption has been used and that the EQUIPMENT has not been tested for radiated RF IMMUNITY over the entire frequency range 80 MHz to 6 GHz		N/A
b)	WARNING: "This EQUIPMENT has been tested for radiated RF IMMUNITY only at selected frequencies, and use nearby of emitters at other frequencies could result in improper operation"		N/A
c)	A list of the frequencies and modulations used to test the IMMUNITY of the ME EQUIPMENT or ME SYSTEMS		N/A
5.2.2.6	Requirements applicable to ME EQUIPMENT that claim compatibility with HF Surgical EQUIPMENT		
	Technical description includes a statement of HF SURGICAL EQUIPMENT compatibility and the conditions of INTENDED USE during HF Surgery		N/A

IEC 60601-1-2			
Clause	Requirement + Test	Result - Remark	Verdict
<b>6.1</b>	<b>Documentation of tests - General</b>		
	The documentation of tests contains all information necessary to facilitate adequate planning (test plan) and execution of tests	all information necessary is included in this test report	P
<b>6.2</b>	<b>Test Plan</b>		
	Prior to the start of formal testing, a detailed test plan provided to the test laboratory. (Note: title / name / version of test plan in remark section)	See Test Plan ATGD_MLC8_EMC_Testplan_1.3	P
<b>7</b>	<b>Electromagnetic EMISSIONS requirements for ME EQUIPMENT and ME SYSTEMS</b>		
7.1.1	Protection of radio services and other equipment - General		P
	Unless otherwise specified herein, ME EQUIPMENT and ME SYSTEMS complies with CISPR 11		P
7.1.2	Operating modes		P
	During Emission testing, ME EQUIPMENT or ME SYSTEM tested in the modes that maximize Emissions. In addition to active modes, the inclusion of standby mode was considered. The operating modes selected for testing documented in the test plan and documented in the test report	See Appended Item Table 1.2	P
7.1.3	Multimedia Equipment		N/A
	Multimedia equipment connected to ME EQUIPMENT or ME SYSTEM complies with CISPR 32. If CISPR 32 class A equipment is supplied as part of the ME SYSTEM classified class A		N/A
7.1.4	Subsystems		N/A
	Compliance with CISPR 11 demonstrated by testing each subsystem of an ME SYSTEM on a subsystem basic, provided the requirements of CISPR 11 for evaluation of EQUIPMENT that interacts with other equipment to form a system are met		N/A
7.1.5	ME EQUIPMENT and ME SYSTEMS specified for use only in a shielded location SPECIAL ENVIRONMENT		N/A



<b>IEC 60601-1-2</b>			
<b>Clause</b>	<b>Requirement + Test</b>	<b>Result - Remark</b>	<b>Verdict</b>
	For ME EQUIPMENT and ME SYSTEMS that are specified for use only in a shielded location SPECIAL ENVIRONMENT, the electromagnetic radiation disturbance limits of CISPR 11 may be increased, when tests are performed on a test site, by an amount up to the applicable specified value of minimum RF shielding effectiveness, provided the minimum RF shielding effectiveness specification		N/A
	For ME EQUIPMENT and ME SYSTEMS that are specified for use only in a shielded location SPECIAL ENVIRONMENT, the mains terminal disturbance voltage limits of CISPR 11 may be increased, when tests are performed on a test site, by an amount up to the applicable specified value of minimum RF filter attenuation for all cables that enter or exit the shielded location, provided the minimum RF filter attenuation specification		N/A
a)	The specified RF shielding effectiveness and RF filter attenuation: <ul style="list-style-type: none"> <li>- expressed in dB;</li> <li>- rounded to the nearest integer; and</li> <li>- at least 20 dB</li> </ul>		N/A
b)	The RF shielding effectiveness and RF filter attenuation specification include the frequency range over which the RF shielding effectiveness and RF filter attenuation apply, and this frequency range is at least one decade in width	Reference to Document:	N/A
c)	The specified value(s) for minimum RF filter attenuation are identical to the specified value(s) for minimum RF shielding effectiveness in each frequency range for which they are specified	Reference to Document:	N/A
d)	In frequency ranges for which the minimum RF shielding effectiveness and RF filter attenuation are not specified or are specified to be less than 20 dB, the RF shielding effectiveness and RF filter attenuation assumed to be 0 dB for the purpose of this collateral standard	Reference to Document:	N/A
<b>7.1.6</b>	<b>ME EQUIPMENT and ME SYSTEMS that include radio equipment</b>		N/A

<b>IEC 60601-1-2</b>			
<b>Clause</b>	<b>Requirement + Test</b>	<b>Result - Remark</b>	<b>Verdict</b>
	ME EQUIPMENT and ME SYSTEMS that include radio equipment (e.g. RF transmitters, receivers, transceivers) and have been tested together with the radio equipment and found to comply with applicable national radio regulations are exempt from testing to CISPR ELECTROMAGNETIC DISTURBANCE requirements		N/A
7.1.7	ME EQUIPMENT whose main functions are performed by motors and switching or regulating devices		N/A
	ME EQUIPMENT whose main functions are performed by motors and switching or regulating devices may be classified in accordance with CISPR 14-1		N/A
7.1.8	ME EQUIPMENT and ME SYSTEMS containing X-ray generators		N/A
	For diagnostic X-ray generators and ME SYSTEMS that include X-ray generators operating in INTERMITTENT MODE, the quasi-peak limits to discontinuous radiated and conducted DISTURBANCES can be relaxed by 20 dB		N/A
7.1.12	PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS		N/A
	PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS was TYPE TESTED by at least one of the following methods: - on a test site as a system; - on a test site on a subsystem basis; - <i>in situ</i> as a system at the premises of a RESPONSIBLE ORGANIZATION		N/A
	TEST METHOD SELECTED		N/A
<b>7.2</b>	<b>Protection of the PUBLIC MAINS NETWORK</b>		P
7.2.1	Harmonic distortion		P
	If the ME EQUIPMENT OR ME SYSTEMS has a PUBLIC MAINS NETWORK it complies with the requirements of IEC 61000-3-2	See Appended Item Table 1.11	P
7.2.2	<b>Voltage fluctuations and flicker</b>		P
	If the ME EQUIPMENT AND ME SYSTEMS has a PUBLIC MAINS NETWORK it complies with the requirements of IEC 61000-3-3.	See Appended Item Table 1.12	P
<b>7.3</b>	<b>Emissions requirements summary</b>		P
	Emission limits per environment	See Appended Item Tables 1.8 to 1.10	P
<b>8</b>	<b>Electromagnetic IMMUNITY requirements for ME EQUIPMENT and ME SYSTEMS</b>		

IEC 60601-1-2			
Clause	Requirement + Test	Result - Remark	Verdict
	For ME EQUIPMENT and ME SYSTEMS for which the INTENDED USE includes types of transportation or other locations as in the <b>HOME HEALTHCARE ENVIRONMENT</b> if additional IMMUNITY tests or IMMUNITY TEST LEVELS that are higher these additional tests to these higher IMMUNITY TEST LEVELS are documented		N/A
	ME EQUIPMENT or ME SYSTEMS intended for use in the EMERGENCY MEDICAL SERVICES ENVIRONMENT for the HOME HEALTHCARE ENVIRONMENT. If locations in the <b>EMERGENCY MEDICAL SERVICES ENVIRONMENT</b> are identified for which the specifications are for the HOME HEALTHCARE ENVIRONMENT are not adequate, then Annexe E may be used to determine appropriate IMMUNITY TEST LEVELS		N/A
	Before IMMUNITY testing begins, the MANUFACTURER determined specific, detailed IMMUNITY Pass/Fail criteria, based on applicable part two standards or RISK MANAGEMENT, for BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to EM DISTURBANCES. The Pass/Fail criteria and the monitoring specification are included in the test plan, in the test report and in the RISK MANAGEMENT FILE	RMF Reference Document:  Documentation in ATGD_MLC8 EMC_Testplan_1.2, chapter 3.5.1 and ATGD-DMF-MLC8-008, 'product risk analysis', # 29 – # 31	P
8.2	PATIENT physiological simulation		N/A
	If a PATIENT simulation is required to verify normal operation of the ME EQUIPMENT or ME SYSTEM, it was provided during IMMUNITY testing		N/A
	Prior to the beginning of the test, the amplitude of simulated PATIENT physiological signals were adjusted to be consistent with normal operation of the ME EQUIPMENT or ME SYSTEM, as specified by the MANUFACTURER		N/A
8.5	Subsystems		N/A
	When subsystems are tested to demonstrate compliance normal operating conditions are simulated		N/A
	The RISK MANAGEMENT PROCESS used to determine whether subsystem testing is allowed.		N/A
8.6	PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS		N/A

IEC 60601-1-2			
Clause	Requirement + Test	Result - Remark	Verdict
	PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS were TYPE TESTED by at least one of the following methods:		N/A
	<ul style="list-style-type: none"> <li>– on a test site as a system;</li> <li>– on a test site on a subsystem basis;</li> <li>– <i>in situ</i> as a system at the premises of a RESPONSIBLE ORGANIZATION</li> </ul>		N/A
	Test Method selected		N/A
8.7	Operating Modes		P
	Operating Modes and settings	See Appended Item Table 1.4 and RMF Reference Document: Operating modes during testing are determined in ATGD_MLC8 EMC Testplan, chapter 3.2.2	P
8.8	Non-ME EQUIPMENT		N/A
	Non-ME EQUIPMENT (e.g. ITE) that is a part of an ME SYSTEM fulfils the pass/fail criteria and IMMUNITY TEST LEVELS of Clause 8 if it has been determined, as a result of the RISK MANAGEMENT PROCESS, that the non-ME EQUIPMENT could affect the BASIC SAFETY or ESSENTIAL PERFORMANCE of the ME SYSTEM. (Inspection of the test report and the RISK MANAGEMENT FILE).		N/A
8.9	IMMUNITY TEST LEVELS	No EM disturbance levels altering from basis immunity levels determined	N/A
	Immunity Test Levels based on environment location of Intended Use		N/A
8.10	Immunity to proximity fields from RF wireless communication equipment		N/A
	Enclosure Port of ME EQUIPMENT and ME SYSTEMS tested as specified in Table 9 as per IEC 61000-4-3		N/A
Supplemental Information: References  [1] Manual_MLC 8_rev 0.7_en, Release date 30.01.2019, Rev 0.7 – Preliminary ATGD-DMF-MLC8-002_Intended Purpose_1.0, Version 1 [2] ATGD-DMF-MLC8-008_RA MLC8_draft_0.6, Version 0.6 [3] ATGD_MLC8 EMC Testplan_1.3, Version 1.3  ATGD-DMF-MLC8-011_internal note EMC test plan_1.0, Version 0.6 ATGD-DMF-MLC8-002_Intended Purpose_1.0, version 1			

**IEC 60601-1-2****1.7 Result Summary**

<b>Requirement – Test</b>	<b>Result/Comments</b>	<b>Verdict</b>
<b>Clause 7 - EMISSIONS</b>		<b>P</b>
Classification		—
Class A or B .....	Class B	—
Group 1 or 2 .....	Group 1	—
CISPR 11, 14-1, or ISO 7137 .....	CISPR 11	—
Conducted RF EMISSIONS .....		<b>P</b>
Radiated RF EMISSIONS .....		<b>P</b>
Disturbance Power (if applicable) .....		<b>N/A</b>
Harmonic Distortion per IEC 61000-3-2 (Class A, B, C, D) .....	Class A	<b>P</b>
Voltage Fluctuations and Flicker per IEC 61000-3-3 .....		<b>P</b>
<b>Clause 8 - IMMUNITY</b>		<b>P</b>
Electrostatic Discharges .....		<b>P</b>
Radiated RF EM Fields .....		<b>P</b>
Radiated RF EM Fields and Proximity Wireless fields.....		<b>P</b>
Electrical Fast Transients and bursts.....		<b>P</b>
Surges .....		<b>P</b>
Conducted Disturbances, induced by RF fields.....		<b>P</b>
Voltage Dips and Interruptions.....		<b>P</b>
Rated Power-frequency Magnetic Field.....		<b>P</b>
Supplemental Information: If tests are not performed, provide rationale here for each test:		
Not applicable		
If applicable, describe methods used to reduce the impact of ambient:		
Not applicable		

<b>Deviations from the Basic EMC standards or from this collateral standard</b>	
<b>Test</b>	<b>Description of Deviation</b>
Not applicable	

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**1.8 Test Conditions and Results – Conducted EMISSIONS**

CISPR 11: 2009 +A1: 2010	TEST: Limits of mains terminal disturbance voltage				Verdict
					P
Laboratory Parameters		Required prior to the test		During the test	
Ambient Temperature		10 to 40 °C		23.7 °C	
Relative Humidity		10 to 90 %		31.1 %	
Fully configured sample scanned over the following frequency range		Frequency range on each side of line		Measurement Point	
		150 kHz to 30 MHz		Mains	
EQUIPMENT mode		Power interface mode		4, 1	
		EUT configurations mode		1	
		Operation mode		5, 6	
Limits – Group 1 - Class A					
Frequency (MHz)	Limit dB (µV)				
	Quasi-Peak	Result*	Average	Result*	
0.15 to 0.50	79	N/A	66	N/A	
0.50 to 30	73	N/A	60	N/A	
Limits - Group 2 - Class A					
Frequency (MHz)	Limit dB (µV)				
	Quasi-Peak	Result*	Average	Result*	
0.15 to 0.50	100	N/A	90	N/A	
0.50 to 5	86	N/A	76	N/A	
5 to 30	90 to 70	N/A	80 to 60	N/A	
Limits - Group 2 - Class A					
Mains supply currents in excess of 100 A per phase					
Frequency (MHz)	Limit dB (µV)				
	Quasi-Peak	Result*	Average	Result*	
0.15 to 0.50	130	N/A	120	N/A	
0.50 to 5	125	N/A	115	N/A	
5 to 30	115	N/A	105	N/A	
Limits - Group 1 and 2 - Class B					
Frequency (MHz)	Limit dB (µV)				
	Quasi-Peak	Result*	Average	Result*	
0.15 to 0.50	66 to 56	P	56 to 46	P	
0.50 to 5	56	P	46	P	
5 to 30	60	P	50	P	
Supplementary information: * - The result in tables may be a minimum margin to the limit. EUT powered at one of the Nominal input voltages and frequencies. Note: In battery mode: power cable attached, but supply voltage turned off					

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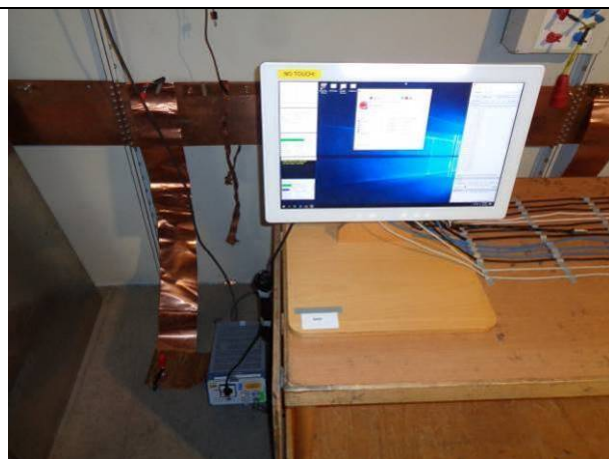
<b>CISPR 14-1: 2005</b>	<b>TEST: Limits of terminal disturbance voltage</b>	<b>Verdict</b>
		<b>N/A</b>
Supplementary information: * - The result in this table may be a minimum margin to the limit. EUT powered at one of the Nominal input voltages and frequencies. Note 1: the World Administrative Radio-Communications Conference (WARC) has in 1979 reduced the lower frequency limit in region 1 to 148.5 kHz; for applications falling in the scope of this standard, tests at 150 kHz are considered adequate, since 148.5 kHz falls within the receiver bandwidth. In limit tables 150 kHz used.		

<b>ISO 7137: 1995</b>	<b>TEST: Limits of mains terminal and I/O disturbance current</b>	<b>Verdict</b>
		<b>N/A</b>
Supplementary information: * - The result in tables may be a minimum margin to the limit. EUT powered at one of the Nominal input voltages and frequencies.		

**IEC 60601-1-2****Test equipment used for Mains Terminal Disturbance Voltage**

ID	Description	Manufacturer	Model	Serial No.	Status	Cal. date	Cal. due
P0339	test chamber 4	Siemens			chk	Feb 22, 2019	Feb 2020
P1445	LISN (integrated pulse limiter P0490)	R&S	ESH3-Z5	829567/009	cal	Apr 02, 2019	Apr 2021
P1915	Data logger for humidity and temperature (MZ4)	testo AG	testo 175 H1	40342591	cal	Aug 19, 2017	Aug 2020
P0320	EMI receiver, MZ4	R&S	ESCS30	100099	cal	Apr 05, 2018	Apr 2020
P1325	EMI receiver	R&S	ESPI-3	101500	cal	Apr 08, 2019	Apr 2021
P1891	RF-Relais-Matrix	R&S	PSU	872584/018	cnn		

cal = Calibration, car = Calibration restricted use, chk = Check, chr = Check restricted use, cpu = Check prior to use, calchk = Calibration and check, ind = for indication only, cnn = Calibration not necessary, man = Maintenance

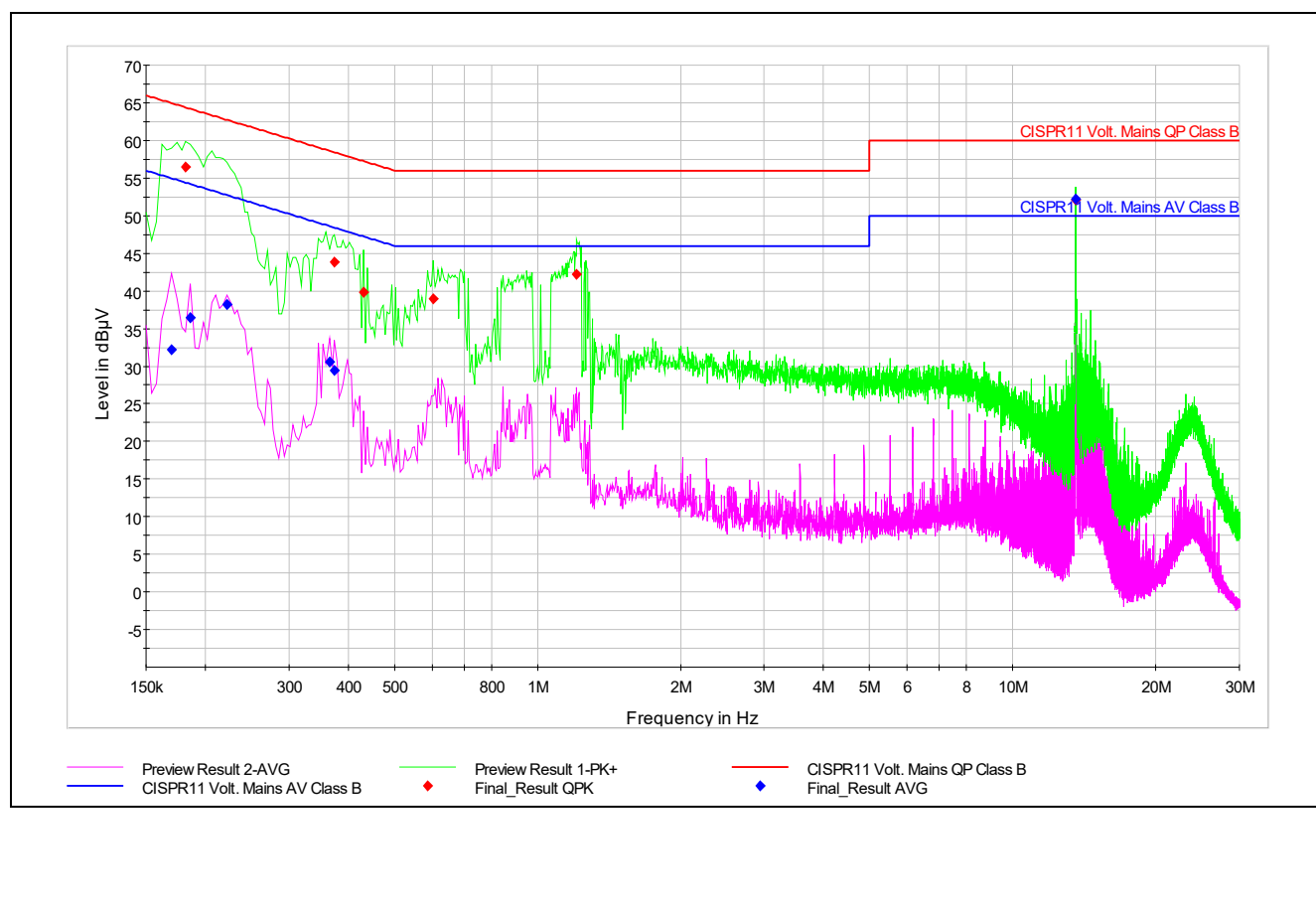
**Photo of test setup for Mains Terminal and Input / Output Disturbance Voltage**



**IEC 60601-1-2****Tabulated Results for Mains Terminal Disturbance Voltage – operation mode 6**

Frequency (MHz)	QuasiPeak (dBμV)	Average (dBμV)	Limit (dBμV)	Margin (dB)	Meas. Time (ms)	Bandwidth (kHz)	Line	PE	Corr. (dB)
0.170000	---	32.14	54.96	22.82	1000.0	9.000	L1	GND	10
0.182000	56.45	---	64.39	7.94	1000.0	9.000	N	GND	10
0.186000	---	36.51	54.21	17.70	1000.0	9.000	N	GND	10
0.222000	---	38.18	52.74	14.56	1000.0	9.000	N	GND	10
0.366000	---	30.52	48.59	18.07	1000.0	9.000	L1	GND	10
0.374000	43.89	---	58.41	14.52	1000.0	9.000	L1	GND	10
0.374000	---	29.44	48.41	18.97	1000.0	9.000	L1	GND	10
0.430000	39.78	---	57.25	17.47	1000.0	9.000	L1	GND	10
0.602000	38.92	---	56.00	17.08	1000.0	9.000	N	GND	10
1.210000	42.17	---	56.00	13.83	1000.0	9.000	L1	GND	10
13.562000	---	52.20	---	---	1000.0	9.000	N	GND	11
13.562000	52.07	---	---	---	1000.0	9.000	N	GND	11

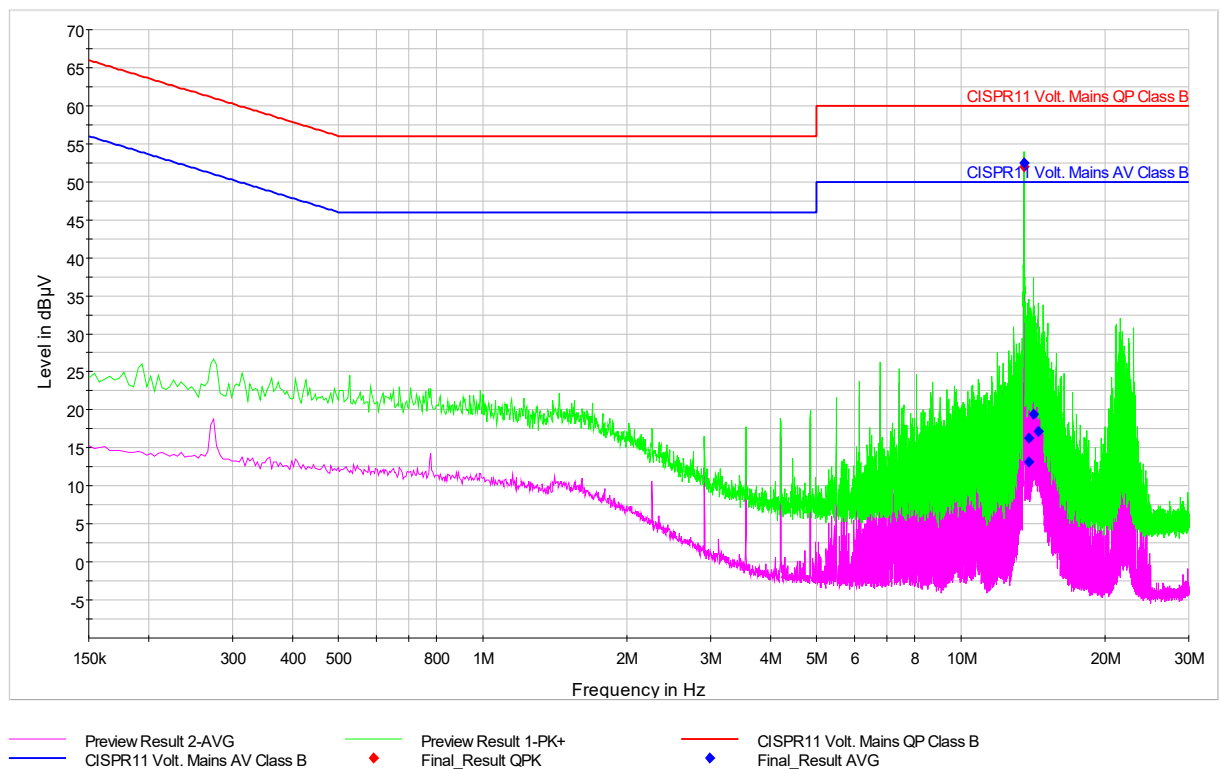
\*) Note: limit not applicable to wanted RFID carrier at 13.56 MHz

**Graphical representation of Mains Terminal Disturbance Voltage Measurement - operation mode 6**

**IEC 60601-1-2****Tabulated Results for Mains Terminal Disturbance Voltage - operation mode 5**

Frequency (MHz)	QuasiPeak (dBμV)	Average (dBμV)	Limit (dBμV)	Margin (dB)	Meas. Time (ms)	Bandwidth (kHz)	Line	PE	Corr. (dB)
13.562000	---	52.50	---	---	1000.0	9.000	N	GND	11
13.562000	52.01	---	---	---	1000.0	9.000	L1	GND	11
13.886000	---	16.26	50.00	33.74	1000.0	9.000	L1	GND	11
13.894000	---	13.18	50.00	36.82	1000.0	9.000	N	GND	11
14.214000	---	19.38	50.00	30.62	1000.0	9.000	N	GND	11
14.530000	---	17.12	50.00	32.88	1000.0	9.000	L1	GND	11

\*) Note: limit not applicable to wanted RFID carrier at 13.56 MHz

**Graphical representation of Mains Terminal Disturbance Voltage Measurement - operation mode 5**

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## 1.9 Test Conditions and Results – Radiated EMISSIONS

CISPR 11: 2009 +A1: 2010		TEST: Limits for radiated disturbance 0.15 MHz –1 GHz		Verdict
Test site:	<input type="checkbox"/> OATS	<input checked="" type="checkbox"/> SAC	<input type="checkbox"/> Alternative Test Site	P
Laboratory Parameters:		Required prior to the test	During the test	
Ambient Temperature		10 to 40 °C	20 °C	
Relative Humidity		10 to 90 %	25 %	
Fully configured sample scanned over the following frequency range		Frequency range	Measurement Distance	
		<input type="checkbox"/> 0.15 MHz – 1 GHz	<input type="checkbox"/> 3 m <input type="checkbox"/> 10 m	
		<input checked="" type="checkbox"/> 30 MHz – 1 GHz	<input checked="" type="checkbox"/> 3 m <input checked="" type="checkbox"/> 10 m	
EQUIPMENT mode		Power interface mode	4	
		EUT configurations mode	1	
		Operation mode	5 (at 10 m), 6 (at 3 m)	
Limits – Group 1 Class A				
Frequency (MHz)		Limit dB (µV/m)		
		Quasi-Peak	Results *	
30 to 230		40	N/A	
230 to 1000		47	N/A	
Limits – Group 1 Class B				
Frequency (MHz)		Limit dB (µV/m)		
		Quasi-Peak	Results *	
30 to 230		30 <sup>1</sup>	P	
230 to 1000		37 <sup>2</sup>	P	
Limits – Group 2 Class A				
Frequency (MHz)		Limits Below 30MHz dB (µA/m); Above 30MHz dB (µV/m)		
		Quasi-Peak	Results *	
0.15 to 30		See standard	N/A	
30 to 1000		See standard	N/A	
Limits – Group 2 Class B				
Frequency (MHz)		Limits Below 30MHz dB (µA/m); Above 30MHz dB (µV/m)		
		Quasi-Peak	Average**	Results *
0.15 to 30		39 to 3***	-	N/A
30 to 80.872		30	25	N/A
80,872 to 81,848		50	45	N/A
81,848 to 134,786		30	25	N/A
134,786 to 136,414		50	45	N/A
136,414 to 230		30	25	N/A
230 to 1000		37	32	N/A

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Supplementary information: EUT powered at one of the Nominal input voltages and frequencies.			
* - The result in this table may be a minimum margin to the limit.			
** - The Average Limits Apply To Magnetron Driven EQUIPMENT Only.			
*** - Decreases linearly with the logarithm of frequency			
QP Limit for Measurement distance at 3m			
		Class A	Class B
1	30 to 230	50 dB (µV/m)	40 dB (µV/m)
2	230 to 1000	57 dB (µV/m)	47 dB (µV/m)
Note: In battery mode: power cable attached, but supply voltage turned off			

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<b>CISPR 11: 2009 +A1: 2010</b>		<b>TEST: Limits for radiated disturbance 1 GHz – 18 GHz</b>		<b>Verdict</b>
<b>Test site:</b>	<input type="checkbox"/> <b>OATS</b>	<input checked="" type="checkbox"/> <b>SAC</b>	<input type="checkbox"/> <b>Alternative Test Site</b>	<b>N/A</b>
Supplementary information: EUT powered at one of the Nominal input voltages and frequencies. * - The result in this table may be a minimum margin to the limit. ** - Weighted measurements with a resolution bandwidth of 1 MHz and a video bandwidth of 10Hz.  <input checked="" type="checkbox"/> Test does not apply. Device is not Group 2 equipment <input type="checkbox"/> Test does not apply. Device is Group 2 equipment but does not operate over 400 MHz.				

ISO 7137: 1995	TEST: Limits for radiated disturbance 100 MHz –6 GHz	Verdict
		N/A
Supplementary information: EUT powered at one of the Nominal input voltages and frequencies. * -The result in this table may be a minimum margin to the limit.		

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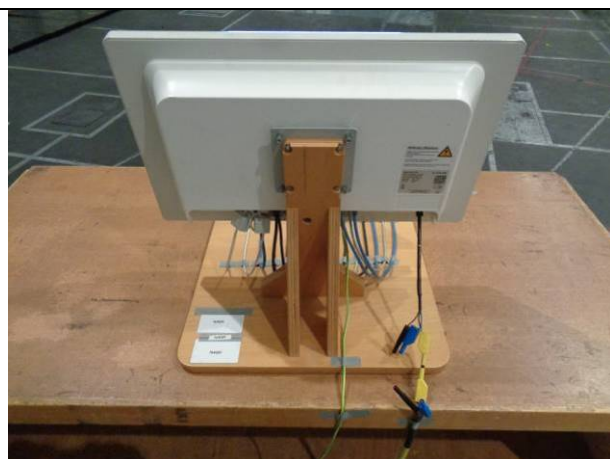
## Test equipment used – operation mode 5

ID	Description	Manufacturer	Model	Serial No.	Status	Cal. date	Cal. due
P0336	test chamber 1	Siemens			chk	Feb 22, 2019	Feb 2020
P1352	antenna, Ultralog	R&S	HL562	100413	cal	Jun 06, 2019	Jun 2021
P1139	Mast	innco GmbH	MA 4000	MA4000/083/91311104/L	cnn		
P1912	Data logger for humidity and temperature (MZ1)	testo AG	testo 175 H1	40342580	cal	Aug 18, 2017	Aug 2020
P1140	Controller	innco GmbH	CO 3000	CO3000/916	cnn		
P2062	EMI receiver	R&S	ESR26	101417	cal	Feb 07, 2018	Feb 2020

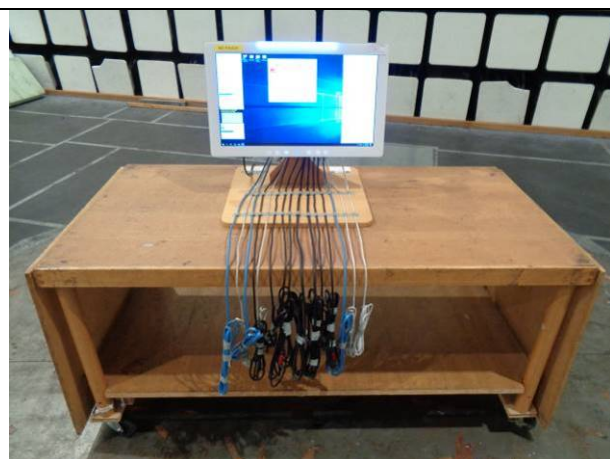
## Test equipment used – operation mode 6

ID	Description	Manufacturer	Model	Serial No.	Status	Cal. date	Cal. due
P0338	test chamber 3	Siemens			chk	Feb 22, 2019	Feb 2020
P0311	antenna	Chase	CBL6111	2409	cal	Mar 30, 2018	Mar 2021
P1303	Mast (MZ3)	innco GmbH	MA 4660-XPET		cnn		
P1326	EMI receiver	R&S	ESU26	100058	cal	Apr 05, 2018	Apr 2020
P1304	Controller	innco GmbH	CO 3000	CO3000/915	cnn		
P1914	Data logger for humidity and temperature (MZ3)	testo AG	testo 175 H1	40342576	cal	Aug 19, 2017	Aug 2020

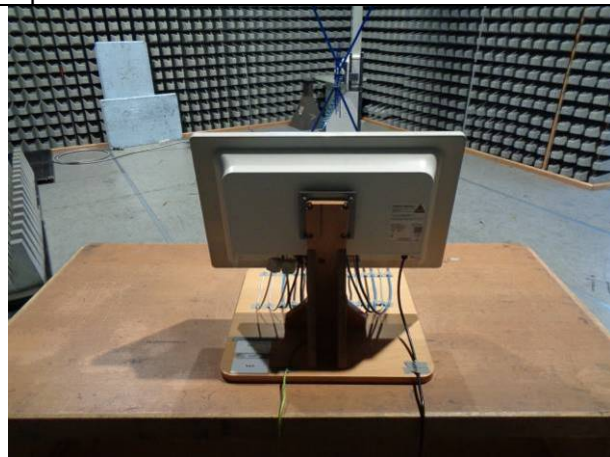
## Photo of test setup for Radiated Disturbance



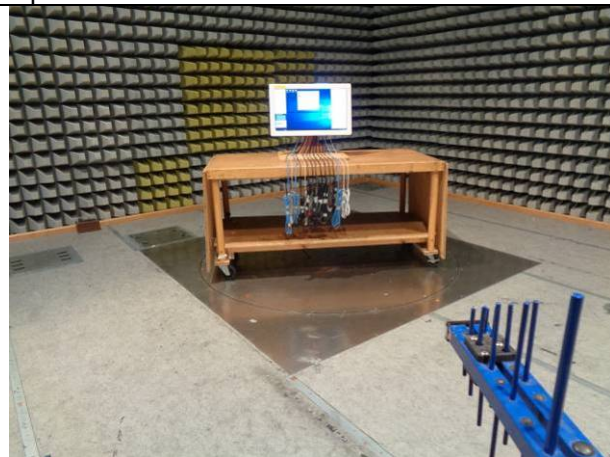
Operation mode 5 rear



Operation mode 5 front



Operation mode 6 rear



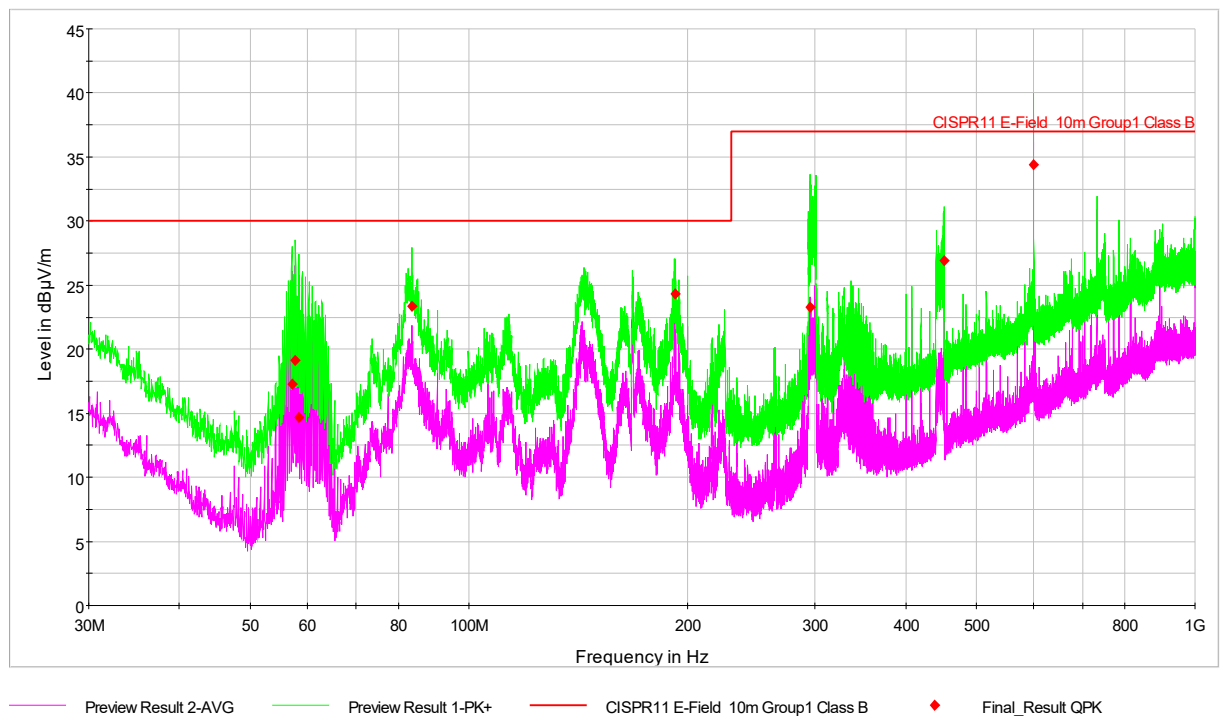
Operation mode 6 front

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## Tabulated Results for Radiated Disturbance - Operation mode 5

Frequency (MHz)	QuasiPeak (dB $\mu$ V/m)	Limit (dB $\mu$ V/m)	Margin (dB)	Meas. Time (ms)	Bandwidth (kHz)	Height (cm)	Pol	Azimuth (deg)	Corr. (dB/m)
57.079167	17.24	30.00	12.76	15000.0	120.000	348.0	V	305.0	6
57.725833	19.12	30.00	10.88	15000.0	120.000	288.0	V	291.0	6
58.372500	14.70	30.00	15.30	15000.0	120.000	378.0	V	298.0	6
83.592500	23.35	30.00	6.65	15000.0	120.000	150.0	V	327.0	9
192.475000	24.31	30.00	5.69	15000.0	120.000	100.0	V	319.0	9
295.254583	23.31	37.00	13.69	15000.0	120.000	109.0	V	195.0	13
451.545833	26.88	37.00	10.12	15000.0	120.000	173.0	H	304.0	17
600.036667	34.36	37.00	2.64	15000.0	120.000	341.0	H	16.0	20

## Graphical representation of Radiated Disturbance Measurement - Operation mode 5

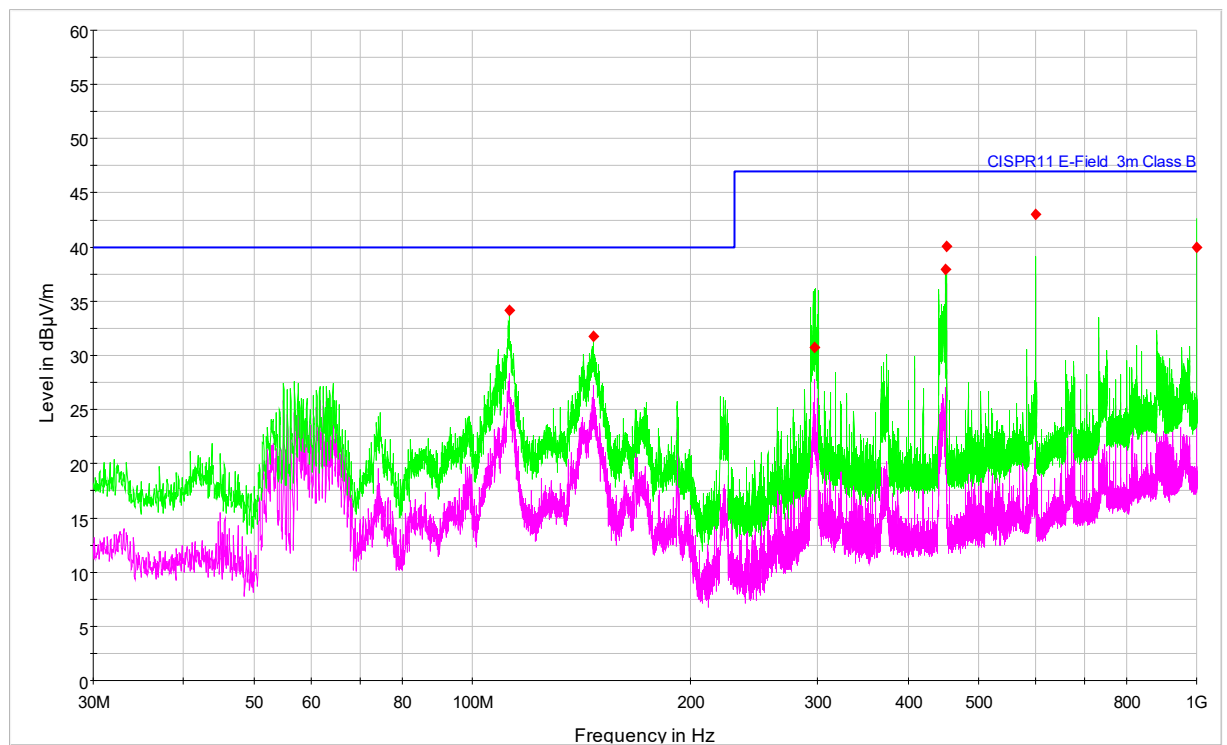


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## Tabulated Results for Radiated Disturbance - Operation mode 6

Frequency (MHz)	QuasiPeak (dB $\mu$ V/m)	DET 2 (dB $\mu$ V/m)	Limit (dB $\mu$ V/m)	Margin (dB)	Meas. Time (ms)	Bandwidth (kHz)	Height (cm)	Pol	Azimuth (deg)	Corr. (dB/m)
112.672500	34.18	---	40.00	5.82	1000.0	120.000	109.0	V	271.0	12
146.962000	31.74	---	40.00	8.26	1000.0	120.000	103.0	V	0.0	12
296.667000	30.70	---	47.00	16.30	1000.0	120.000	158.0	V	332.0	14
450.732000	37.94	---	47.00	9.06	1000.0	120.000	100.0	V	0.0	18
451.662000	40.06	---	47.00	6.94	1000.0	120.000	112.0	V	0.0	18
599.992000	42.99	---	47.00	4.01	1000.0	120.000	197.0	H	322.0	22
999.980000	40.00	---	47.00	7.00	1000.0	120.000	102.0	V	150.0	27

## Graphical representation of Radiated Disturbance Measurement - Operation mode 6



— Preview Result 2-AVG   
 — Preview Result 1-PK+   
 — CISPR11 E-Field 3m Class B   
 ◆ Final\_Result QPK



**IEC 60601-1-2****1.10 Test Conditions and Results – Disturbance Power EMISSIONS**

<b>CISPR 14-1: 2005</b>	<b>TEST: Limits of disturbance power</b>	<b>Verdict</b>
		<b>N/A</b>
Supplementary information: * - The result in this table may be a minimum margin to the limit. EUT powered at one of the Nominal input voltages and frequencies.		

**IEC 60601-1-2****1.11 Test Conditions and Results – Harmonic Current Emissions**

<b>IEC 61000-3-2:2005 +A1: 2008 +A2: 2009</b>		<b>TEST: Limits for harmonic current emissions (EQUIPMENT input current <math>\leq 16</math> A per phase)</b>	<b>Verdict</b>
			<b>P</b>
<b>Laboratory Parameters:</b>	<b>Required prior to the test</b>	<b>During the test</b>	
<b>Ambient Temperature</b>	<b>15 to 35 °C</b>	<b>26.0 °C</b>	
<b>Relative Humidity</b>	<b>30 to 60 %</b>	<b>25.6 %</b>	
<b>EQUIPMENT mode</b>	<b>Power interface mode</b>	<b>1</b>	
	<b>EUT configurations mode</b>	<b>1</b>	
	<b>Operation mode</b>	<b>6</b>	
<b>Classification of EQUIPMENT .....</b>			<b>Class A</b>
Supplementary information:			

**Test equipment used**

ID	Description	Manufacturer	Model	Serial No.	Status	Cal. date	Cal. due
P1088	4-quadrant amplifier (L1)	SPIBE	PAS 20000	A339201/0 0904	cnn		
P1288	power supply	SPIBE		A3758 02/0 1006	cnn		
P1286	4-quadrant amplifier (L2)	SPIBE	PAS 20000	A3758 01/1 1006	cnn		
P1287	4-quadrant amplifier (L3)	SPIBE	PAS 20000	A3758 01/2 1006	cnn		
P1090	control unit	SPIBE	SyCore 1k4		cnn		
P1091	analyzer reference system	SPIBE	ARS 16/3	A3392 07/1 0904	cal	Apr 03, 2019	Apr 2021
P1911	Data logger for pressure, humidity and temperature (Spibe)	testo AG	testo 176 P1	41000861 403+ 60244991	cal	Aug 22, 2017	Aug 2020

cal = Calibration, car = Calibration restricted use, chk = Check, chr = Check restricted use, cpu = Check prior to use, calchk = Calibration and check, ind = for indication only, cnn = Calibration not necessary, man = Maintenance

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**Photo of test setup for Harmonic Current EMISSIONS**



## IEC 60601-1-2

## Tabulated Results for Harmonic Current EMISSIONS

Name: Ratkovic Manufacturer: ADLINK MLC8-23 EUT 3  
 Department: EMV-Labor Serial no:  
 Company: SGS Operating modes: AC 230V 50Hz  
 Comment1:  
 Comment2:  
 Date of test: 15.05.2019

Maximum RMS current and corresponding values in timewindow 1:

Voltage: 230.60 Vrms THD=0.02 % THV=0.046 V POHV=0.016 V PWHD=0.05 %  
 Current: 0.492 Arms -0.837 Apk THD=31.68 % THC=0.149 A POHC=0.013 A PWHD=17.58 %  
 Power: 105.2 W P1= 105.2 W 113.5 VA  
 Power factor: 0.927 CosPhi1: 0.973

Test conditions: EN 61000-3-2:2014, f=50 Hz, Phase=L1, Range=0.80 A  
 Time window= 10/12 (200ms), Grouping (>2nd harm.)=on  
 No Ztest selected  
 harmonic currents < 0.6 % of I or < 5 mA are disregarded for calc. of THD, THC, POHC, PWHD

HARMONIC ANALYSIS: Test PASS

Tobs = entire measurement; POHC: avg=0.01 A, limits=0.25 A

Iavg=0.492 Arms

Ha	Entire measurement (0.200 s = 1 time window(s))							Worst 2.5 min		Average		P A S S	F A I L
	Maximum	Window	EN61000-3-2 Class A	Margin in MaxWin	100 to 150%	150 to 200%	Ex- ceeded	100 to 150%	Ex- ceeded	Value	Ex- ceeded		
DC	-0.0014 A	1	- - - -	- - - -	0	0	0	n.e.	n.e.	-0.0014 A	0	X	
1	0.4689 A	1	- - - -	- - - -	0	0	0	n.e.	n.e.	0.4689 A	0	X	
2	0.0033 A	1	1.0800 A	-99.7 %	0	0	0	n.e.	n.e.	0.0033 A	0	X	
3	0.1442 A	1	2.3000 A	-93.7 %	0	0	0	n.e.	n.e.	0.1442 A	0	X	
4	0.0010 A	1	0.4300 A	-99.8 %	0	0	0	n.e.	n.e.	0.0010 A	0	X	
5	0.0226 A	1	1.1400 A	-98.0 %	0	0	0	n.e.	n.e.	0.0226 A	0	X	
6	0.0009 A	1	0.3000 A	-99.7 %	0	0	0	n.e.	n.e.	0.0009 A	0	X	
7	0.0144 A	1	0.7700 A	-98.1 %	0	0	0	n.e.	n.e.	0.0144 A	0	X	
8	0.0006 A	1	0.2300 A	-99.7 %	0	0	0	n.e.	n.e.	0.0006 A	0	X	
9	0.0131 A	1	0.4000 A	-96.7 %	0	0	0	n.e.	n.e.	0.0131 A	0	X	
10	0.0004 A	1	0.1840 A	-99.8 %	0	0	0	n.e.	n.e.	0.0004 A	0	X	
11	0.0075 A	1	0.3300 A	-97.7 %	0	0	0	n.e.	n.e.	0.0075 A	0	X	
12	0.0005 A	1	0.1533 A	-99.7 %	0	0	0	n.e.	n.e.	0.0005 A	0	X	
13	0.0067 A	1	0.2100 A	-96.8 %	0	0	0	n.e.	n.e.	0.0067 A	0	X	
14	0.0004 A	1	0.1314 A	-99.7 %	0	0	0	n.e.	n.e.	0.0004 A	0	X	
15	0.0051 A	1	0.1500 A	-96.6 %	0	0	0	n.e.	n.e.	0.0051 A	0	X	
16	0.0006 A	1	0.1150 A	-99.5 %	0	0	0	n.e.	n.e.	0.0006 A	0	X	
17	0.0058 A	1	0.1324 A	-95.6 %	0	0	0	n.e.	n.e.	0.0058 A	0	X	
18	0.0005 A	1	0.1022 A	-99.6 %	0	0	0	n.e.	n.e.	0.0005 A	0	X	
19	0.0046 A	1	0.1184 A	-96.1 %	0	0	0	n.e.	n.e.	0.0046 A	0	X	
20	0.0005 A	1	0.0920 A	-99.5 %	0	0	0	n.e.	n.e.	0.0005 A	0	X	
21	0.0030 A	1	0.1071 A	-97.2 %	0	0	0	n.e.	n.e.	0.0030 A	0	X	
22	0.0006 A	1	0.0836 A	-99.3 %	0	0	0	n.e.	n.e.	0.0006 A	0	X	
23	0.0055 A	1	0.0978 A	-94.4 %	0	0	0	n.e.	n.e.	0.0055 A	0	X	
24	0.0007 A	1	0.0767 A	-99.1 %	0	0	0	n.e.	n.e.	0.0007 A	0	X	
25	0.0031 A	1	0.0900 A	-96.5 %	0	0	0	n.e.	n.e.	0.0031 A	0	X	
26	0.0008 A	1	0.0708 A	-98.8 %	0	0	0	n.e.	n.e.	0.0008 A	0	X	
27	0.0079 A	1	0.0833 A	-90.5 %	0	0	0	n.e.	n.e.	0.0079 A	0	X	
28	0.0008 A	1	0.0657 A	-98.7 %	0	0	0	n.e.	n.e.	0.0008 A	0	X	
29	0.0023 A	1	0.0776 A	-97.1 %	0	0	0	n.e.	n.e.	0.0023 A	0	X	
30	0.0008 A	1	0.0613 A	-98.6 %	0	0	0	n.e.	n.e.	0.0008 A	0	X	
31	0.0026 A	1	0.0726 A	-96.4 %	0	0	0	n.e.	n.e.	0.0026 A	0	X	
32	0.0009 A	1	0.0575 A	-98.5 %	0	0	0	n.e.	n.e.	0.0009 A	0	X	
33	0.0043 A	1	0.0682 A	-93.6 %	0	0	0	n.e.	n.e.	0.0043 A	0	X	
34	0.0009 A	1	0.0541 A	-98.3 %	0	0	0	n.e.	n.e.	0.0009 A	0	X	
35	0.0038 A	1	0.0643 A	-94.1 %	0	0	0	n.e.	n.e.	0.0038 A	0	X	
36	0.0009 A	1	0.0511 A	-98.3 %	0	0	0	n.e.	n.e.	0.0009 A	0	X	
37	0.0047 A	1	0.0608 A	-92.3 %	0	0	0	n.e.	n.e.	0.0047 A	0	X	
38	0.0008 A	1	0.0484 A	-98.3 %	0	0	0	n.e.	n.e.	0.0008 A	0	X	
39	0.0017 A	1	0.0577 A	-97.1 %	0	0	0	n.e.	n.e.	0.0017 A	0	X	
40	0.0006 A	1	0.0460 A	-98.7 %	0	0	0	n.e.	n.e.	0.0006 A	0	X	

average value < 0.6 % of Iavg or < 5 mA n.e. = not evaluated

Tested with SPS EMC 4.1.3/ PAS20000 by Spitzenberger & Spies GmbH & Co. KG, Schmidst. 32/34, 94234 Viechtach, Germany, 15.05.2019

**IEC 60601-1-2****1.12 Test Conditions and Results – Voltage changes, voltage fluctuations and flicker**

IEC 61000-3-3: 2013	Test Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection		Verdict
			P
Laboratory Parameters:	Required prior to the test	During the test	
Ambient Temperature	15 to 35 °C	26.0 °C	
Relative Humidity	30 to 60 %	25.6 %	
EQUIPMENT mode	Power interface mode ..... :	1	
	EUT configurations mode..... :	1	
	Operation mode ..... :	6	
Control Method of EQUIPMENT (see below) ..... :		1	
1 - without additional conditions			
2 - switched manually, or switched automatically more frequently than twice per day, and also has either a delayed restart (the delay being not less than a few tens of seconds), or manual restart, after a power supply interruption.			
3 - attended while in use, or switched on automatically, or is intended to be switched on manually, no more than twice per day, and also has either a delayed restart (the delay being not less than a few tens of seconds) or manual restart, after a power supply interruption.			
Supplementary information:			

**Test Equipment Used**

<b>ID</b>	<b>Description</b>	<b>Manufacturer</b>	<b>Model</b>	<b>Serial No.</b>	<b>Status</b>	<b>Cal. date</b>	<b>Cal. due</b>
P1088	4-quadrant amplifier (L1)	SPIBE	PAS 20000	A339201/0 0904	cnn		
P1288	power supply	SPIBE		A3758 02/0 1006	cnn		
P1286	4-quadrant amplifier (L2)	SPIBE	PAS 20000	A3758 01/1 1006	cnn		
P1287	4-quadrant amplifier (L3)	SPIBE	PAS 20000	A3758 01/2 1006	cnn		
P1090	control unit	SPIBE	SyCore 1k4		cnn		
P1091	analyzer reference system	SPIBE	ARS 16/3	A3392 07/1 0904	cal	Apr 03, 2019	Apr 2021
P1911	Data logger for pressure, humidity and temperature (Spibe)	testo AG	testo 176 P1	41000861 403+ 60244991	cal	Aug 22, 2017	Aug 2020

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## Photo of test setup for Voltage Fluctuations and Flicker



## Tabulated Results for Voltage Fluctuations and Flicker

Name:	Ratkovic	Manufacturer:	ADLINK MLC8-23 EUT 3					
Department:	EMV-Labor	Serial no:						
Company:	SGS	Operating modes:	AC 230V 50Hz					
		Comment1:						
		Comment2:						
		Date of test:	15.05.2019					
Test conditions: EN 61000-3-3:2013 / 230 V / 50 Hz / Phase L1								
EN 61000-4-15:2011 / Obs 1 x 10 min / Ztest (0.400+j0.250) Ohm								
Ra+jXa (0.2400+j0.1500) Ohm / Rn+jXn (0.1600+j0.1000) Ohm								
FLICKER: Test PASS!								
Time	Pmax	Pst	Sliding Plt	Tmax[s]	dmax[%]	dc [%]	PASS	FAIL
16:08:35	0.010	0.0720	- . - . - .	0.000	+0.000	- . - . - .	X	
Limits:		1.000	0.650	0.500	4.000	3.300		
Plt: 0.031449 (calculated over 12 periods)							X	
Evaluated: PST, PLT, Sliding PLT, dc, dmax Tmax								
FLICKER: Source test PASS!								
Time	Pmax	Pst	Sliding Plt	Tmax[s]	dmax[%]	dc [%]	PASS	FAIL
16:08:35	0.000	0.0090	- . - . - .	0.000	+0.000	- . - . - .	X	
Plt: 0.003931 (calculated over 12 periods)								
Evaluated: PST <= 0.4 dmax < 20 % dmax1								
Tested with SPS EMC 4.1.3 / PA S20000 by Spitzenberger & Spies GmbH & Co. KG, Schindler 32-34, 94634 Viechtach, Germany, 15.05.2019								

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**1.13 Test Conditions and Results – Electrostatic discharge IMMUNITY**

IEC 61000-4-2: 2008		TEST: Electrostatic discharge IMMUNITY		Verdict
				P
Laboratory Parameters:	Required prior to the test		During the test	
Ambient Temperature	15 to 35 °C		27.5 °C	
Relative Humidity	30 to 60 %		36.7 %	
Atmospheric Pressure	86 kPa (860 mbar) to 106 kPa (1060 mbar)		101 kPa (1012 mbar)	
EQUIPMENT mode	Power interface mode		4, 1	
	EUT configurations mode		1	
	Operation mode		5, 6	
IMMUNITY TEST LEVELS				
Discharge type	Discharge Level (kV)		Number of discharges per location (each polarity)	
	Positive	Negative		
Air – Direct	2, 4, 8, 15	2, 4, 8, 15	10	
Contact – Direct	8	8	10	
Contact – Indirect	8	8	10	
Discharge location	See photo documentation of the test set-up All external locations accessible by hand, Horizontal plate (HCP) Vertical coupling plate (VCP)			
Supplementary information: EUT powered at one of the Nominal input voltages and frequencies				
Note: In battery mode: power cable attached, but supply voltage turned off				

**Test Equipment Used**

ID	Description	Manufacturer	Model	Serial No.	Status	Cal. date	Cal. due
P0726	vertical coupling plane	Keytek	VCP-1	9209343	cnn		
P0983	ESD generator, basic unit	EMC Partner	ESD3000	243/70	cal	Apr 02, 2019	Apr 2021
P0984	ESD generator, discharge module	EMC Partner	ESD3000DM1	068	cal	Apr 02, 2019	Apr 2021
P0977	test chamber 6	Siemens			chk	Feb 22, 2019	Feb 2020
P1917	Data logger for humidity and temperature (MZ6)	testo AG	testo 175 H1	40342579	cal	Aug 19, 2017	Aug 2020

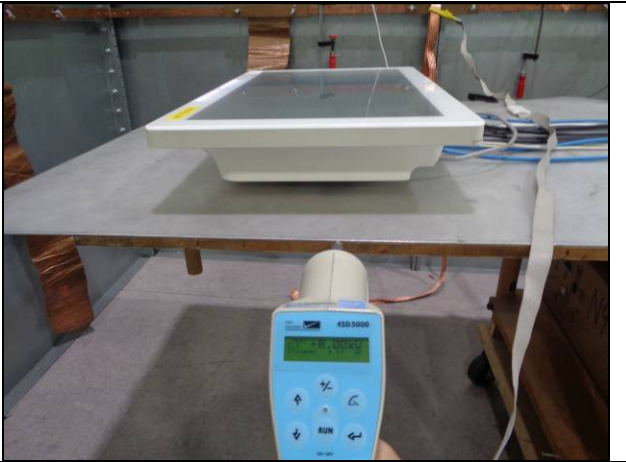
cal = Calibration, car = Calibration restricted use, chk = Check, chr = Check restricted use, cpu = Check prior to use, calchk = Calibration and check, ind = for indication only, cnn = Calibration not necessary, man = Maintenance

IEC 60601-1-2

Photo of test setup for IMMUNITY to Electrostatic Discharges



Test Setup



Indirect discharges on HCP



Indirect discharges on VCP



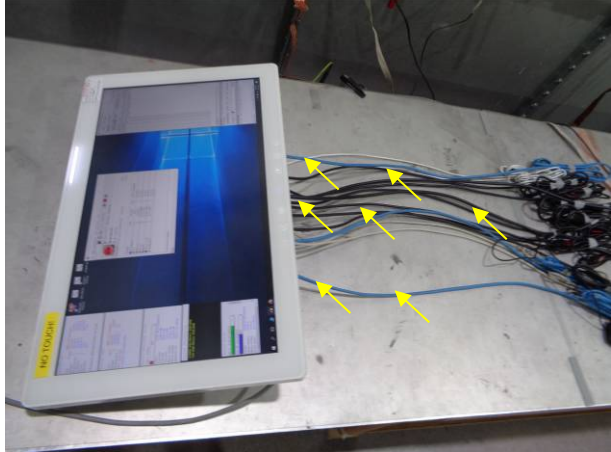
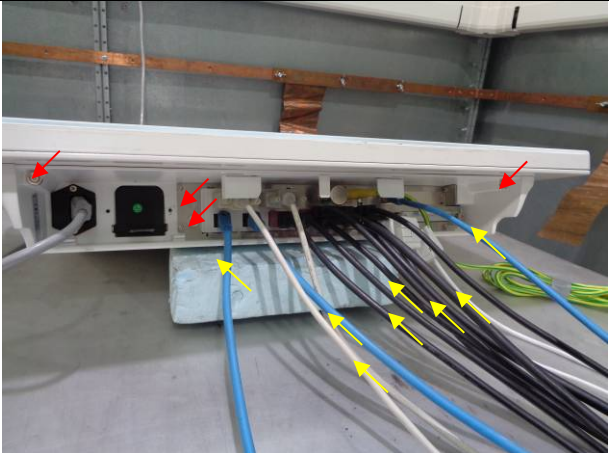
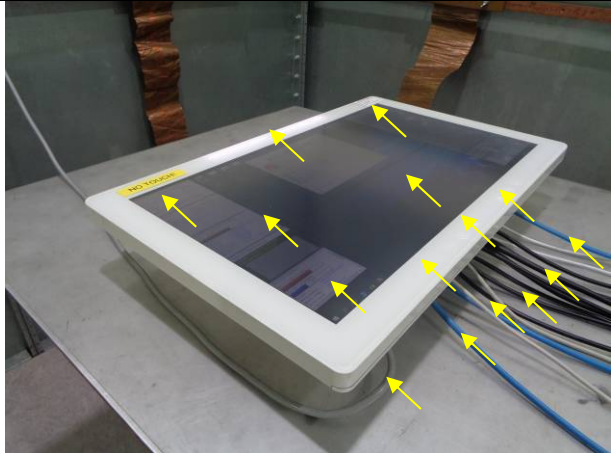


**IEC 60601-1-2**

Tabulated Results for Electrostatic Discharges - operation mode 5			
Nominal Voltage (V) ..... :		24 VDC	
Nominal Frequency (Hz)..... :		-	
Direct discharges: Air and Contact			
point accessible for INTENDED USE (if not shown on attached photos)	Air discharge voltage (kV)	Polarity	Result
See photos of discharge test locations	2	+/-	1
	4	+/-	1
	8	+/-	1
	15	+/-	1
point accessible for INTENDED USE (if not shown on attached photos)	Contact discharge voltage (kV)	Polarity	Result
See photos of discharge test locations	2	+/-	1
	4	+/-	1
	8	+/-	1
Indirect discharges			
point accessible for INTENDED USE (if not shown on attached photos)	Contact discharge voltage (kV)	Polarity	Result
HCP	8	+/-	1
VCP - Front	8	+/-	1
VCP - Left	8	+/-	1
VCP - Right	8	+/-	1
VCP - Rear	8	+/-	1
Results Descriptions: X - Not Performed nor required. 1 – Compliant - No perceived discharge, no observed response from EUT. 2 – Compliant – Discharge observed; no observed response from EUT.			
Note: When further description/comments are need, use result numbers beyond description two (2) to detail observations during testing (add more numbers where needed).			

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Tabulated Results for Electrostatic Discharges operation mode 6			
Nominal Voltage (V) ..... :		230 VAC	
Nominal Frequency (Hz)..... :		50 Hz	
Direct discharges: Air and Contact			
point accessible for INTENDED USE (if not shown on attached photos)	Air discharge voltage (kV)	Polarity	Result
See photos of discharge test locations	2	+/-	1
	4	+/-	1
	8	+/-	1
	15	+/-	1
point accessible for INTENDED USE (if not shown on attached photos)	Contact discharge voltage (kV)	Polarity	Result
See photos of discharge test locations	2	+/-	1
	4	+/-	1
	8	+/-	1
Indirect discharges			
point accessible for INTENDED USE (if not shown on attached photos)	Contact discharge voltage (kV)	Polarity	Result
HCP	8	+/-	1
VCP - Front	8	+/-	1
VCP - Left	8	+/-	1
VCP - Right	8	+/-	1
VCP - Rear	8	+/-	1
Results Descriptions: X - Not Performed nor required. 1 – Compliant - No perceived discharge, no observed response from EUT. 2 – Compliant – Discharge observed; no observed response from EUT.			
Note: When further description/comments are need, use result numbers beyond description two (2) to detail observations during testing (add more numbers where needed).			

IEC 60601-1-2

Photo of Electrostatic Discharges Test Locations	
<div></div>	
	Contact discharge
	Air discharge

## IEC 60601-1-2

**1.14 Test Conditions and Results - Radiated, radio-frequency, electromagnetic field IMMUNITY**

IEC 61000-4-3: 2006 +A1: 2007 +A2: 2010		TEST: Radiated, radio-frequency, electromagnetic field IMMUNITY		Verdict
				<b>P</b>
Laboratory Parameters:		Required prior to the test		During the test
Ambient Temperature		15 to 35 °C		25.3 °C
Relative Humidity		30 to 60 %		35.3 %
EQUIPMENT mode		Power interface mode		4, 1
		EUT configurations mode		1
		Operation mode		5, 6
Test specifications				
Frequency bandwidth		80 MHz to 2700 MHz		
Modulation		<input checked="" type="checkbox"/> 80% AM at 1 kHz*		<input type="checkbox"/> Other _____
Level Applied (V/m)	Professional Healthcare Environment	<input type="checkbox"/> 3V/m		
	Home Healthcare Environment	<input checked="" type="checkbox"/> 10V/m		
	Special Environment	<input type="checkbox"/> Other _____		
	Others	<input type="checkbox"/> _____		
Frequency step		<input checked="" type="checkbox"/> 1%		<input type="checkbox"/> Other _____
<p>Supplementary information:</p> <p>EUT powered at one of the Nominal input voltages and frequencies.</p> <p>Dwell time minimum 1 s. Actual dwell time noted in results table.</p> <p>Actual IMMUNITY TEST LEVEL noted in results table.</p> <p>Note * - Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.</p>				

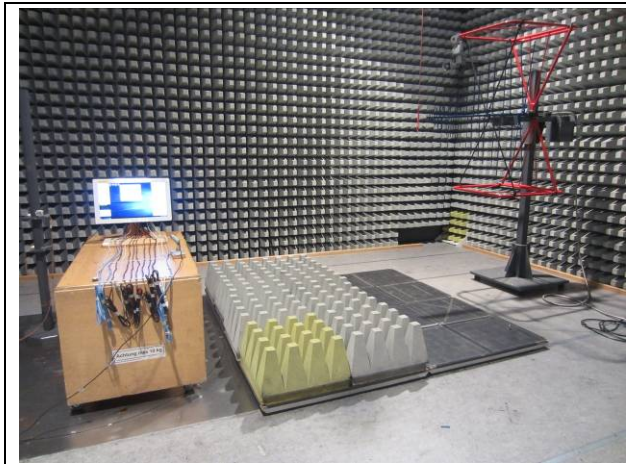
## IEC 60601-1-2

Test Equipment Used							
ID	Description	Manufacturer	Model	Serial No.	Status	Cal. date	Cal. due
<b>Equipment for 80 MHz – 1000 MHz</b>							
P0261	power meter	R&S	NRVS	864297/029	cal	Apr 02, 2019	Apr 2021
P0287	power sensor	R&S	NRV-Z51	829004/017	cal	Apr 02, 2019	Apr 2020
P0338	test chamber 3	Siemens			chk	Feb 22, 2019	Feb 2020
P0769	attenuator 20dB	Narda	768-20	8004	chk	Oct 15, 2018	Oct 2019
P0906	EM radiation meter, readout unit (MZ3)	Dare	RadiSense IV	04D00215SN O28	cal	Jun 12, 2017	Jun 2019
P0907	EM radiation meter, probe (MZ3)	Dare	RadiSense IV	28	cal	Jun 12, 2017	Jun 2019
P1328	amplifier	AR	500 W/1000A	0326009	cnn		
P1621	terminator (MZ3)	MECA Electronics	50 Ohm/ 15 W		chk	Sep 05, 2018	Sep 2019
P2399	Dual Directional Coupler	Werlatone	C6338-20 (50 dB/ 2500W)	116624	chk	Jul 25, 2018	Jul 2019
P0998	signal generator	R&S	SML 03	100539	cal	Mar 23, 2017	Mar 2020
P0032	antenna K (MZ3)	Emco	3140	1003	cnn		
<b>Equipment for 1 GHz – 2.7 GHz</b>							
P0338	test chamber 3	Siemens			chk	Feb 22, 2019	Feb 2020
P0568	signal generator	R&S	SMR 20	100370	cal	Apr 04, 2019	Apr 2020
P1196	amplifier, Dual Band Solid State	Milmega	AS0104-400/200-1-3b-22	1012671	cnn		
P0525	RF coupler	AR	DC 7144	28855	chk	Nov 19, 2018	Nov 2019
P0288	power sensor	R&S	NRV-Z51	829004/013	cal	Apr 02, 2019	Apr 2020
P0264	power meter	R&S	NRVS	836020/19	cal	Apr 04, 2018	Apr 2020
P0029	antenna	Emco	3105	2025	chk	Oct 17, 2018	Oct 2020
P0190	EM radiation meter	W&G	EMR-200	BN 2244/21	cal	Oct 12, 2017	Oct 2019
P1183	EM radiation probe	W&G	Type 9.2	AG-0006	cal	Oct 12, 2017	Oct 2019

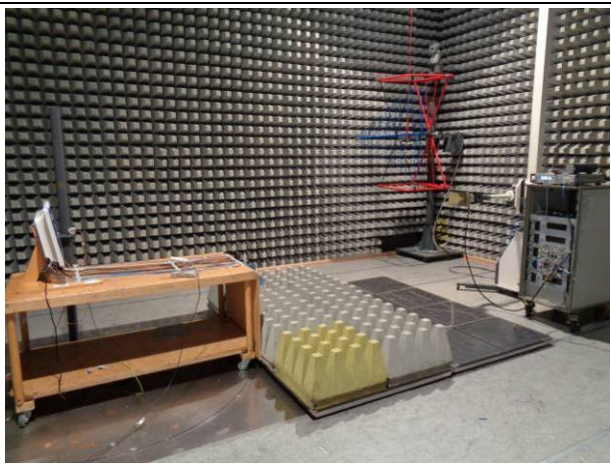
cal = Calibration, car = Calibration restricted use, chk = Check, chr = Check restricted use, cpu = Check prior to use, calchk = Calibration and check, ind = for indication only, cnn = Calibration not necessary, man = Maintenance

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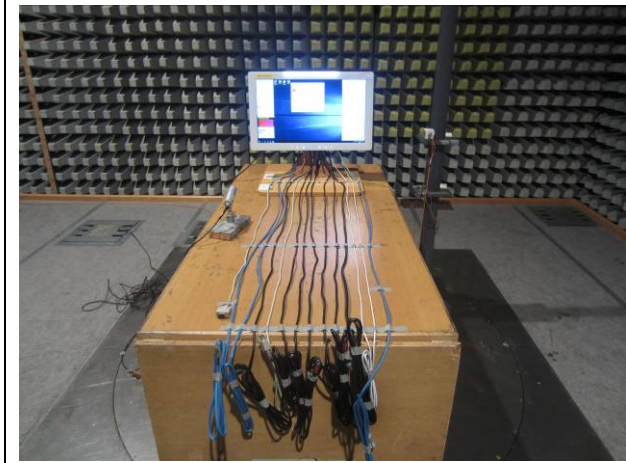
Photo of test setup for Radio Frequency Electromagnetic Fields



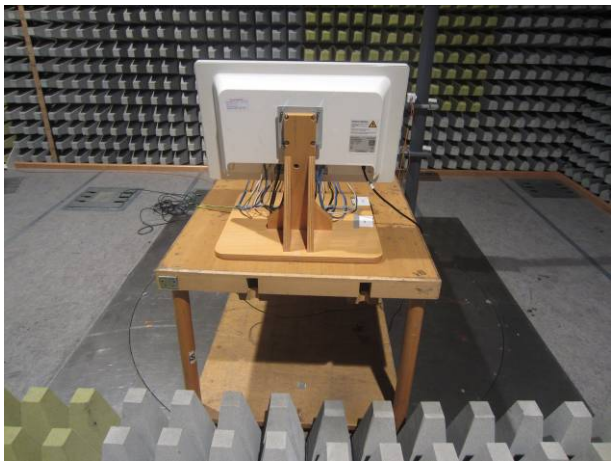
Setup 80 MHz – 1000 MHz



Setup 1 GHz – 6 GHz



Front



Rear



Left



Right



IEC 60601-1-2



Operation Mode 5



Operation Mode 6

**IEC 60601-1-2****Tabulated Results for RF Electromagnetic Field  
80 MHz to 2700 MHz - operation mode 5**

<b>EUT orientation</b>	<b>IMMUNITY TEST LEVEL (V/m)</b>	<b>Antenna polarization (V/H)</b>	<b>Dwell Time (second)</b>	<b>Result</b>
<b>Front</b>		<b>H</b>	<b>1</b>	<b>1</b>
		<b>V</b>	<b>1</b>	<b>1</b>
<b>Back</b>		<b>H</b>	<b>1</b>	<b>1</b>
		<b>V</b>	<b>1</b>	<b>1</b>
<b>Left</b>		<b>H</b>	<b>1</b>	<b>1</b>
		<b>V</b>	<b>1</b>	<b>1</b>
<b>Right</b>		<b>H</b>	<b>1</b>	<b>1</b>
		<b>V</b>	<b>1</b>	<b>1</b>
<b>Top</b>		<b>H</b>	<b>-</b>	<b>X</b>
		<b>V</b>	<b>-</b>	<b>X</b>
<b>Bottom</b>		<b>H</b>	<b>-</b>	<b>X</b>
		<b>V</b>	<b>-</b>	<b>X</b>

**Results Descriptions:****X - Not performed nor required.****1 – Compliant - No observed response from EUT.**

Note: Description of the response should detail observations during testing.

**Tabulated Results for RF Electromagnetic Field  
80 MHz to 2700 MHz – operation mode 6**

<b>EUT orientation</b>	<b>IMMUNITY TEST LEVEL (V/m)</b>	<b>Antenna polarization (V/H)</b>	<b>Dwell Time (second)</b>	<b>Result</b>
<b>Front</b>		<b>H</b>	<b>1</b>	<b>1</b>
		<b>V</b>	<b>1</b>	<b>1</b>
<b>Back</b>		<b>H</b>	<b>1</b>	<b>1</b>
		<b>V</b>	<b>1</b>	<b>1</b>
<b>Left</b>		<b>H</b>	<b>1</b>	<b>1</b>
		<b>V</b>	<b>1</b>	<b>1</b>
<b>Right</b>		<b>H</b>	<b>1</b>	<b>1</b>
		<b>V</b>	<b>1</b>	<b>1</b>
<b>Top</b>		<b>H</b>	<b>-</b>	<b>X</b>
		<b>V</b>	<b>-</b>	<b>X</b>
<b>Bottom</b>		<b>H</b>	<b>-</b>	<b>X</b>
		<b>V</b>	<b>-</b>	<b>X</b>

**Results Descriptions:****X - Not performed nor required.****1 – Compliant - No observed response from EUT.**

Note: Description of the response should detail observations during testing.



## IEC 60601-1-2

**1.15 Test Conditions and Results – Proximity fields from RF wireless communications EQUIPMENT**

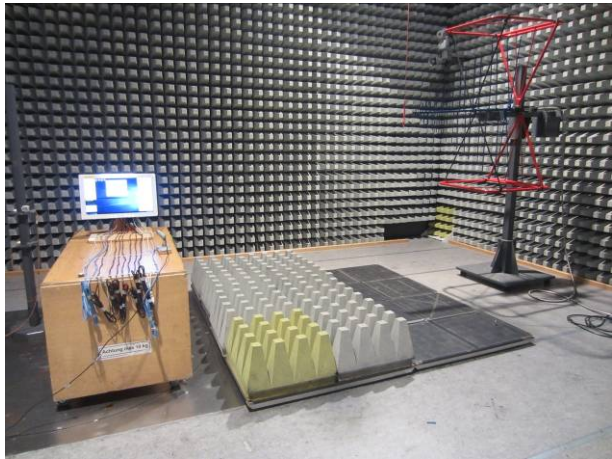
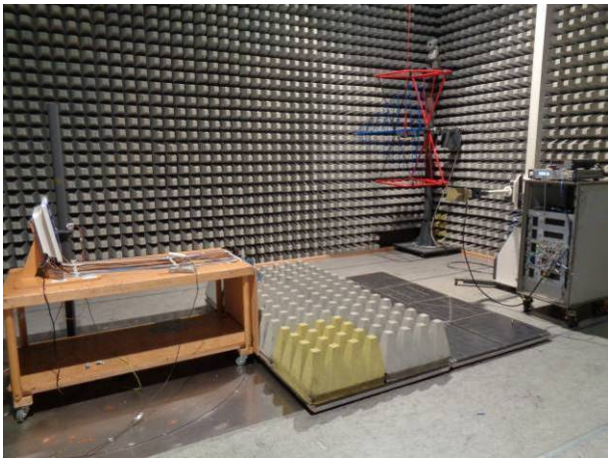
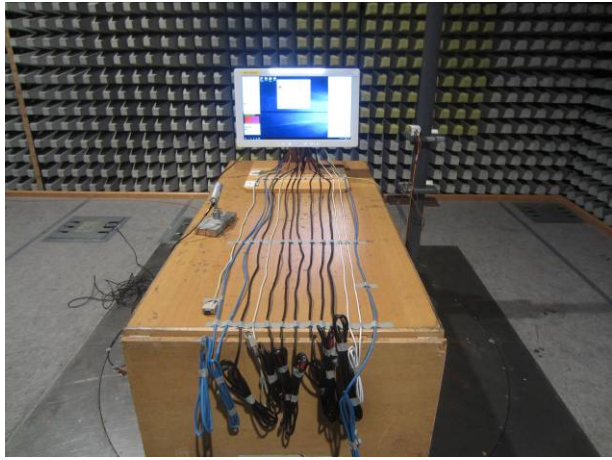
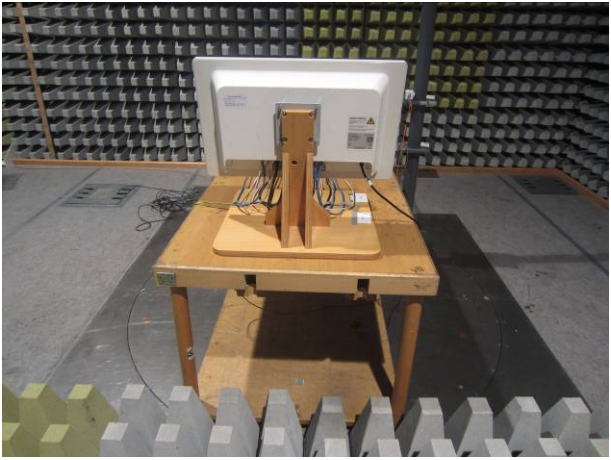
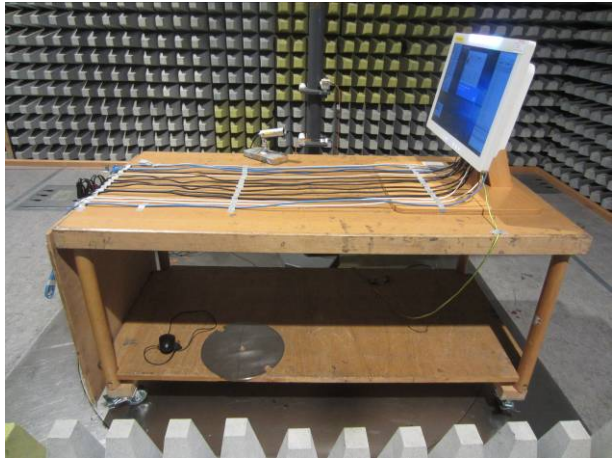
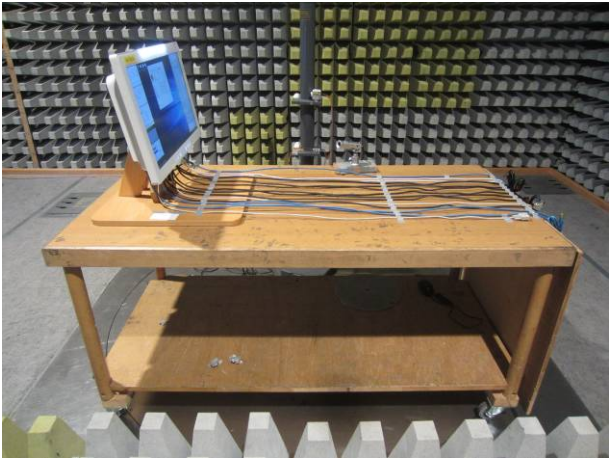
IEC 61000-4-3: 2006 +A1: 2007 +A2: 2010		TEST: Proximity fields from RF wireless communications EQUIPMENT		Verdict
				P
Laboratory Parameters:		Required prior to the test	During the test	
Ambient Temperature		15 to 35 °C	25.3 °C	
Relative Humidity		30 to 60 %	35.3 %	
EQUIPMENT mode		Power interface mode	4, 1	
		EUT configurations mode	1	
		Operation mode	5, 6	
Test specifications				
Frequency Range and Level: RF wireless communication EQUIPMENT				
Test Frequency (MHz)	Modulation		Minimum IMMUNITY Level (V/m)	IMMUNITY Level Applied (V/m)
385	**Pulse Modulation: 18 Hz		27	27
450	<input checked="" type="checkbox"/> *FM ± 5 Hz deviation: 1 kHz sine  <input type="checkbox"/> **Pulse Modulation: 18 Hz		28	28
710 745 780	**Pulse Modulation: 217 Hz		9	9
810 870 930	**Pulse Modulation: 18 Hz		28	28
1720 1845 1970	**Pulse Modulation: 217 Hz		28	28
2450	**Pulse Modulation: 217 Hz		28	28
5240 5500 5785	**Pulse Modulation: 217 Hz		9	9
Supplementary information: Add more rows above if additional frequencies are required to be tested as identified in the RISK MANAGEMENT PROCESS.  EUT powered at one of the Nominal input voltages and frequencies. Dwell time minimum 1 s. Actual dwell time noted in results table.  Note * - As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case. CBTL shall indicate which modulation was used.  Note** - The carrier shall be modulated using a 50 % duty cycle square wave signal.				

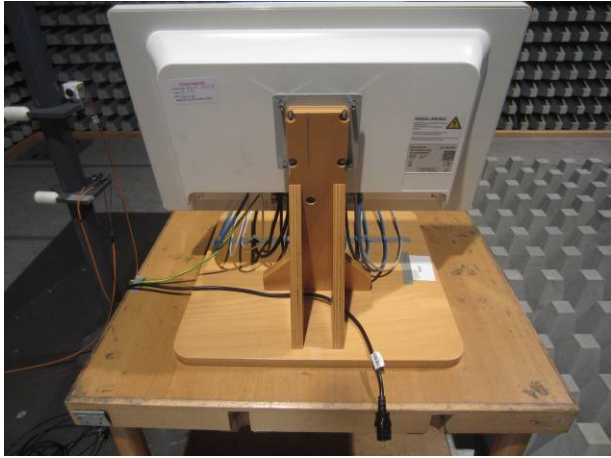
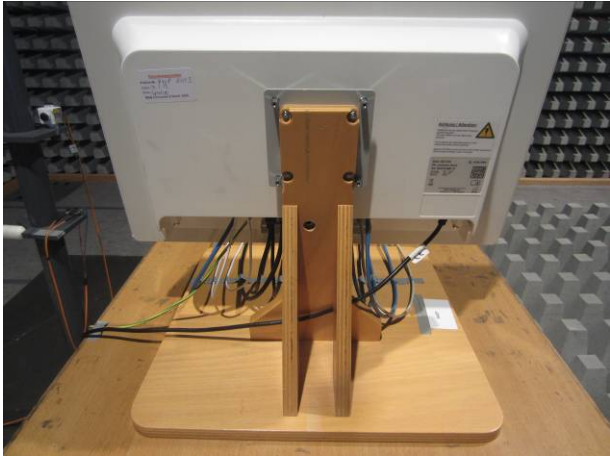
## IEC 60601-1-2

Test Equipment Used							
ID	Description	Manufacturer	Model	Serial No.	Status	Cal. date	Cal. due
<b>Equipment for 80 MHz – 1000 MHz</b>							
P0261	power meter	R&S	NRVS	864297/029	cal	Apr 02, 2019	Apr 2021
P0287	power sensor	R&S	NRV-Z51	829004/017	cal	Apr 02, 2019	Apr 2020
P0338	test chamber 3	Siemens			chk	Feb 22, 2019	Feb 2020
P0769	attenuator 20dB	Narda	768-20	8004	chk	Oct 15, 2018	Oct 2019
P0906	EM radiation meter, readout unit (MZ3)	Dare	RadiSense IV	04D00215SN O28	cal	Jun 12, 2017	Jun 2019
P0907	EM radiation meter, probe (MZ3)	Dare	RadiSense IV	28	cal	Jun 12, 2017	Jun 2019
P1328	amplifier	AR	500 W/1000A	0326009	cnn		
P1621	terminator (MZ3)	MECA Electronics	50 Ohm/ 15 W		chk	Sep 05, 2018	Sep 2019
P2399	Dual Directional Coupler	Werlatone	C6338-20 (50 dB/ 2500W)	116624	chk	Jul 25, 2018	Jul 2019
P0998	signal generator	R&S	SML 03	100539	cal	Mar 23, 2017	Mar 2020
P0032	antenna K (MZ3)	Emco	3140	1003	cnn		
<b>Equipment for 1 GHz – 2.7 GHz</b>							
P0338	test chamber 3	Siemens			chk	Feb 22, 2019	Feb 2020
P0568	signal generator	R&S	SMR 20	100370	cal	Apr 04, 2019	Apr 2020
P1196	amplifier, Dual Band Solid State	Milmega	AS0104-400/200-1-3b-22	1012671	cnn		
P0525	RF coupler	AR	DC 7144	28855	chk	Nov 19, 2018	Nov 2019
P0288	power sensor	R&S	NRV-Z51	829004/013	cal	Apr 02, 2019	Apr 2020
P0264	power meter	R&S	NRVS	836020/19	cal	Apr 04, 2018	Apr 2020
P0029	antenna	Emco	3105	2025	chk	Oct 17, 2018	Oct 2020
P0190	EM radiation meter	W&G	EMR-200	BN 2244/21	cal	Oct 12, 2017	Oct 2019
P1183	EM radiation probe	W&G	Type 9.2	AG-0006	cal	Oct 12, 2017	Oct 2019
<b>Equipment for 5 GHz – 6 GHz</b>							
P0338	test chamber 3	Siemens			chk	Feb 22, 2019	Feb 2020
P0568	signal generator	R&S	SMR 20	100370	cal	Apr 04, 2019	Apr 2020
P1594	amplifier 1-18 GHz	Bonn	TWAL 0118-30/20D	12880	cnn		
P0288	power sensor	R&S	NRV-Z51	829004/013	cal	Apr 02, 2019	Apr 2020
P0264	power meter	R&S	NRVS	836020/19	cal	Apr 04, 2018	Apr 2020
P0029	antenna	Emco	3105	2025	chk	Oct 17, 2018	Oct 2020
P0190	EM radiation meter	W&G	EMR-200	BN 2244/21	cal	Oct 12, 2017	Oct 2019
P1183	EM radiation probe	W&G	Type 9.2	AG-0006	cal	Oct 12, 2017	Oct 2019

cal = Calibration, car = Calibration restricted use, chk = Check, chr = Check restricted use, cpu = Check prior to use, calchk = Calibration and check, ind = for indication only, cnn = Calibration not necessary, man = Maintenance

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Photo of test setup for Proximity fields from RF wireless communications EQUIPMENT	
	
Setup 80 MHz – 1000 MHz	Setup 1 GHz – 6 GHz
	
Front	Rear
	
Left	Right

IEC 60601-1-2	
	
Operation Mode 5	Operation Mode 6

**IEC 60601-1-2**

<b>Tabulated Results for Proximity Fields From RF Wireless Communications EQUIPMENT OPERATION MODES 1 AND 2</b>				
<b>EUT Orientation</b>	<b>Test frequency (MHz)</b>	<b>Antenna polarization (V/H)</b>	<b>Dwell Time (second)</b>	<b>Result</b>
<b>Front</b>	<b>385</b>	<b>H</b>	<b>1</b>	<b>1</b>
	<b>450</b>	<b>H</b>	<b>1</b>	<b>1</b>
	<b>710 745 780</b>	<b>H</b>	<b>1</b>	<b>1</b>
	<b>810 870 930</b>	<b>H</b>	<b>1</b>	<b>1</b>
	<b>1720 1845 1970</b>	<b>H</b>	<b>1</b>	<b>1</b>
	<b>2450</b>	<b>H</b>	<b>1</b>	<b>1</b>
	<b>5240 5500 5785</b>	<b>H</b>	<b>1</b>	<b>1</b>
<b>Front</b>	<b>385</b>	<b>V</b>	<b>1</b>	<b>1</b>
	<b>450</b>	<b>V</b>	<b>1</b>	
	<b>710 745 780</b>	<b>V</b>	<b>1</b>	<b>1</b>
	<b>810 870 930</b>	<b>V</b>	<b>1</b>	<b>1</b>
	<b>1720 1845 1970</b>	<b>V</b>	<b>1</b>	<b>1</b>
	<b>2450</b>	<b>V</b>	<b>1</b>	<b>1</b>
	<b>5240 5500 5785</b>	<b>V</b>	<b>1</b>	<b>1</b>
<b>Back</b>	<b>385</b>	<b>H</b>	<b>1</b>	<b>1</b>
	<b>450</b>	<b>H</b>	<b>1</b>	<b>1</b>
	<b>710 745 780</b>	<b>H</b>	<b>1</b>	<b>1</b>
	<b>810 870 930</b>	<b>H</b>	<b>1</b>	<b>1</b>
	<b>1720</b>	<b>H</b>	<b>1</b>	<b>1</b>

<b>IEC 60601-1-2</b>				
<b>Tabulated Results for Proximity Fields From RF Wireless Communications EQUIPMENT OPERATION MODES 1 AND 2</b>				
<b>EUT Orientation</b>	<b>Test frequency (MHz)</b>	<b>Antenna polarization (V/H)</b>	<b>Dwell Time (second)</b>	<b>Result</b>
	1845 1970			
	2450	H	1	1
	5240 5500 5785	H	1	1
<b>Back</b>	385	V	1	1
	450	V	1	1
	710 745 780	V	1	1
	810 870 930	V	1	1
	1720 1845 1970	V	1	1
	2450	V	1	1
	5240 5500 5785	V	1	1
<b>Left</b>	385	H	1	1
	450	H	1	1
	710 745 780	H	1	1
	810 870 930	H	1	1
	1720 1845 1970	H	1	1
	2450	H	1	1
	5240 5500 5785	H	1	1
<b>Left</b>	385	V	1	1
	450	V	1	1
	710 745 780	V	1	1

<b>IEC 60601-1-2</b>				
<b>Tabulated Results for Proximity Fields From RF Wireless Communications EQUIPMENT OPERATION MODES 1 AND 2</b>				
<b>EUT Orientation</b>	<b>Test frequency (MHz)</b>	<b>Antenna polarization (V/H)</b>	<b>Dwell Time (second)</b>	<b>Result</b>
	810 870 930	V	1	1
	1720 1845 1970	V	1	1
	2450	V	1	1
	5240 5500 5785	V	1	1
<b>Right</b>	385	H	1	1
	450	H	1	1
	710 745 780	H	1	1
	810 870 930	H	1	1
	1720 1845 1970	H	1	1
	2450	H	1	1
	5240 5500 5785	H	1	1
<b>Right</b>	385	V	1	1
	450	V	1	1
	710 745 780	V	1	1
	810 870 930	V	1	1
	1720 1845 1970	V	1	1
	2450	V	1	1
	5240 5500 5785	V	1	1
<b>Top</b>	385	H		<b>X</b>

<b>IEC 60601-1-2</b>				
<b>Tabulated Results for Proximity Fields From RF Wireless Communications EQUIPMENT OPERATION MODES 1 AND 2</b>				
<b>EUT Orientation</b>	<b>Test frequency (MHz)</b>	<b>Antenna polarization (V/H)</b>	<b>Dwell Time (second)</b>	<b>Result</b>
	<b>450</b>	<b>H</b>		<b>X</b>
	<b>710 745 780</b>	<b>H</b>		<b>X</b>
	<b>810 870 930</b>	<b>H</b>		<b>X</b>
	<b>1720 1845 1970</b>	<b>H</b>		<b>X</b>
	<b>2450</b>	<b>H</b>		<b>X</b>
	<b>5240 5500 5785</b>	<b>H</b>		<b>X</b>
<b>Top</b>	<b>385</b>	<b>V</b>		<b>X</b>
	<b>450</b>	<b>V</b>		<b>X</b>
	<b>710 745 780</b>	<b>V</b>		<b>X</b>
	<b>810 870 930</b>	<b>V</b>		<b>X</b>
	<b>1720 1845 1970</b>	<b>V</b>		<b>X</b>
	<b>2450</b>	<b>V</b>		<b>X</b>
	<b>5240 5500 5785</b>	<b>V</b>		<b>X</b>
<b>Bottom</b>	<b>385</b>	<b>H</b>		<b>X</b>
	<b>450</b>	<b>H</b>		<b>X</b>
	<b>710 745 780</b>	<b>H</b>		<b>X</b>
	<b>810 870 930</b>	<b>H</b>		<b>X</b>
	<b>1720 1845 1970</b>	<b>H</b>		<b>X</b>
	<b>2450</b>	<b>H</b>		<b>X</b>



<b>IEC 60601-1-2</b>				
<b>Tabulated Results for Proximity Fields From RF Wireless Communications EQUIPMENT OPERATION MODES 1 AND 2</b>				
<b>EUT Orientation</b>	<b>Test frequency (MHz)</b>	<b>Antenna polarization (V/H)</b>	<b>Dwell Time (second)</b>	<b>Result</b>
	<b>5240 5500 5785</b>	<b>H</b>		<b>X</b>
<b>Bottom</b>	<b>385</b>	<b>V</b>		<b>X</b>
	<b>450</b>	<b>V</b>		<b>X</b>
	<b>710 745 780</b>	<b>V</b>		<b>X</b>
	<b>810 870 930</b>	<b>V</b>		<b>X</b>
	<b>1720 1845 1970</b>	<b>V</b>		<b>X</b>
	<b>2450</b>	<b>V</b>		<b>X</b>
	<b>5240 5500 5785</b>	<b>V</b>		<b>X</b>
<b>Results Descriptions:</b> <b>X - Not performed nor required.</b> <b>1 – Compliant - No observed response from EUT.</b>				
Supplementary information: Note: Description of the response should detail observations during testing.				

## IEC 60601-1-2

## 1.16 Test Conditions and Results – Electrical fast transient/burst IMMUNITY

IEC 61000-4-4: 2012	TEST: Electrical fast transient/burst IMMUNITY		Verdict
			P
Laboratory Parameters:	Required prior to the test	During the test	
Ambient Temperature	10 to 40 °C	27.0 °C	
Relative Humidity	10 to 90 %	30.4 %	
Fully configured sample subject to the levels shown below.	Measurement Point		
	Input a.c. Power Ports		
	Input d.c. Power Ports		
	Signal Input/Output Ports		
EQUIPMENT mode	Power interface mode	4, 1	
	EUT configurations mode	1	
	Operation mode	5, 6	
Applied Level			
Application Point	(kV)	Coupling Method	Repetition Frequency (kHz)
Input a.c. Power Ports	±2	Direct Injection	100
Input d.c. Power Ports	±2	Direct Injection	100
Signal Input/Output Ports	±1	Capacitive Clamp	100
Supplementary information:			
EUT powered at one of the Nominal input voltages and frequencies.			

ID	Description	Manufacturer	Model	Serial No.	Status	Cal. date	Cal. due
P0339	test chamber 4	Siemens			chk	Feb 22, 2019	Feb 2020
P0595	burst generator	Schloeder	SFT 4000	704002	cal	Apr 02, 2019	Apr 2022
P0593	burst coupling clamp	Schloeder	SFT410	kz01	chk	Mar 27, 2018	Mar 2020
P1915	Data logger for humidity and temperature (MZ4)	testo AG	testo 175 H1	40342591	cal	Aug 19, 2017	Aug 2020

cal = Calibration, car = Calibration restricted use, chk = Check, chr = Check restricted use, cpu = Check prior to use, calchk = Calibration and check, ind = for indication only, cnn = Calibration not necessary, man = Maintenance

## IEC 60601-1-2

## Photo of test setup for Electrical Fast Transients OP Mode 6



Mains



SIP/SOP COM port RS 232



SIP/SOP Ethernet

## Tabulated Results for Electrical Fast Transients - operation mode 6

Point of application	Results
Mains	1
SIP/SOP Ethernet	1
SIP/SOP COM port RS 232	1
<b>Results Descriptions:</b> X - Not performed nor required. 1 – Compliant - No observed response from EUT.	
Supplementary information: Note: Description of the response should detail observations during testing.	

**IEC 60601-1-2****Photo of test setup for Electrical Fast Transients - operation mode 5**

SIP/SOP Ethernet



SIP/SOP COM port RS 232

**Tabulated Results for Electrical Fast Transients - operation mode 5**

<b>Point of application</b>	<b>Results</b>
<b>Mains</b>	<b>1</b>
<b>SIP/SOP Ethernet</b>	<b>1</b>
<b>SIP/SOP COM port RS 232</b>	<b>1</b>
<b>Results Descriptions:</b> <b>X - Not performed nor required.</b> <b>1 – Compliant - No observed response from EUT.</b>	
Supplementary information: Note: Description of the response should detail observations during testing.	

**IEC 60601-1-2****1.17 Test Conditions and Results – Surge IMMUNITY**

IEC 61000-4-5: 2005	TEST: Surge IMMUNITY		Verdict
			P
Laboratory Parameters:	Required prior to the test	During the test	
Ambient Temperature	10 to 40 °C	27.6 °C	
Relative Humidity	10 to 90 %	40.1 %	
Fully configured sample subject to the levels shown below.	Measurement Point		
	Input AC and DC Power Ports		
EQUIPMENT mode	Power interface mode	1	
	EUT configurations mode	1	
	Operation mode	6	
Applied Level			
Application Point	[kV]	Required Surge Waveform	
Input Power Ports	0.5 and 1.0 (Line to Line)	Combination Wave (1.2 μs x 50 μs Voltage, 8 μs x 20 μs Current)	
	0.5, 1.0 and 2.0 (Line to Earth)	Combination Wave (1.2 μs x 50 μs Voltage, 8 μs x 20 μs Current)	
Signal input/output*	2.0 (Line to Earth)	Combination Wave (1.2 μs x 50 μs Voltage, 8 μs x 20 μs Current)	
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).			
Supplementary information:			
EUT powered at one of the Nominal input voltages and frequencies.			
Note* - Applicable to output lines intended to connect directly to outdoor cables			

**Test Equipment Used**

<b>ID</b>	<b>Description</b>	<b>Manufacturer</b>	<b>Model</b>	<b>Serial No.</b>	<b>Status</b>	<b>Cal. date</b>	<b>Cal. due</b>
P0977	test chamber 6	Siemens			chk	Feb 22, 2019	Feb 2020
P1614	Ultra Compact Simulator (3-Phase Testsystem)	EMTest	UCS 500 N5	V1222112714	cal	Apr 03, 2019	Apr 2021
P2428	Coupling/decoupling network, 63 A (3-Phase Testsystem)	EMTest	CNI 503 A4	P1828221682	cal	Apr 03, 2019	Apr 2021
P1632	Electrical socket distributor (for Surge/Burst 63A)	Steidele-Stromverteiler GmbH	SVG 63/111-0-S	063292	cnn		
P1629	Oscilloscope, (used for Surge/Burst 63A)	LeCroy	WaveJet 354	LCRY0101J26657/22798	cal	Apr 02, 2019	Apr 2020
P1557	Notebook Labor EMV 03 (used for Surge/EFT 63A)	Lenovo	Think Pad T400	L3-ADN3C 08/11	cnn		
P1917	Data logger for humidity and temperature (MZ6)	testo AG	testo 175 H1	40342579	cal	Aug 19, 2017	Aug 2020

**IEC 60601-1-2**

**Photo of test setup for Surge IMMUNITY**



**IEC 60601-1-2**

Tabulated Results for Surge – Mains – operation mode 6			
Mode of Application	Level	Polarity	Results
Line 1 to Line 2 (Differential mode)	0.5 kV	Positive	1
		Negative	1
	1.0 kV	Positive	1
		Negative	1
Line 1 to Earth (Common mode)	0.5 kV	Positive	1
		Negative	1
	1.0 kV	Positive	1
		Negative	1
	2.0 kV	Positive	1
		Negative	1
Line 2 to Earth (Common mode)	0.5 kV	Positive	X
		Negative	X
	1.0 kV	Positive	X
		Negative	X
	2.0 kV	Positive	X
		Negative	X
Line 3 to Earth (Common mode)	0.5 kV	Positive	X
		Negative	X
	1.0 kV	Positive	X
		Negative	X
	2.0 kV	Positive	X
		Negative	X
Line Neutral to Earth (Common mode)	0.5 kV	Positive	1
		Negative	1
	1.0 kV	Positive	1
		Negative	1
	2.0 kV	Positive	1
		Negative	1
Results Descriptions: X - Not performed nor required. 1 – Compliant - No observed response from EUT.			
Supplementary information: Note: Description of the response should detail observations during testing.			

## IEC 60601-1-2

Tabulated Results for Surge – Signal Input/output Lines Directly Connected to Outdoor Lines			
Mode of Application	Level	Polarity	Results
Line 1 to Earth (Common mode)	2 kV	Positive	N/A
		Negative	N/A
Line 2 to Earth (Common mode)	2 kV	Positive	N/A
		Negative	N/A
<b>Results Descriptions:</b> <b>X - Not performed nor required.</b> <b>1 – Compliant - No observed response from EUT.</b>			
Supplementary information: Note: Description of the response should detail observations during testing.			



## IEC 60601-1-2

**1.18 Test Conditions and Results – IMMUNITY to conducted disturbances, induced by radio-frequency fields**

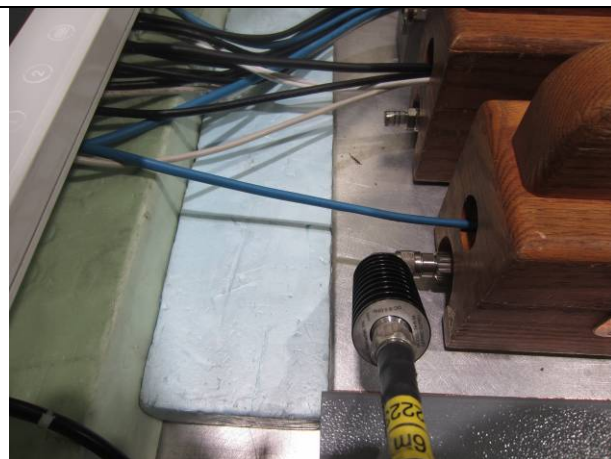
<b>IEC 61000-4-6: 2013</b>		<b>TEST: IMMUNITY to conducted disturbances, induced by radio-frequency fields</b>		<b>Verdict</b>
				<b>P</b>
<b>Laboratory Parameters:</b>		<b>Required prior to the test</b>	<b>During the test</b>	
<b>Ambient Temperature</b>		<b>10 to 40 °C</b>	<b>25.3 °C</b>	
<b>Relative Humidity</b>		<b>10 to 90 %</b>	<b>38.7 %</b>	
<b>EQUIPMENT mode</b>		<b>Power interface mode</b>	<b>4, 1</b>	
		<b>EUT configurations mode</b>	<b>1</b>	
		<b>Operation mode</b>	<b>5, 6</b>	
<b>Test Specifications:</b>		<b>Frequency range</b>	<b>Measurement Point</b>	
<b>Fully configured sample scanned over the following frequency range</b>		<b>150 kHz to 80 MHz</b>	<b>Input a.c. Power Ports</b> <b>Input d.c. Power Ports</b> <b>Signal Input/output Ports</b> <b>PATIENT Connected Ports</b>	
<b>Level</b>	<b>Home Healthcare Environment</b>	<input type="checkbox"/> 3 V RMS outside the ISM band, 6 V RMS in the ISM and amateur radio bands		
	<b>Professional Healthcare Environment</b>	<input checked="" type="checkbox"/> 3 V RMS outside the ISM band, 6 V RMS in the ISM band		
	<b>Special Environment</b>			
<b>Frequency step</b>		<input type="checkbox"/> 1%	<input type="checkbox"/> Other _____	
<b>Modulation</b>		<input checked="" type="checkbox"/> 80% AM at 1 kHz*	<input type="checkbox"/> Other _____	
Supplementary information: EUT powered at one of the Nominal input voltages and frequencies. Dwell time minimum 1 s. Note * - Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.				

**IEC 60601-1-2****Test Equipment Used**

ID	Description	Manufacturer	Model	Serial No.	Status	Cal. date	Cal. due
P0977	test chamber 6	Siemens			chk	Feb 22, 2019	Feb 2020
P1094	signal generator MZ6	R&S	SML 03	836927/030	cal	Mar 23, 2017	Mar 2020
P1387	amplifier	Instruments for Industry	M50	M637-0508	cnn		
P1194	RF coupler	Werlatone	C6021-10	19541	chk	Nov 19, 2018	Nov 2019
P0287	power sensor	R&S	NRV-Z51	829004/017	cal	Apr 02, 2019	Apr 2020
P0262	power meter	R&S	NRVS	864270/007	cal	Apr 04, 2018	Apr 2020
P0115	cdn	FCC	FCC-801-M3-16A	98103	cal	Apr 05, 2019	Apr 2021
P1117	cdn, 32A	EM-test	CDN-M1	0202-01	cal	Apr 08, 2019	Apr 2021
P0612	injection clamp	FCC	FCC-203I-EM	67	cal	Apr 10, 2018	Apr 2020
P0997	injection clamp	FCC	FCC-203I-EM	303	cal	Apr 01, 2019	Apr 2021
P0611	injection clamp	Luethi	EM 101	9435124	cal	Apr 01, 2019	Apr 2021
P0189	EM radiation meter	W&G	EMR20	C0076	cal	Jul 20, 2018	Jul 2020
P1028	EM radiation probe	W&G	Type 8.2	C-0076	cal	Jul 20, 2018	Jul 2020

**Photo of test setup for Conducted Disturbances - operation mode 6**

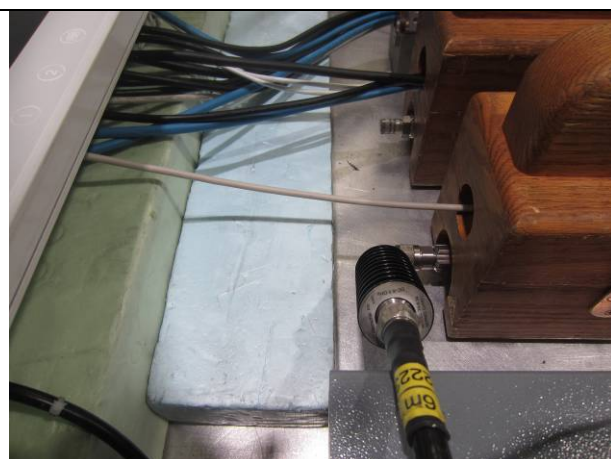
General setup



Ethernet



AC Mains



Com port RS232

<b>IEC 60601-1-2</b>
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Tabulated Results for Conducted Disturbances – operation mode 6		
Point of Application	Results	Dwell Time (second)
Mains	1	1
SIP/SOP 1 – Com port RS232	1	1
SIP/SOP 2 - Ethernet	1	1
Supplementary information: Results Descriptions: X - Not performed nor required. 1 – Compliant - No observed response from EUT. Note: Description of the response should detail observations during testing. Note: Describe each <b>PORT</b> tested. Note: Delete rows not used		

## IEC 60601-1-2

## Photo of test setup for Conducted Disturbances - operation mode 5



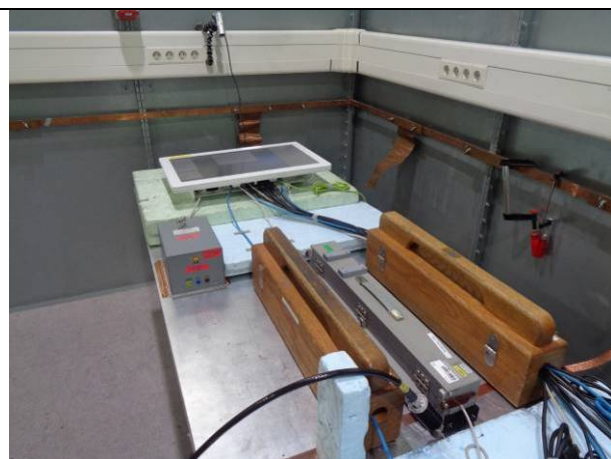
General setup



Ethernet OP



AC Mains Ethernet



Com port RS232

## Tabulated Results for Conducted Disturbances - operation mode 5

Point of Application	Results	Dwell Time (second)
Mains	1	1
SIP/SOP 1 – Com port RS232	1	1
SIP/SOP 2 - Ethernet	1	1

Supplementary information: Results Descriptions:

X - Not performed nor required.

1 – Compliant - No observed response from EUT.

Note: Description of the response should detail observations during testing.

Note: Describe each **PORT** tested. Note: Delete rows not used

## IEC 60601-1-2

**1.19 Test Conditions and Results – Power frequency magnetic field IMMUNITY**

IEC 61000-4-8: 2009	TEST: Power frequency magnetic field IMMUNITY		Verdict
			P
Laboratory Parameters:	Required prior to the test	During the test	
Ambient Temperature	10 to 40 °C	25.6 °C	
Relative Humidity	10 to 90 %	27.3 %	
EQUIPMENT mode	Power interface mode	4, 1	
	EUT configurations mode	1	
	Operation mode	5, 6	
Fully configured sample tested at the power line frequency (See Note 1)	Frequency	Application Point	
	50 Hz and 60 Hz	Enclosure	
IMMUNITY TEST LEVEL	30 (A/m)		
Supplementary information:			
Note 1: EUT powered at one of the Nominal input voltages and frequency of either 50 Hz or 60 Hz. During the test, the frequency of the field and line frequency of the ME EQUIPMENT were the same.			
<input type="checkbox"/> Test does not apply. Device under test does not contain magnetically sensitive components or circuitry.			

**Test EQUIPMENT Used**

ID	Description	Manufacturer	Model	Serial No.	Status	Cal. date	Cal. due
P2076	Power Supply	PCE Power Control GmbH & Co. KG	Chroma 61605, AC-/DC Source	616050001644	ind		
P1297	EM radiation meter	Chauvin Arnoux	C.A 42	100426AEK	cal	Jul 17, 2018	Jul 2019
P1238	antenna	QE13	Loop 2m x 3m		cnn		
P0081	antenna	QE13	Loop	L01	cnn		
P1298	EM radiation probe	Chauvin Arnoux	MF-400	100394AEK	cal	Jul 17, 2018	Jul 2019
P1911	Data logger for pressure, humidity and temperature (Spibe)	testo AG	testo 176 P1	41000861 403+ 60244991	cal	Aug 22, 2017	Aug 2020



## IEC 60601-1-2

## Photo of test setup for Power- Frequency Magnetic Fields



X-Axis



Y-Axis



Z-Axis

## Tabulated Results for Power Frequency Magnetic Field - operation mode 6

Point of application	Results
<b>X-Axis</b>	<b>1</b>
<b>Y-Axis</b>	<b>1</b>
<b>Z-Axis</b>	<b>1</b>

Supplementary information:

Results Descriptions:

X - Not performed nor required.

1 – Compliant - No observed response from EUT.

Note: Description of the response should detail observations during testing.

**IEC 60601-1-2**

<b>Tabulated Results for Power Frequency Magnetic Field - operation mode 5</b>	
<b>Point of application</b>	<b>Results</b>
<b>X-Axis</b>	<b>1</b>
<b>Y-Axis</b>	<b>1</b>
<b>Z-Axis</b>	<b>1</b>
Supplementary information: Results Descriptions: X - Not performed nor required. 1 – Compliant - No observed response from EUT. Note: Description of the response should detail observations during testing.	

## IEC 60601-1-2

## 1.20 Test Conditions and Results – Voltage dips, short interruptions and voltage variations IMMUNITY

IEC 61000-4-11: 2004	TEST: Voltage dips, short interruptions and voltage variations IMMUNITY		Verdict
			P
Laboratory Parameters:	Required prior to the test	During the test	
Ambient Temperature	10 to 40 °C	26.0 °C	
Relative Humidity	10 to 90 %	25.6 %	
Fully configured subjected to the levels indicated below.	Measurement Point		
	Input A.C. Power Ports		
EQUIPMENT mode	Power interface mode	2, 3	
	EUT configurations mode	1	
	Operation mode	6	
Applied Levels			
Voltage Dips (% U <sub>T</sub> )	Cycles	Sync Angle (degrees)	
0	0.5*	0; 45; 90; 135; 180; 225; 270; 315	
0	1	0	
70	25 (50 Hz) 30 (60 Hz)	0	
Voltage Interruption % U <sub>T</sub>	Cycles	Sync Angle [degrees]	
0	250 (50 Hz),300 (60 Hz)	Any	
Supplementary information: If the Rated voltage range <25 % of the lowest rated input voltage, one rated input voltage. Otherwise, minimum and maximum rated voltage. EUT powered at one of the Nominal input frequencies. ME EQUIPMENT and ME SYSTEMS with power input voltage selection by transformer taps tested at only one tap setting. Note* - Only applicable to ME EQUIPMENT with single phase a.c. mains			

Supply Voltage Range	Difference of Max Voltage – Min Voltage	25 % of Lowest Rated input Voltage	Test at Min/Max Voltages required (Y/N)
100-240 VAC	140 VAC	25 VAC	Y



## IEC 60601-1-2

## Test Equipment Used

ID	Description	Manufacturer	Model	Serial No.	Status	Cal. date	Cal. due
P1088	4-quadrant amplifier (L1)	SPIBE	PAS 20000	A339201/0 0904	cnn		
P1288	power supply	SPIBE		A3758 02/0 1006	cnn		
P1286	4-quadrant amplifier (L2)	SPIBE	PAS 20000	A3758 01/1 1006	cnn		
P1287	4-quadrant amplifier (L3)	SPIBE	PAS 20000	A3758 01/2 1006	cnn		
P1090	control unit	SPIBE	SyCore 1k4		cnn		
P1091	analyzer reference system	SPIBE	ARS 16/3	A3392 07/1 0904	cal	Apr 03, 2019	Apr 2021
P1911	Data logger for pressure, humidity and temperature (Spibe)	testo AG	testo 176 P1	41000861 403+ 60244991	cal	Aug 22, 2017	Aug 2020

## Photo of test setup for Voltage Dips, Interruptions, and Variations



**IEC 60601-1-2****Tabulated Results for Voltage Dips and Interruptions**

Minimum Rated Voltage (V).....			100
Frequency (Hz) .....			60
Point of application	Voltage Dips	Period (Cycles)	Results
Mains	0	0.5	1
Mains	0	1	1
Mains	70	25/30 (50/60 Hz)	1
Point of application	Voltage Interruptions	Period (Cycles)	Results
Mains	0	250/300 (50/60 Hz)	1

Supplementary information:

Results Descriptions:

X - Not performed nor required.

1 – Compliant - No observed response from EUT.

Note: Description of the response should detail observations during testing.

<div>Name: Ratkovic Department: EMV-Labor Company: SGS</div> <div>Manufacturer: ADLINK MLC8-23 EUT 3 Serial no: Operating modes: AC 100V 60Hz Comment1: Comment2: Date of test: 15.05.2019</div> <div>Test conditions: EN 61000-4-11 voltage dips, short interruptions and variations test Voltage / frequency: 100.0 V / 60.0 Hz Test phase: Single phase / L1-N Executed test: _61000-4-11_0% 0.5per Test description: -- Disturbances per step: 3 (per phase angle) / 10.5 sec delay between</div>					<div>Name: Ratkovic Department: EMV-Labor Company: SGS</div> <div>Manufacturer: ADLINK MCL8-23 EUT 3 Serial no: Operating modes: AC 100V 60Hz Comment1: Comment2: Date of test: 15.05.2019</div> <div>Test conditions: EN 61000-4-11 voltage dips, short interruptions and variations test Voltage / frequency: 100.0 V / 60.0 Hz Test phase: Single phase / L1-N Executed test: _61000-4-11_0% 1per Test description: -- Disturbances per step: 3 (per phase angle) / 10.5 sec delay between</div>																								
<table><tr><td>Step</td><td>Disturbance</td><td>Test level</td><td>Duration</td><td>Phase angle(s) (Ref. L1)</td></tr><tr><td>1</td><td>Voltage dip / short interruption</td><td>0 %</td><td>0.5 periods</td><td>0° L1 (45° steps)</td></tr></table>					Step	Disturbance	Test level	Duration	Phase angle(s) (Ref. L1)	1	Voltage dip / short interruption	0 %	0.5 periods	0° L1 (45° steps)	<table><tr><td>Step</td><td>Disturbance</td><td>Test level</td><td>Duration</td><td>Phase angle(s) (Ref. L1)</td></tr><tr><td>1</td><td>Voltage dip / short interruption</td><td>0 %</td><td>1 period</td><td>0° L1 (45° steps)</td></tr></table>					Step	Disturbance	Test level	Duration	Phase angle(s) (Ref. L1)	1	Voltage dip / short interruption	0 %	1 period	0° L1 (45° steps)
Step	Disturbance	Test level	Duration	Phase angle(s) (Ref. L1)																									
1	Voltage dip / short interruption	0 %	0.5 periods	0° L1 (45° steps)																									
Step	Disturbance	Test level	Duration	Phase angle(s) (Ref. L1)																									
1	Voltage dip / short interruption	0 %	1 period	0° L1 (45° steps)																									
<div>Test results:</div> <div><ul style="list-style-type: none"><li>Normal performance within limits specified by manufacturer, requestor or purchaser</li><li>Temporary loss of function or degradation of performance which ceases after the disturbance ceases, and from which the equipment under test recovers its normal performance, without operator intervention</li><li>Temporary loss of function or degradation of performance, the correction of which requires operator intervention</li><li>Loss of function or degradation of performance which is not recoverable, owing to damage to hardware or software, or loss of data</li></ul></div> <div>Comments:</div>					<div>Test results:</div> <div><ul style="list-style-type: none"><li>Normal performance within limits specified by manufacturer, requestor or purchaser</li><li>Temporary loss of function or degradation of performance which ceases after the disturbance ceases, and from which the equipment under test recovers its normal performance, without operator intervention</li><li>Temporary loss of function or degradation of performance, the correction of which requires operator intervention</li><li>Loss of function or degradation of performance which is not recoverable, owing to damage to hardware or software, or loss of data</li></ul></div> <div>Comments:</div>																								
<div><small>Tested with SPFS EMC 4.1.3 / PA 520000 by Spitzenberger &amp; Spies GmbH &amp; Co. K.G. Schneider 3334, 9424V Weibach, Germany, 15.05.2019</small></div>					<div><small>Tested with SPFS EMC 4.1.3 / PA 520000 by Spitzenberger &amp; Spies GmbH &amp; Co. K.G. Schneider 3334, 9424V Weibach, Germany, 15.05.2019</small></div>																								
<div>Name: Ratkovic Department: EMV-Labor Company: SGS</div> <div>Manufacturer: ADLINK MLC8-23 EUT 3 Serial no: Operating modes: AC 100V 60Hz Comment1: Comment2: Date of test: 15.05.2019</div> <div>Test conditions: EN 61000-4-11 voltage dips, short interruptions and variations test Voltage / frequency: 100.0 V / 60.0 Hz Test phase: Single phase / L1-N Executed test: _61000-4-11_70%-25per Test description: -- Disturbances per step: 3 (per phase angle) / 10.5 sec delay between</div>					<div>Name: Ratkovic Department: EMV-Labor Company: SGS</div> <div>Manufacturer: ADLINK MLC8-23 EUT 3 Serial no: Operating modes: AC 100V 60Hz Comment1: Comment2: Date of test: 15.05.2019</div> <div>Test conditions: EN 61000-4-11 voltage dips, short interruptions and variations test Voltage / frequency: 100.0 V / 60.0 Hz Test phase: Single phase / L1-N Executed test: _61000-4-11_0%-250per Test description: -- Disturbances per step: 3 (per phase angle) / 10.5 sec delay between</div>																								
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**IEC 60601-1-2****Tabulated Results for Voltage Dips and Interruptions**

Maximum Rated Voltage (V)....			240
Frequency (Hz) .....			50
Point of application	Voltage reduction	Period (Cycles)	Results
Mains	0	0.5	1
Mains	0	1	1
Mains	70	25/30 (50/60 Hz)	1
Point of application	Voltage Interruptions	Period (Cycles)	Results
Mains	0	250/300 (50/60 Hz)	1

Supplementary information:

Results Descriptions:

X – Not performed nor required.

1 – Compliant – No observed response from EUT.

Note: Description of the response should detail observations during testing.

Name: Ratkovic Department: EMV-Labor Company: SGS  Manufacturer: ADLINK MLC8-23 EUT 3 Serial no: Operating modes: AC 240V 50Hz Comment1: Comment2: Date of test: 15.05.2019  Test conditions: EN 61000-4-11 voltage dips, short interruptions and variations test Voltage / frequency: 240.0 V / 50.0 Hz Test phase: Single phase / L1-N Executed test: _61000-4-11_0% 0.5per Test description: -- Disturbances per step: 3 (per phase angle) / 10.5 sec delay between					Name: Ratkovic Department: EMV-Labor Company: SGS  Manufacturer: ADLINK MLC8-23 EUT 3 Serial no: Operating modes: AC 240V 50Hz Comment1: Comment2: Date of test: 15.05.2019  Test conditions: EN 61000-4-11 voltage dips, short interruptions and variations test Voltage / frequency: 240.0 V / 50.0 Hz Test phase: Single phase / L1-N Executed test: _61000-4-11_0% 1per Test description: -- Disturbances per step: 3 (per phase angle) / 10.5 sec delay between				
Step		Disturbance		Test level	Duration	Phase angle(s) (Ref. L1)			
1		Voltage dip / short interruption		0 %	0.5 periods	0° L1 (45° steps)			
Test results:									
<ul style="list-style-type: none"><li>Normal performance within limits specified by manufacturer, requestor or purchaser</li><li>Temporary loss of function or degradation of performance which ceases after the disturbance ceases, and from which the equipment under test recovers its normal performance, without operator intervention</li><li>Temporary loss of function or degradation of performance, the correction of which requires operator intervention</li><li>Loss of function or degradation of performance which is not recoverable, owing to damage to hardware or software, or loss of data</li></ul>									
Comments:									
Tested with SPSS EMC 4.1.3 / PA-S20000 by Spitzenberger & Spire GmbH & Co. K.G. Schindler 3334, 94234 Vöcklabach, Germany, 15.05.2019									

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Step		Disturbance		Test level	Duration	Phase angle(s) (Ref. L1)			
1		Voltage dip / short interruption		70 %	25 periods	0° L1 (45° steps)			
Test results:									
<ul style="list-style-type: none"><li>Normal performance within limits specified by manufacturer, requestor or purchaser</li><li>Temporary loss of function or degradation of performance which ceases after the disturbance ceases, and from which the equipment under test recovers its normal performance, without operator intervention</li><li>Temporary loss of function or degradation of performance, the correction of which requires operator intervention</li><li>Loss of function or degradation of performance which is not recoverable, owing to damage to hardware or software, or loss of data</li></ul>									
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Step		Disturbance		Test level	Duration	Phase angle(s) (Ref. L1)			
1		Voltage dip / short interruption		0 %	250 periods	0° L1 (45° steps)			
Test results:									
<ul style="list-style-type: none"><li>Normal performance within limits specified by manufacturer, requestor or purchaser</li><li>Temporary loss of function or degradation of performance which ceases after the disturbance ceases, and from which the equipment under test recovers its normal performance, without operator intervention</li><li>Temporary loss of function or degradation of performance, the correction of which requires operator intervention</li><li>Loss of function or degradation of performance which is not recoverable, owing to damage to hardware or software, or loss of data</li></ul>									
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**IEC 60601-1-2****1.21 Test Conditions and Results – Electrical transient conduction along supply lines**

<b>ISO 7637-2: 2011</b>	<b>TEST: Electrical transient conduction along supply lines</b>	<b>Verdict</b>
		<b>N/A</b>
Supplementary information: For ME EQUIPMENT and ME SYSTEMS intended to be installed in passenger cars and light commercial vehicles including ambulances fitted with 12 V electrical systems or commercial vehicles including ambulances fitted with 24 V electrical systems.		

<b>IEC 60601-1-2</b>
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## **2.0 Disclaimer**

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**End of the Report**