



TEST REPORT IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests	
Report Number.....	E215901.01
Date of issue.....	01 November 2020
Total number of pages	37
Name of Testing Laboratory preparing the Report	I.T.L. (PRODUCT TESTING) LTD.
Applicant's name	Flight Medical Innovations Ltd.
Address.....	7 Hatnufa St., Petah Tikva 4951025, Israel
Test specification:	
Standard.....	IEC 60601-1-2:2014
Test procedure	PM 111
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 :	Lung Ventilator	
Trade Mark :		
Manufacturer	Flight Medical Innovations Ltd.	
Model/Type reference :	Flight 60 Turbine/ F60T (V200)	
Ratings	100 – 240 Vac, 50 -60 Hz, Max 1.25 A; 12 – 15 Vdc max 4.8 A	
Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):		
<input checked="" type="checkbox"/>	Testing Laboratory:	I.T.L. (PRODUCT TESTING) LTD.
	Testing location/ address :	1 Batsheva St., Lod Israel 7120101
	Tested by (name, function, signature) :	Yuri Mordohovich Test Engineer 
	Approved by (name, function, signature) ... :	D. Shidlowsky Technical Reviewer 
<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) :	

List of Attachments (including a total number of pages in each attachment): Attachment 1 Correction Factors (3 pages) Attachment 2 Measurement Uncertainty (1 page)	
Summary of testing:	
Tests performed (name of test and subclause): Conducted EMISSIONS (7.3) Radiated EMISSIONS (7.3)	Testing location: I.T.L. (PRODUCT TESTING) LTD. 1 Batsheva St., Lod Israel 7120101
Note: delete tests not conducted in the list above.	
Summary of compliance with National Differences: N/A	
Device modifications necessary for compliance: Not applicable	
A statement that manufacturer will incorporate all changes into production units. N/A <input type="checkbox"/> Manufacturer provided declaration statement. <input type="checkbox"/> Manufacturer did not provide declaration statement.	

Test item particulars :	
Classification of installation and use : Portable	
Supply Connection : Appliance coupler / Internally powered	
Possible test case verdicts:	
- 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)	
Testing:	
Date of receipt of test item: 24/07/2020	
Date (s) of performance of tests: 24/07/2020 – 26/07/2020	
General remarks:	
"(See Enclosure #)" refers to additional information appended to the report. "(See appended table)" refers to a table appended to the report.	
Throughout this report a <input type="checkbox"/> comma / <input checked="" type="checkbox"/> point is used as the decimal separator.	
Manufacturer's Declaration per sub-clause 4.2.5 of IEC60002:	
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"/> Yes <input checked="" type="checkbox"/> Not applicable
Name and address of factory (ies) : Same as Applicant	
General product information : For test equipment description refer to item 1.1	
Describe any deviations from the Basic EMC standards or from this collateral standard: N/A	

Report Index:			
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Note: To update all fields in this TRF, including the Page numbers on the Index page, click Select All on the Edit menu, and then press F9.

1.1 Equipment Description

The Flight 60 Turbine/ F60T (V200) Ventilator is a piston driven electro-mechanical device used to assist a patient's respiratory effort. It is intended to provide continuous or intermittent mechanical ventilation support for the care of individuals who require mechanical ventilation. The Flight 60 Turbine/ F60T (V200) is driven by a double-piston internal electrical pump. The pump can be operated by an external AC or DC voltage, or by the internal rechargeable LI-Ion Battery.

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:

SW 4.31:001

Prototype : **Production Version:**

Unit(s) Tested (include serial numbers):

P/N : V100-0004, S/N 20068026

Rationale for number of samples tested:

One sample is required for type testing

Intended use:

The Flight 60 Turbine/ F60T (V200) Ventilator is intended to provide continuous or intermittent mechanical ventilation support for the care of individuals who require mechanical ventilation. Specifically, the Flight 60 Turbine/ F60T (V200) is applicable for adult and pediatric (i.e., infant, child and adolescent) patients who weigh at least 5 kg (11 lbs).

The Flight 60 Turbine/ F60T (V200) Ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician; it is suitable for use in hospitals, sub-acute emergency rooms, and home care environments, as well as for transport and emergency response applications.

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

The EUT is suitable for use in hospital, sub-acute, emergency room, home care environments as well as for transport and emergency response applications.

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

Yes No

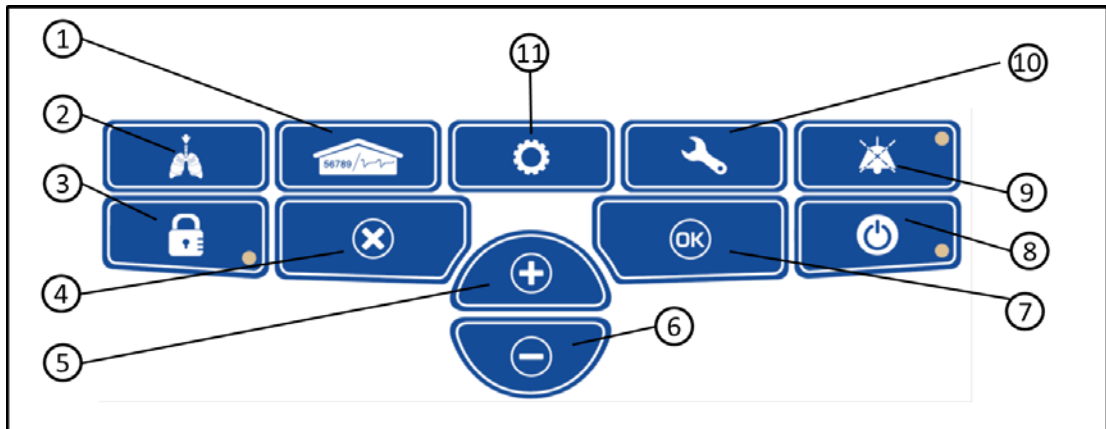
If Yes, include the following information

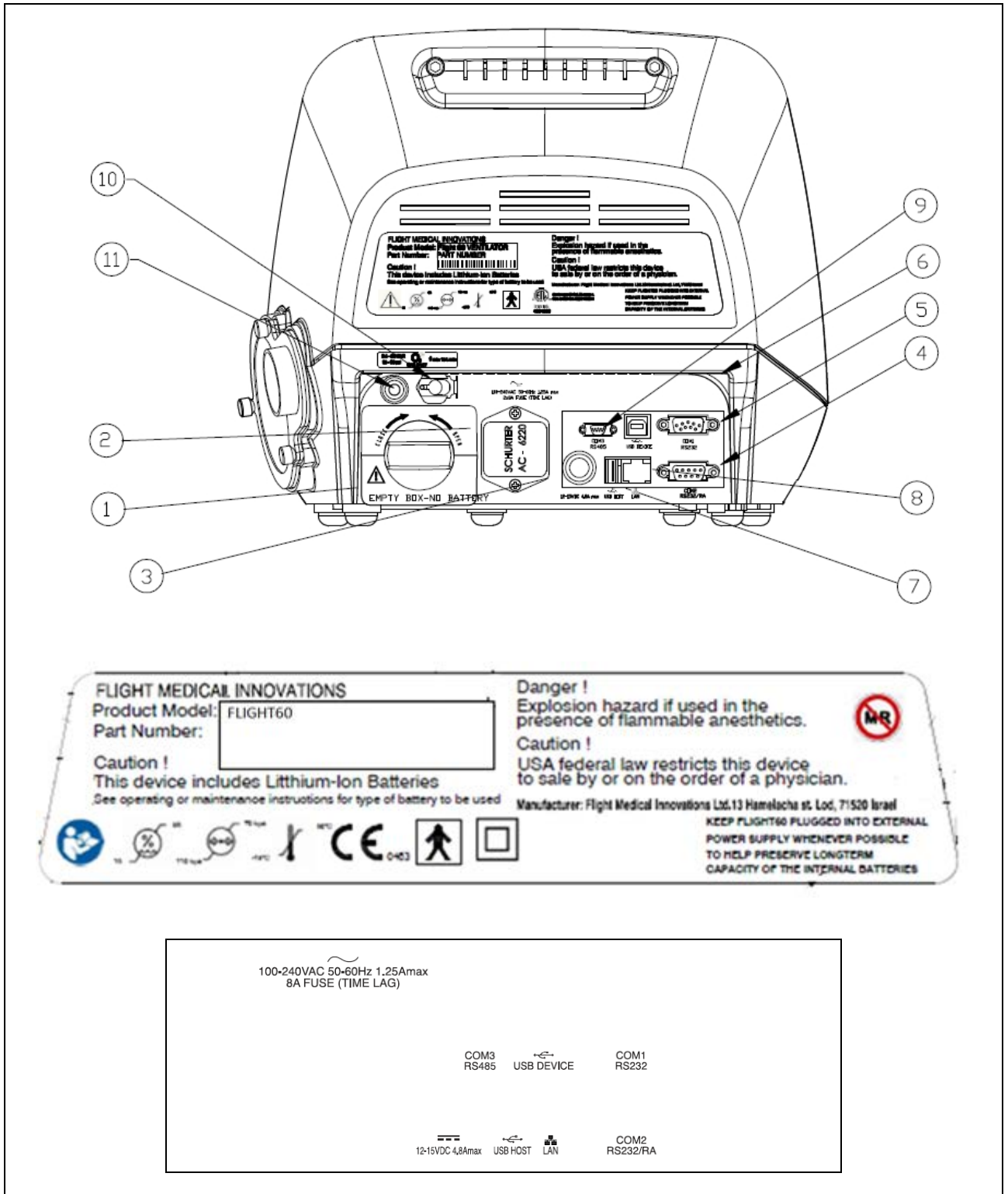
Frequencies tested	
Power levels of RF test sources	
Modulation of RF test sources	
Test distance used	
Other relevant information related to test	

1.1.1 EQUIPMENT Marking Plate

(The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBS that own these marks.)

Control Buttons





1.1.2 EUT and Supporting EQUIPMENT Used During Test:

Use*	Product Type	Manufacturer	Model	Comments
EUT	Ventilator	Flight Medical Innovations	Flight 60 Turbine/ F60T (V200)	Turbine version
Sim	Artificial lung	Vadi	KIT-0011	

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:

1.1.3 SIP/SOP and Input/output Ports:

PORT No.	Name	Type*	Cable Length	Cable Shielded (Y/N)	Comments (SIP/SOP lines must include description of use) (PATIENT-coupled cable termination must be described) (Interconnecting cables – describe construction details, ferrites, etc.)
0	Enclosure	N/E	—	—	None
1	AC Mains	AC			
2	Mains	DC			Internal Batteries
3					

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

1.1.4 EUT Internal Operating Frequencies (Optional):

Frequency	Description	Frequency	Description
32 kHz	RTC	20 MHz	CPU 2
200 MHz	CPU 1		
50 kHz	Charger		

Supplementary information:

1.1.5 Power Interface						
Mode No.	Voltage (V)	Current (A)	Power (W)	Frequency (DC/AC-Hz)	Phases (No.)	Comments
Rated	100-240	Max 1.25A		50 – 60 Hz	1	AC Mains
Rated	12 – 15V	Max 4.8		DC		Internal Battery
1	230	Max 1.25A		50 – 60 Hz	1	
2	12 – 15V	Max 4.8		DC		Internal Battery
Supplementary information:						

1.2 EUT Operation Modes:	
Mode #	Description
1	Ventilating powered from DC mains
2	Ventilating powered from AC mains (Tested configuration)
3	Ventilating powered from internal power source
4	Standby
Supplementary information:	

1.3 EUT Configuration	
Configuration #	Description
1	The EUT was connected to the SIM lounge and to the AC mains.
Supplementary information (include any special ME EQUIPMENT or ME SYSTEM hardware or software needed to perform the tests).	

1.4 BASIC SAFETY, ESSENTIAL PERFORMANCE and Pass/Fail Criteria as determined by the Manufacturer

Description of BASIC SAFETY and ESSENTIAL PERFORMANCE

Refer to Flight 60 Turbine/ F60T (V200) Essential Performance Documnet Dated 29.01.19

Basic safety relies on integrity of enclosure

Essential performance:

The following DEGRADATIONS, shall not be allowed:

1. component failures.
2. changes in programmable parameters or settings.
3. reset to default settings.
4. change of operating mode.
5. initiation of an unintended operation.
6. error of DELIVERED VOLUME of individual breaths greater than 35 % and error of the DELIVERED VOLUME averaged over a one minute interval greater than 25 %.
7. The VENTILATOR may exhibit temporary DEGRADATION of performance (e.g. deviation from the performance indicated in the instructions for use) that does not affect BASIC SAFETY or ESSENTIAL PERFORMANCE.
8. Restart of the device after each test. If self-diagnostic fails and no alarm sounded considered a fail.
9. Before restarting the device mode of operation and settings are verified. If changed from the pre-test value considered fail
10. If the device is immune to EM disturbances and no parameters has changed (2-4) the device will not start unintentionally.
11. If there is no error in delivery volume: PASS
12. If there is an error in delivery volume but the alarm is sounded: PASS
13. If there is an error in delivery volume but no alarm was sounded: FAIL

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

Visual monitoring of Device display and alarms. Review of device settings during and after each test

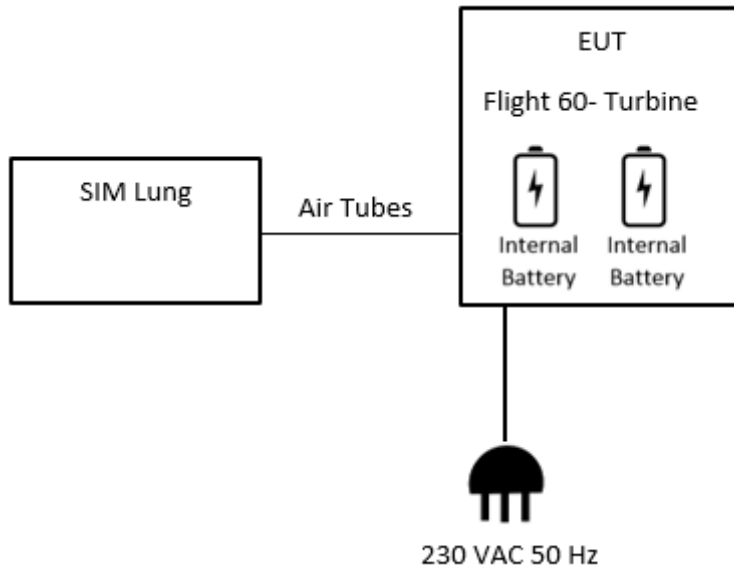
IMMUNITY Pass/Fail Criteria		
Test Description	Pass/Fail Criteria description	Part 2 reference
Electrostatic Discharges	N/A	
Radiated RF EM Fields		
Proximity Wireless fields		
Electrical Fast Transients and bursts		
Surges		
Conducted Disturbances, induced by RF fields		
Voltage Dips and Interruptions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

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

are to be described in the table below.

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

1.5 Configuration Block Diagram:



1.6 Compliance Summary	
List of ACCOMPANYING DOCUMENTS reviewed	RMF Doc No: DOC-0402 Rev A04
	UM Doc No: LIT-0014 Rev A13

IEC 60601-1-2			
Clause	Requirement + Test	Result - Remark	Verdict

4	GENERAL REQUIREMENTS		
4.1	RISKS resulting from reasonably foreseeable ELECTROMAGNETIC DISTURBANCES taken into account in the RISK MANAGEMENT PROCESS.	RMF Reference Document: 18.3, 19.1,19.2 Risk No: DOC-0402 Rev A04	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		
	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		
	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		
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	P
4.3.3	Power input and frequencies	See appended Table Item 1.1.5	P

5	IDENTIFICATION, MARKING AND DOCUMENTS		
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		P
	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	See appended Table Item 1.1.1	P
5.2	ACCOMPANYING DOCUMENTS		
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: Clause: Risk No: DOC-0402 Rev A04	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.	Page or Clause in User manual Section 16.3.3	P
c)	A warning regarding stacking and location close to other EQUIPMENT	Page or Clause in User manual Section 16.3.3	P
d)	List of cables, transducers and accessories	Page or Clause in User manual Section 16.3.3	P
e)	A warning that other cables and accessories may negatively affect EMC performance	Page or Clause in User manual Section 16.3.3	P
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"	Page or Clause in User manual Section 16.3.3	P
5.2.1.2	Requirements applicable to ME EQUIPMENT and ME SYSTEMS classified class A according to CISPR 11		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: 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."	Page or Clause in User manual Section 16.3.3	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 Docume Page or Clause in User manual Section 16.3.nt:	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	Page or Clause in User manual Section 16.3.	P
b)	Any deviations from this collateral standard and allowances used	Page or Clause in User manual Section 16.3.	P
c)	All necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to ELECTROMAGNETIC DISTURBANCES for the EXPECTED SERVICE LIFE	Page or Clause in User manual Section 16.3.	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
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		N/A

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)..... :		N/A
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
6.1	Documentation of tests - General		
	The documentation of tests contains all information necessary to facilitate adequate planning (test plan) and execution of tests	See Appended Item Tables 1.1 and 1.1.2 to 1.1.4 and 1.5 to 1.7	P
6.2	Test Plan		
	Prior to the start of formal testing, a detailed test plan provided to the test laboratory. <i>(Note: title / name / version of test plan in remark section)</i>	See Appended Item Table 1.0	P
7	Electromagnetic EMISSIONS requirements for ME EQUIPMENT and ME SYSTEMS		
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		

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		
7.1.5	ME EQUIPMENT and ME SYSTEMS specified for use only in a shielded location SPECIAL ENVIRONMENT		N/A
	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		
	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		
a)	The specified RF shielding effectiveness and RF filter attenuation: <ul style="list-style-type: none"> - expressed in dB; - rounded to the nearest integer; and - at least 20 dB 		
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:	
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:	
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:	
7.1.6	ME EQUIPMENT and ME SYSTEMS that include radio equipment		N/A
	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		

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		
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		
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		
	TEST METHOD SELECTED		
7.2	Protection of the PUBLIC MAINS NETWORK		N/A
7.2.1	Harmonic distortion		
	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	
7.2.2	Voltage fluctuations and flicker		N/A
	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	
7.3	Emissions requirements summary		P
	Emission limits per environment	See Appended Item Tables 1.8 to 1.10	P

8	Electromagnetic IMMUNITY requirements for ME EQUIPMENT and ME SYSTEMS		
	For ME EQUIPMENT and ME SYSTEMS for which the INTENDED USE includes types of transportation or other locations as in the HOME HEALTHCARE ENVIRONMENT if additional IMMUNITY tests or IMMUNITY TEST LEVELS that are higher these additional tests to these higher IMMUNITY TEST LEVELS are documented	RMF Reference Document: Clause: Risk No: DOC-0402 Rev A04	P
	ME EQUIPMENT or ME SYSTEMS intended for use in the EMERGENCY MEDICAL SERVICES ENVIRONMENT for the HOME HEALTHCARE ENVIRONMENT. If locations in the EMERGENCY MEDICAL SERVICES ENVIRONMENT 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	RMF Reference Document: Clause: Risk No: DOC-0402 Rev A04	P
	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: Clause: Risk No: DOC-0402 Rev A04	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	Document reference to Type of patient stimulator or setup used:	
	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	Document reference to Patient physiological settings used:	
8.5	Subsystems		N/A
	When subsystems are tested to demonstrate compliance normal operating conditions are simulated		
	The RISK MANAGEMENT PROCESS used to determine whether subsystem testing is allowed.	RMF Reference Document:	
8.6	PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS		N/A
	PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS were TYPE TESTED by at least one of the following methods:		
	<ul style="list-style-type: none"> – 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 		
	Test Method selected		

8.7	Operating Modes		P
	Operating Modes and settings	See Appended Item Table 1.4	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).		
8.9	IMMUNITY TEST LEVELS		P
	Immunity Test Levels based on environment location of Intended Use	See Appended Item Tables 1.13 to 1.14 and 1.16 to 1.21 and RMF Reference Document: Clause: 19.1 Risk No: DOC-0402 Rev A04	P
8.10	Immunity to proximity fields from RF wireless communication equipment		P
	Enclosure Port of ME EQUIPMENT and ME SYSTEMS tested as specified in Table 9 as per IEC 61000-4-3	See Appended Item Tables 1.15 and RMF Reference Document: Clause: 19.2 Risk No: DOC-0402 Rev A04	P

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1.7 Result Summary		
Requirement – Test	Result/Comments	Verdict
Clause 7 - EMISSIONS		P
Classification		—
Class A or B	Class B	—
Group 1 or 2	Group 1	—
CISPR 11, 14-1, or ISO 7137		—
Conducted RF EMISSIONS.....		P
Radiated RF EMISSIONS.....		P
Disturbance Power (if applicable)		N/A
Harmonic Distortion per IEC 61000-3-2 (Class A, B, C, D) ...		N/A
Voltage Fluctuations and Flicker per IEC 61000-3-3.....		N/A
Clause 8 - IMMUNITY		N/A
Electrostatic Discharges		N/A
Radiated RF EM Fields.....		N/A
Radiated RF EM Fields and Proximity Wireless fields		N/A
Electrical Fast Transients and bursts		N/A
Surges.....		N/A
Conducted Disturbances, induced by RF fields.....		N/A
Voltage Dips and Interruptions		N/A
Rated Power-frequency Magnetic Field		N/A
Supplemental Information: If tests are not performed, provide rationale here for each test: The manufacturer made the following changes to the EUT: - PCB layout update was made for Boards due to production purposes - Ferrites were added on few internal cables - Wires were added to connect internal metal enclosure. As agreed upon with the customer, the EUT was tested towards: radiated emissions; conducted emissions tests only.		
If applicable, describe methods used to reduce the impact of ambient:		

Deviations from the Basic EMC standards or from this collateral standard	
Test	Description of Deviation

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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		23.0 °C	
Relative Humidity	10 to 90 %		59.0 %	
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		1	
	EUT configurations mode		1	
	Operation mode		1	
Limits – Group 1 - Class A				
Frequency (MHz)	Limit dB (µV)			
	Quasi-Peak	Result*	Average	Result*
0.15 to 0.50	79		66	
0.50 to 30	73		60	
Limits - Group 2 - Class A				
Frequency (MHz)	Limit dB (µV)			
	Quasi-Peak	Result*	Average	Result*
0.15 to 0.50	100		90	
0.50 to 5	86		76	
5 to 30	90 to 70		80 to 60	
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		120	
0.50 to 5	125		115	
5 to 30	115		105	
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	-5.978	56 to 46	-13.178
0.50 to 5	56	-11.12	46	-24.33
5 to 30	60	N/A	50	N/A
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.				

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CISPR 14-1: 2005	TEST: Limits of terminal disturbance voltage	Verdict
		N/A

ISO 7137: 1995	TEST: Limits of mains terminal and I/O disturbance current	Verdict
		N/A

Test equipment used					
Description	Manufacturer	Model	Identifier	Last Calibration date	Calibration due date
LISN	FCC	FCC-LISN-2A (25AMP)	128	24/07/2020	24/07/2021
Transient Limiter	HP	11947A	3107A03041	25/06/2020	25/06/2021
EMI Receiver	Rohde & Schwarz	ESC17	100724	19/02/2020	19/02/2021

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



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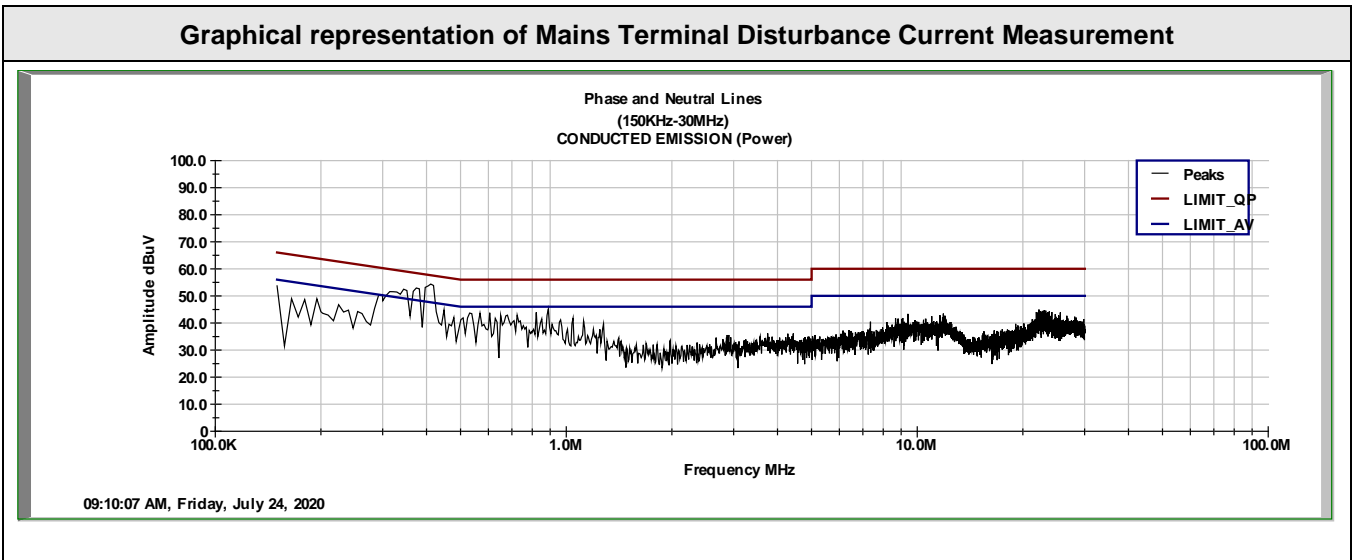
Tabulated Results for Mains Phase Terminal Disturbance Current

Terminal	Test Frequency (MHz)	Meter Reading dB (µV)	Detector (Pk/QP/Av)	Gain/Loss Factor (dB)	Transducer Factor (dB)	Level dB (µA)	Limit 1 dB (µA)	Margin (dB)

Supplementary information:
 Note: This table is to be used for combined correction factors (Gain/Loss and Transducer). Use column "Terminal" to identify the Line and /or Neutral that was tested. Other table formats are allowed as long as all information is included.

	1	2	3	4	5	6	7
Frequency	Peaks	QP	LIMIT_QP	Margin	Avg	Limit Avg	Margin
	dBuV	dBuV	dBuV	dB	dBuV	dBuV	dB
164.55 KHz	53.06	49.86	65.58	-15.72	21.99	55.58	-33.59
257.71 KHz	42.31	52.04	62.92	-10.89	22.40	52.92	-30.52
330.64 KHz	52.16	51.74	60.84	-9.09	25.46	50.84	-25.38
384.83 KHz	53.74	53.18	59.29	-6.12	33.97	49.29	-15.32
515.59 KHz	45.31	44.88	56.00	-11.12	21.67	46.00	-24.33
801.08 KHz	44.40	38.76	56.00	-17.24	19.23	46.00	-26.77

Tabulated Results for Mains Phase Terminal Disturbance Current Phase Level includes Gain/Loss Factor and Transducer Factor.



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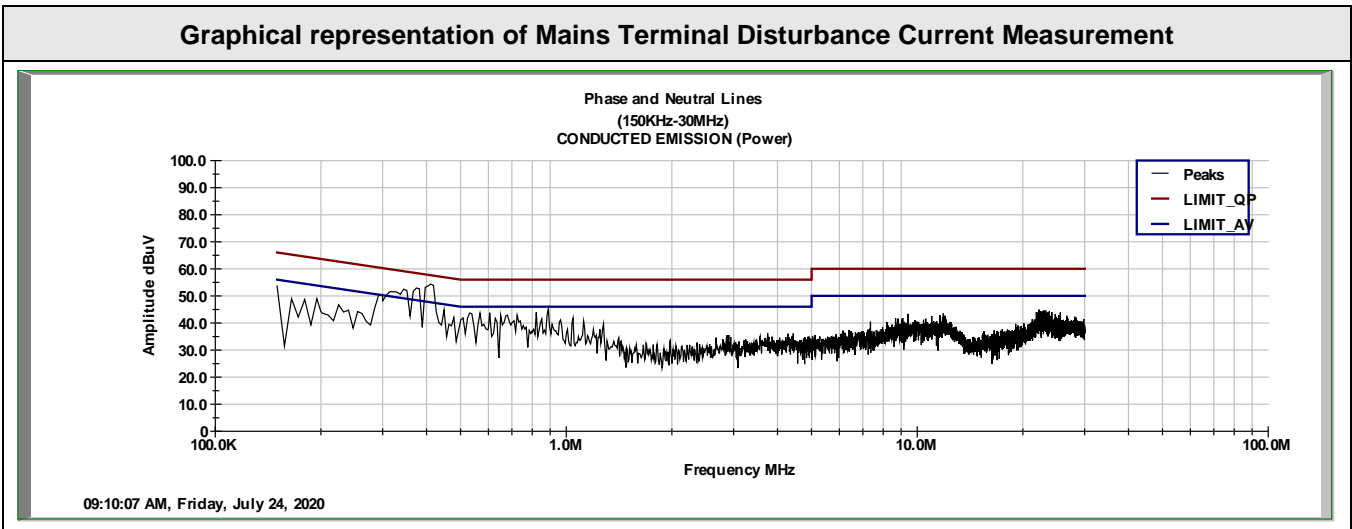
Tabulated Results for Mains Neutral Terminal Disturbance Current

Terminal	Test Frequency (MHz)	Meter Reading dB (µV)	Detector (Pk/QP/Av)	Gain/Loss Factor (dB)	Transducer Factor (dB)	Level dB (µA)	Limit 1 dB (µA)	Margin (dB)

Supplementary information:
 Note: This table is to be used for combined correction factors (Gain/Loss and Transducer). Use column "Terminal" to identify the Line and /or Neutral that was tested. Other table formats are allowed as long as all information is included.

	1	2	3	4	5	6
Frequency	Max Peaks	QP_neg	N_qp_Delim	AV_neg	LIMIT_AV	N_av_Delim
	dB/µV	dB/µV	dB	dB/µV	dB/µV	dB
185.26 KHz	49.203	52.523	-12.469	21.203	54.993	-33.789
243.01 KHz	49.977	49.307	-14.035	29.165	53.343	-24.178
264.49 KHz	45.270	51.920	-10.809	30.005	52.729	-22.724
346.69 KHz	53.136	52.966	-7.415	31.293	50.380	-19.087
364.76 KHz	53.746	53.886	-5.978	30.239	49.864	-19.625
428.29 KHz	55.073	47.093	-10.955	34.871	48.049	-13.178

Tabulated Results for Mains Neutral Terminal Disturbance Current Phase Level includes Gain/Loss Factor and Transducer Factor.



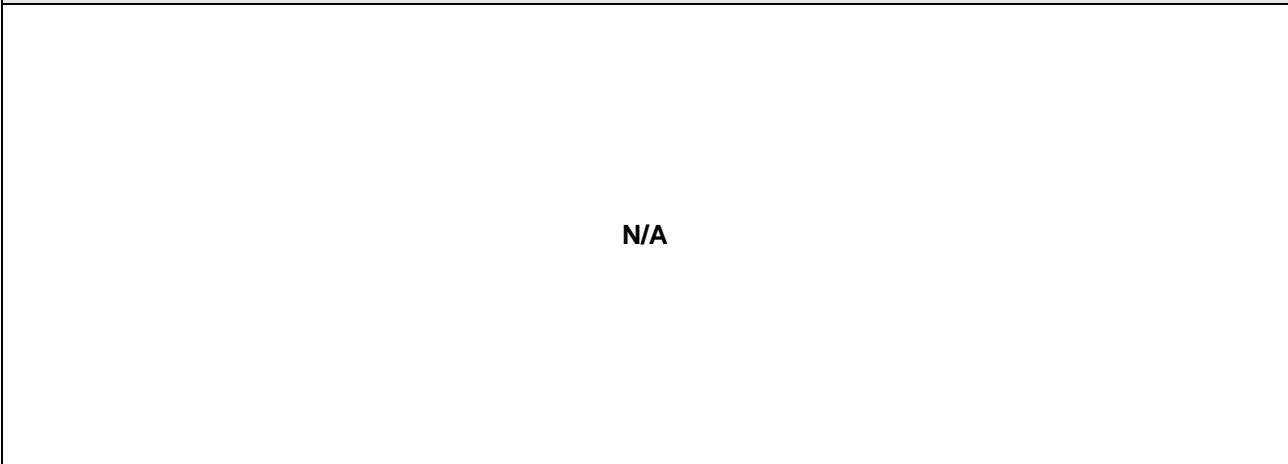
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Tabulated Results for Input/Output Terminal Disturbance Current

Terminal	Test Frequency (MHz)	Meter Reading dB (μV)	Detector (Pk/QP/Av)	Gain/Loss Factor (dB)	Transducer Factor (dB)	Level dB (μA)	Limit 1 dB (μA)	Margin (dB)

Supplementary information:
 Note: This table is to be used for combined correction factors (Gain/Loss and Transducer). Use column "Terminal" to identify the Line and /or Neutral that was tested. Other table formats are allowed as long as all information is included.

Graphical representation of Input/Output Terminal Disturbance Current Measurement



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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 checked="" type="checkbox"/> OATS	<input 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	32.0 °C	
Relative Humidity		10 to 90 %	52.0 %	
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 type="checkbox"/> 10 m	
EQUIPMENT mode	Power interface mode		1	
	EUT configurations mode		1	
	Operation mode		1	
Limits – Group 1 Class A				
Frequency (MHz)		Limit dB (µV/m)		
		Quasi-Peak	Results *	
30 to 230		50		
230 to 1000		57		
Limits – Group 1 Class B				
Frequency (MHz)		Limit dB (µV/m)		
		Quasi-Peak	Results *	
30 to 230		40	N/A	
230 to 1000		47	-4.4	
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		
30 to 1000		See standard		
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***	-	
30 to 80.872		30	25	
80,872 to 81,848		50	45	
81,848 to 134,786		30	25	
134,786 to 136,414		50	45	
136,414 to 230		30	25	
230 to 1000		37	32	

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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

CISPR 11: 2009 +A1: 2010		TEST: Limits for radiated disturbance 1 GHz – 18 GHz		Verdict
Test site:	<input type="checkbox"/> OATS	<input type="checkbox"/> SAC	<input type="checkbox"/> Alternative Test Site	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.				
** - Weighted measurements with a resolution bandwidth of 1 MHz and a video bandwidth of 10Hz.				
<input 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

Test equipment used					
Description	Manufacturer	Model	Identifier	Last Calibration date	Calibration due date
EMI Receiver	HP	8542E	3906A00276	19/02/2020	19/02/2021
EMI Receiver Filter	HP	85420E	3705A00248	19/02/2020	19/02/2021
EMC Analyzer	HP	HP8593	3536A00120	20/02/2020	20/02/2021
Biconical Antenna	EMCO	3104	2606	31/05/2020	31/05/2021
Log-periodic Antenna	EMCO	3146	9505-4081	31/05/2020	31/05/2021
Antenna Mast	ETS	2070-2	9608-1497	NCR	NCR
Turntable	ETS	2087	-	NCR	NCR
Mast & Table Controller	ETS/EMCO	2090	9608-1456	NCR	NCR
AC Power Supply 0-400Hz	KIKUSUI	PCR1000M	TK000848	NCR	NCR

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Photo of test setup for Radiated Disturbance Below 200 MHz



Photo of test setup for Radiated Disturbance Above 200 MHz



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Tabulated Results for Radiated Disturbance

Test Frequency (MHz)	Meter Reading dB(μ V)	Detector (Pk/QP/Av)	Polarity (V/H)	Azimuth (Degrees)	Antenna Height (cm)	Gain/Loss Factor (dB)	Transducer Factor (dB)	Level dB(μ V/m)	Limit dB(μ V/m)	Margin (dB)

Supplementary information:

Note: Other table formats are allowed as long as all information is included. Copy/paste this table as needed for frequency band tested.

Frequency (MHz)	Antenna Polarization		Azimuth (Degrees)	Antenna Height (cm)	Peak Reading (dB μ V/m)	QP Reading (dB μ V/m)	Limit (dB μ V/m)	Margin (dB)
	Hor.	Ver.						
336.95	<input checked="" type="checkbox"/>	<input type="checkbox"/>	29.3	142.7	41.5	36.9	47.0	-10.1
362.83	<input checked="" type="checkbox"/>	<input type="checkbox"/>	59.3	141	38.6	31.4	47.0	-15.6
622.00	<input checked="" type="checkbox"/>	<input type="checkbox"/>	329.5	138	47.0	42.6	47.0	-4.4
724.18	<input checked="" type="checkbox"/>	<input type="checkbox"/>	119.6	194	38.6	35.7	47.0	-11.2
414.61	<input type="checkbox"/>	<input checked="" type="checkbox"/>	29.5	129	37.5	32.6	47.0	-14.4
518.40	<input type="checkbox"/>	<input checked="" type="checkbox"/>	59.2	210	40.3	35.3	47.0	-11.7

Graphical representation of Radiated Disturbance Measurement

N/A

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1.10 Test Conditions and Results – Disturbance Power EMISSIONS

CISPR 14-1: 2005	TEST: Limits of disturbance power	Verdict
		N/A

1.11 Test Conditions and Results – Harmonic Current Emissions

IEC 61000-3-2:2005 +A1: 2008 +A2: 2009	TEST: Limits for harmonic current emissions (EQUIPMENT input current \leq 16 A per phase)	Verdict
		N/A

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 \leq 16 A per phase and not subject to conditional connection	Verdict
		N/A

1.13 Test Conditions and Results – Electrostatic discharge IMMUNITY

IEC 61000-4-2: 2008	TEST: Electrostatic discharge IMMUNITY	Verdict
		N/A

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
		N/A

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
		N/A

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

IEC 61000-4-4: 2012	TEST: Electrical fast transient/burst IMMUNITY	Verdict
		N/A

1.17 Test Conditions and Results – Surge IMMUNITY

IEC 61000-4-5: 2005	TEST: Surge IMMUNITY	Verdict
		N/A

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

IEC 61000-4-6: 2013	TEST: IMMUNITY to conducted disturbances, induced by radio-frequency fields	Verdict
		N/A

1.19 Test Conditions and Results – Power frequency magnetic field IMMUNITY

IEC 61000-4-8: 2009	TEST: Power frequency magnetic field IMMUNITY	Verdict
		N/A

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
		N/A

1.21 Test Conditions and Results – Electrical transient conduction along supply lines

ISO 7637-2: 2011	TEST: Electrical transient conduction along supply lines	Verdict
		N/A

IEC 60601-1-2**1.22 Attachment 1 Correction Factors****Correction factors for RF OATS Cable 35m***ITL #1911*

Frequency (MHz)	loss (dB)
30.0	1.3
50.0	1.7
100.0	2.6
200.0	3.7
300.0	4.7
400.0	5.5
500.0	6.3
600.0	7.0
700.0	7.6
800.0	8.4
900.0	9.0
1000.0	9.6

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Correction factors for **Biconical antenna**
Model: 3110B
Antenna serial number: 9912-3337

Frequency	AF
[MHz]	[dB/m]
30	13.00
35	10.89
40	10.59
45	10.63
50	10.12
60	9.26
70	7.74
80	6.63
90	8.23
100	11.12
120	13.16
140	13.07
160	14.80
180	16.95
200	17.17

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Correction factors for **Log Periodic ANTENNA**
Model: 3146
Antenna serial number: 9505-4081
3 meter range

Frequency	AF
[MHz]	[dB/m]
200	11.58
250	12.04
300	14.76
400	15.55
500	17.85
600	18.66
700	20.87
800	21.15
900	22.32
1000	24.22

IEC 60601-1-2**1.23 Attachment 2 Measurement Uncertainty**

Test Method	Expanded Uncertainty (95% Confidence K=2)
Conducted Emission (EN 55011/CISPR11, EN55022/CISPR 22, ANSI C63.4)	± 3.44 dB
Radiated Emission (EN 55011/CISPR11, EN55022/CISPR 22, ANSI C63.4)	± 4.98 dB

End of the Report