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RAPORT DE ÎNCERCĂRI

TEST REPORT

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Exemplar no. 5 from 6

ÎNCERCAREA SOLICITATĂ Required Test	**Tests according to** **SR EN 60601-1-2:2016 + A1:2021**
PRODUSUL Equipment	**UNIVERSAL ELECTROPHYSIOLOGICAL BIOFEEDBACK SYSTEM type ED.X**
PRODUCĂTOR Manufacturer	**QUANTUM MEDICAL S.R.L.**
CLIENT (nume, adresă, cerere) Customer (name, address, order)	**QUANTUM MEDICAL S.R.L.** 61 Miron Costin street, Satu Mare, Romania Order no. 01/ 2023.01.27
MANAGER LABORATOR Laboratory Manager	**Eng. Răzvan NEACŞU**
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ELECTRIC PRODUCTS CERTIFICATION INDEPENDENT BODY
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SOCIETATE CU RĂSPUNDERE LIMITATĂ

PRODUCT TECHNICAL DATA:
UNIVERSAL ELECTROPHYSIOLOGICAL BIOFEEDBACK SYSTEM type ED.X

The system consists of :

The ED.X module

Power supply	: 5 V_{dc} (USB port)
Input current	: maximum 0,5 A
Applied parts	: BF-type
Protection degree provided by enclosure	: IP40
Output channels	: 12
Time to change the signal	: maximum 300 ms
Time to change the channel	: maximum 100 ms
Rated output current /channel	: maximum 1 mA
Output voltage /channel	: 0 ... 4 V
Output frequency range	: 0 ... 100 kHz (dual channel, sinusoidal) 0 ... 100 kHz (single channel, sinusoidal, 64 points)) 0 ... 25 kHz (single channel, sinusoidal, 256 points))
Frequency resolution	: 0,01 Hz
Frequency accuracy	: maximum ± 1,5 %
Dimensions (length, width, height)	: [200 x 150 x 60] mm ± 0,5 mm
Operate temperature	: 10 °C .....40 °C
The control unit / interface	: laptop (recommended)

Use (as a universal electrophysiological biofeedback system) for:
- Pain therapy caused by various traumas, through (MENS [microcurrent transcutaneous electro-nerval stimulation)
- Treatment of neuromuscular dystonia and muscle contractures, muscle tension and/or muscle spasm through muscle re-education (EMG; EEG-based visual-haptic biofeedback)

Serial	: 1EX230103 (ED.X module) CND137C22J (HP laptop, model 15-dw3043nq)
Product type	: sample
Date product received	: 2023.01.30
Tests period	: 2023.01.30... 2023.03.14
Sampling	: Unknown The product was presented for tests by the client
Number of tested products	: one system

Tested by	Eng. Alexandru STANESCU	

Clause	Requirement according to SR EN 60601-1-2:2016 + A1:2021	Results	Fulfilling the requirement
4	**General requirements**		
4.1	**Risk management process for ME equipment and ME systems**		
	Risks resulting from reasonably foreseeable electromagnetic disturbances shall be taken into account in the risk management process	The risk management process specifies the electromagnetic environment conditions in which the equipment can be used without being affected.	P
4.2	**Non-ME equipment used in an ME system**		
	In addition to 16.1 of the general standard: – non-ME equipment used in an ME system shall comply with IEC and ISO EMC standards applicable to that equipment – 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 shall be tested according to the requirements of this collateral standard	The HP laptop, model 15-dw3043nq comply with EN 55032 and EN 55035	P NA
4.3	**General test conditions**		
4.3.1	**Configurations**		
	ME equipment and ME systems shall be tested in representative configurations, consistent with intended use, that are most likely to result in unacceptable risk, as determined by the manufacturer. These configurations shall include: – attachment of cables to all ports as necessary to achieve the intended use (including SIP/SOPS and, if applicable, the potential equalization conductor) – attachment of all tubing and filling of all fluid containers – termination of the cables with the intended equipment, subsystem simulators as specified in 7.1.4 and 8.5, patient physiological simulators as specified in 7.1.9 and 8.2 or artificial hands as specified in 7.1.10 and 8.4 – earthing on the enclosure port, if applicable, including connections to the terminal for the connection of a potential equalization conductor – use of cables and connectors that meet the specifications of the ME equipment or ME system manufacturer Special ME equipment or ME system hardware or software might be needed to perform the tests specified in Clause 7 and Clause 8.	The equipment was tested in operational conditions, powered via USB port of the laptop, and with the applied parts to patient connected to him. The applied parts to patient connected to equipment Not applicable. Not applicable. Not applicable.	P P NA P NA P NA
4.3.2	**Artificial hand**		
	If an artificial hand is used, an RC network should be used for each connection to the patient (C = 220 pF ± 20%; R = 510 Ω ± 10%), connected to the reference plane.		P
4.3.3 *Modification A1*	**Power input voltages and frequencies** If a test is applicable, it shall be performed using the follow power input voltages and frequencies (according to Table 1): 1) Mains terminal disturbance voltage (conducted emissions) (CISPR 11)	The tests were performed with the following power supply levels, depending on the test conditions: Stabilized DC power supply (5 V_{dc}) via the laptop USB port.	NA

Clause	Requirement according to SR EN 60601-1-2:2016 + A1:2021	Results	Fulfilling the requirement
	2) Electromagnetic radiation disturbance (radiated emissions) (CISPR 11) - power input voltage : any one voltage - line frequency : any one frequency	Stabilized DC power supply (5 V_{dc}) via the laptop USB port. -	P NA
	3) Harmonic current emissions (IEC 61000-3-2)	Stabilized DC power supply (5 V_{dc}) via the laptop USB port.	NA
	4) Voltage changes, voltage fluctuations and flicker emissions (IEC 61000-3-3)	Stabilized DC power supply (5 V_{dc}) via the laptop USB port.	NA
	5) Electrostatic discharge immunity (IEC 61000-4-2) - power input voltage : any one voltage - line frequency : any one frequency	Stabilized DC power supply (5 V_{dc}) via the laptop USB port. -	P NA
	6) Radiated RF electromagnetic field immunity (IEC 61000-4-3) - power input voltage : any one voltage - line frequency : any one frequency	Stabilized DC power supply (5 V_{dc}) via the laptop USB port. -	P NA
	7) Immunity to proximity fields from RF wireless communications equipment (IEC 61000-4-3) (interim method) - power input voltage : any one voltage - line frequency : any one frequency	Stabilized DC power supply (5 V_{dc}) via the laptop USB port. -	P NA
	8) Electrical fast transient/burst immunity – a.c. mains (IEC 61000-4-4)	Stabilized DC power supply (5 V_{dc}) via the laptop USB port.	NA
	9) Electrical fast transient/burst immunity – I/O SIP/SOP ports (IEC 61000-4-4)	Without I/O SIP/SOP ports provided with cables longer than 3 m.	NA
	10) Surge immunity (IEC 61000-4-5)	Stabilized DC power supply (5 V_{dc}) via the laptop USB port.	NA
	11) Immunity to conducted disturbances induced by RF fields (conducted RF disturbance immunity) – a.c. mains (IEC 61000-4-6)	Stabilized DC power supply (5 V_{dc}) via the laptop USB port.	NA
	12) Immunity to conducted disturbances induced by RF fields (conducted disturbance immunity) – SIP/SOP ports (IEC 61000-4-6)	Without I/O SIP/SOP ports provided with cables longer than 3 m.	NA
	13) Power frequency magnetic field immunity (IEC 61000-4-8) - power input voltage : any one voltage - line frequency : 50 Hz or 60 Hz (same with line frequency of the ME equipment or ME system)	Stabilized DC power supply (5 V_{dc}) via the laptop USB port. The frequency of the national AC mains supply (50 Hz) was used	P P
	14) Voltage dips immunity (IEC 61000-4-11)	Stabilized DC power supply (5 V_{dc}) via the laptop USB port.	NA
	15) Voltage short interruptions and voltage variations immunity (IEC 61000-4-11)	Stabilized DC power supply (5 V_{dc}) via the laptop USB port.	NA
	16) Proximity magnetic fields (IEC 61000-4-39) - power input voltage : any one voltage - line frequency : any one frequency	Not contain magnetically sensitive components or circuitry.	NA
5	**ME equipment and ME systems identification, marking and documents**		
5.1	**Additional requirements for marking on the outside of ME equipment and ME systems that are specified for use only in a shielded location special environment**		NA

Clause	Requirement according to SR EN 60601-1-2:2016 + A1:2021	Results	Fulfilling the requirement
5.2	**Accompanying documents**		
5.2.1	**Instructions for use**		
5.2.1.1	**General**		
	In addition to the requirements of 7.9.2 of the general standard, the instructions for use shall include the following:		
	a) a statement of the environments for which the ME equipment or ME system is suitable.	Used in medical areas by the therapist.	P
	b) the performance of the ME equipment or ME system that was determined to be essential performance and a description of what the operator can expect if the essential performance is lost or degraded due to EM disturbances	The risk management process specifies the electromagnetic environment conditions in which the equipment can be used without being affected.	P
	c) a warning statement to the effect that "WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally."	Not applicable.	NA
	d) a list of all cables and maximum lengths of cables (if applicable), transducers and other accessories that are replaceable by the responsible organization and that are likely to affect compliance of the ME equipment or ME system with the requirements of Clause 7 (Emissions) and Clause 8 (Immunity).	Not applicable.	NA
	e) a warning statement to the effect that "WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation."	The user manual specify that to the equipment is only connected the applied parts delivery by the manufacturer and the suitable USB cables .	P
	f) a warning statement to the effect that: "WARNING: Portable RF communications equipment should be used no closer than 30 cm (12 inches) to any part of the ME equipment or ME system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result."	The user instructions provide for the use of portable RF equipment a minimum distance of 30 cm from the equipment	P
	To assure the levels of immunity specified in Table 9, the test conditions shall be calculated with the equation specified in 8.10	The test conditions (RF power, distance) were calculated with the equation from 8.10.	P
5.2.1.2	**Requirements applicable to ME equipment and ME systems classified class A according to CISPR 11**	Not applicable.	NA
5.2.2	**Technical description**		
5.2.2.1	**Requirements applicable to all ME equipment and ME systems**		
	In addition to the requirements of 7.9.3 of the general standard, the technical description shall describe precautions to be taken to prevent adverse events to the patient and operator due to electromagnetic disturbances	The user manual specifies the electromagnetic environment conditions in which the equipment can be used without being affected.	P

Clause	Requirement according to SR EN 60601-1-2:2016 + A1:2021	Results	Fulfilling the requirement
	For all ME equipment and ME systems, the technical description shall include the following information: a) the compliance for each emissions and immunity standard or test specified by this collateral standard, e.g. emissions class and group and immunity test level; b) any deviations from this collateral standard and allowances used; c) all necessary instructions for maintaining basic safety and essential performance with regard to electromagnetic disturbances for the expected service life	The user manual specify the emissions and immunity standards and the levels used for tests. The user manual specifies the electromagnetic environment conditions in which the equipment can be used without being affected.	P NA P
5.2.2.2	**Requirements applicable to ME equipment and ME systems specified for use only in a shielded location special environment**	Not applicable.	NA
5.2.2.3	**Requirements applicable to ME equipment that intentionally receives RF electromagnetic energy for the purpose of its operation**	Not applicable.	NA
5.2.2.4	**Requirements applicable to ME equipment that includes RF transmitters**	Not applicable.	NA
5.2.2.5	**Requirements applicable to permanently installed large ME equipment and large ME systems**	Not applicable.	NA
5.2.2.6	**Requirements applicable to ME equipment and ME systems that claim compatibility with HF surgical equipment**	Not applicable.	NA
6	**Documentation of the tests**		
6.1	**General**		
	The documentation of the tests shall contain all the information necessary to facilitate dequate planning (test plan) and execution (test report) of the tests so that they can be readily reproduced	The tests were performer with all applicable requirements of SR EN 60601-1-2:2016, under the conditions imposed by the standard.	P
6.2	**Test plan**		
	Prior to the start of formal testing, a detailed test plan shall be provided to the test laboratory.	The tests were performer according with all applicable requirements of SR EN 60601-1-2:2016 + A1:2021	P
6.3	**Test report**		
	The test report shall meet the requirements of Clause 9	See this TR.	P
7	**Electromagnetic emissions requirements for ME equipment and ME systems**		
7.1	**Protection of radio services and other equipment**		
7.1.1	**General**		
	Unless otherwise specified herein, ME equipment and ME systems shall comply with CISPR 11.	The tests were performer according to SR EN 55011:2016 + A1:2017 (CISPR 11). For tests see Annex 1 from this TR.	P
7.1.2	**Operating modes**		
	During emissions testing, the ME equipment or ME system shall be tested in the modes that maximize emissions In addition to testing for emissions in active modes, inclusion of standby mode should be considered.	The equipment was tested in normal operating mode by used the software installed on the laptop Shortly after attaching the applied parts to the patient, the program has been run	P NA

Clause	Requirement according to SR EN 60601-1-2:2016 + A1:2021	Results	Fulfilling the requirement
7.1.3	**Multimedia equipment**		
	Multimedia equipment connected to ME equipment and ME systems shall comply with CISPR 32. If CISPR 32 class A equipment is supplied as part of an ME system, the ME system shall be classified class A.	The HP laptop, model 15-dw3043nq comply with EN 55032 (CISPR 32)	P P
7.1.4	**Subsystems**	Not applicable.	NA
7.1.5	**ME equipment and ME systems specified for use only in a shielded location special environment**	Not applicable.	NA
7.1.6	**ME equipment and ME systems that include radio equipment**	Not applicable.	NA
7.1.7	**ME equipment whose main functions are performed by motors and switching or regulating devices**	Not applicable.	NA
7.1.8	**ME equipment and ME systems containing X-ray generators**	Not applicable.	NA
7.1.9	**Patient physiological simulation**		
	The risks occuring from reasonably foreseeable electromagnetic disturbances must be considered in the risk management process.	The risk management process specifies the electromagnetic environment conditions in which the equipment can be used without being affected.	P
7.1.10	**Artificial hand**		
	The risks occuring from reasonably foreseeable electromagnetic disturbances must be considered in the risk management process.	The risk management process specifies the electromagnetic environment conditions in which the equipment can be used without being affected.	P
7.1.11	**Patient-coupled cables**		
	Patient-coupled cables shall be considered interconnecting cables in accordance with the requirements of CISPR 11.	Applied parts to patient.	P
7.1.12 *Modification A1*	**Permanently installed large ME equipment and large ME systems**	Not applicable.	NA
7.2	**Protection of the public mains network**		
7.2.1	**Harmonic distortion**	Stabilized DC power supply (5 V_{dc}) via the laptop USB port.	NA
7.2.2	**Voltage fluctuations and flicker**		
7.3	**Emissions requirements summary**		
	The emissions requirements are summarized as follow:		
	1) Conducted and radiated RF emissions - for professional healthcare facility environment: CISPR 11 - for home healthcare environment: CISPR 11	For tests see Annex 1 from this TR.	P NA
	2) Harmonic distortion	Stabilized DC power supply (5 V_{dc}) via the laptop USB port.	NA
	3) Voltage fluctuations and flicker	Stabilized DC power supply (5 V_{dc}) via the laptop USB port.	
8	**Electromagnetic immunity requirements for ME equipment and ME systems**		
8.1*	**General**		
	The immunity test requirements for ME equipment and ME systems are specified by this collateral standard on a port-by-port basis. This follows the convention of the IEC 61000-6 series of generic EMC standards.	For tests see Annexs 2.....6 from this TR.	P

Clause	Requirement according to SR EN 60601-1-2:2016 + A1:2021	Results	Fulfilling the requirement
	Electromagnetic immunity tests: – shall be performed in a well-defined and reproducible manner – shall be performed individually as single tests in sequence, and – may be performed in any order		P P P
	At least one of each type of port (e.g. having the same input or output electronic circuits,loads, connected equipment) shall be connected during immunity testing.		P
	If the ME equipment or ME system has multiple identical ports, it is only necessary to test one of each type during immunity testing		P
	For the case in which the ME equipment or ME system is damaged by an immunity test signal, the remainder of the immunity test shall be take account of defect.		NA
Modification A1	The immunity test requirements shall be applied to the ports of the ME equipment or ME system as specified in Table 4 through Table 9 and Table 11 according to the environments (locations) of intended use.	Used in medical areas environment, by the therapist.	P
Modification A1	Table 4 through Table 9 and Table 11 specify immunity requirements and test conditions for the professional healthcare facility environment and the home healthcare environment.	Used in medical areas environment, by the therapist.	P
Modification A1	The procedure specified in Annex E can be used to determine immunity test levels for special environments, or, if justified, can be used to modify the immunity test levels of Table 4 through Table 9 and Table 11, based on specific environmental characteristics or mitigations	Used in medical areas environment, by the therapist.	NA
Modification A1	For ME equipment and ME systems for which the intended use includes types of transportation (e.g. land, sea and air vehicles) or other locations in the home healthcare environment such as those that can be accessed by walking (e.g. near radiofrequency identification (RFID) systems, anti-theft systems), if additional immunity tests or immunity test levels that are higher than those specified in Table 4 through Table 9 and Table 11 are appropriate or are specified by standards applicable to a mode or EM environment of transportation, these additional tests and higher immunity test levels shall apply.	Used in medical areas environment, by the therapist.	NA
Modification A1	ME equipment or ME systems intended for use in the emergency medical services environment shall meet the requirements of Table 4 through Table 9 for the home healthcare environment and Table 11. If locations in the emergency medical services environment are identified for which the specifications for the home healthcare environment are not adequate, Annex E may be used to determine appropriate immunity test levels	Used in medical areas environment, by the therapist	NA

Clause	Requirement according to SR EN 60601-1-2:2016 + A1:2021	Results	Fulfilling the requirement
	If the intended use of the ME equipment or ME system includes more than one environment, the most stringent immunity test levels among all the applicable environments shall apply	Used in medical areas environment, by the therapist	P
Modification A1	The power frequency for all immunity tests may be selected at any one of the nominal power frequencies of the ME equipment or ME system, except as otherwise specified in Table 1 and Table 4 through Table 9 and Table 11	The ME system (for data processing) can be powered by the public AC mains with a frequency of 50 Hz	P
	Before immunity testing begins, the manufacturer shall determine specific, detailed immunity pass/fail criteria.		P
	Immunity pass/fail criteria may specify degradations that are acceptable because they do not result in unacceptable risk		NA
	ME equipment and ME systems shall meet the immunity pass/fail criteria during and after the immunity tests.		P
8.2	**Patient physiological simulation**		
	If simulation of the patient is required to verify normal operation of the ME equipment or ME system, it shall be provided during immunity testing.	The RC networks were used to simulate the patient.	P
8.3	**Termination of patient-coupled parts**		
	For testing according to IEC 61000-4-4 and IEC 61000-4-6, the conditions specified in 4.3.2 apply. These conditions may also be used in other tests, as specified by the manufacturer	Provided with terminals for applied parts to patient.	P
8.4	**Hand-held ME equipment and parts intended to be hand-held**	Not applicable.	NA
8.5	**Subsystems**	Not applicable.	NA
8.6 *Modification A1*	**Permanently installed large ME equipment and large ME systems**	Not applicable.	NA
8.7	**Operating modes**		
	During immunity testing, the basic safety and essential performance shall be tested in the modes and settings that are most likely to result in an unacceptable risk, as determined by the manufacturer.		P
	This shall be determined using risk analysis, experience, engineering analysis, or pretesting.	The risk management process specifies the electromagnetic environment conditions in which the equipment can be used without being affected.	P
	If the ME equipment or ME system is not rated for continuous duty, a duty cycle may be selected that is appropriate for the ME equipment or ME system under test.		NA
	The standby mode should be considered for inclusion in immunity testing, particularly for ME equipment and ME systems that are in standby mode for long periods of time in the presence of patients or operators.	Shortly after attaching the applied parts to the patient, the program is run	NA

Clause	Requirement according to SR EN 60601-1-2:2016 + A1:2021	Results	Fulfilling the requirement
8.8	**Non-ME equipment**		
	Non-ME equipment (e.g. ITE) that is a part of an ME system shall fulfil 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	Stabilized DC power supply (5 V_{dc}) via the laptop USB port. The HP laptop, model 15-dw3043nq comply with EN 55032, EN 55035, EN 61000-3-3 for EMC and for safety requirements with EN 60950-1	P
8.9	**Immunity test levels**		
Modification A1	Immunity test levels for basic safety and essential performance of EM equipment and EM systems shall be according to the professional healthcare facility environment, home healthcare environment, and special environment, and specified in Table 4 through Table 9 and 8.11	Used in medical areas environment, by the therapist	P
	If applicable, an unknown intended use location shall be assigned to an environment with a similar location, as determined by the manufacturer		NA
Modification A1	When a manufacturer knows from experience, published data, or representative measurements that the environment of intended use has unique characteristics, he shall take this into consideration in the risk management process.		NA
	Level for enclosure port (Table 4)		
*	1) Electrostatic discharge (IEC 61000-4-2) - for home healthcare environment • ± 8 kV by contact • ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV by air	For test see Annex 2 from this TR.	NA
	- for professional healthcare facility environment • ± 8 kV by contact • ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV by air	± 8 kV (contact) ± 15 kV (air)	P P
*	2) Radiated RF EM fields (IEC 61000-4-3)	For test see Annex 3 from this TR.	
	- for home healthcare environment: • 10 V/m • 80 MHz – 2,7 GHz • 80 % AM at 1 kHz		NA
	- for professional healthcare facility environment • 3 V/m • 80 MHz – 2,7 GHz • 80 % AM at 1 kHz	Field intensity : 3 V/m Frequencies : 80 MHz – 2,7 GHz Modulation signal: 1 kHz Degree of modulation : 80 % AM Vertical and horizontal polarization	P P P
*	3) Proximity fields from RF wireless communications equipment (IEC 61000-4-3)	For test see Annex 4 from this TR.	
	- for home healthcare environment: • see 8.10		NA
	- for professional healthcare facility environment • see 8.10	See subclause 8.10 for specific levels at each test frequency.	P

Clause	Requirement according to SR EN 60601-1-2:2016 + A1:2021	Results	Fulfilling the requirement
Replace A1	4) Rated power frequency magnetic fields (IEC 61000-4-8)	For test see Annex 5 from this TR.	
	- for home healthcare environment: • 30 A/m • 50 Hz or 60 Hz		NA
	- for professional healthcare facility environment • 30 A/m • 50 Hz or 60 Hz	 Field intensity : 30 A/m 50 Hz	 P P
Addition A1	5) Proximity magnetic fields (IEC 61000-4-39) • see 8.11	Not contain magnetically sensitive components or circuitry.	NA
Modification A1	**Level for input a.c. power port (Table 5)**	Stabilized DC power supply (5 V_{dc}) via the laptop USB port.	NA
	Level for input d.c. power port (Table 6)		
	1) Electrical fast transients/bursts (IEC 61000-4-4)	Stabilized DC power supply (5 V_{dc}) via the laptop USB port, with a detachable cable less than 3 m long	NA
	2) Surges (line–to–line) (IEC 61000-4-5)	Stabilized DC power supply (5 V_{dc}) via the laptop USB port, with a detachable cable less than 3 m long	NA
	3) Surges (line–to–ground) (IEC 61000-4-5)	Without protective earthing circuits.	NA
	4) Conducted disturbances induced by RF fields (IEC 61000-4-6)	Stabilized DC power supply (5 V_{dc}) via the laptop USB port, with a detachable cable less than 3 m long	NA
	5) Electrical transient conduction along supply lines (ISO 7637-2)	The equipment is not intended for installation and use on vehicles.	NA
	Level for patient coupling port (Table 7)		
*	1) Electrostatic discharge (IEC 61000-4-2)	For test see Annex 2 from this TR.	
	- for home healthcare environment •± 8 kV by contact •± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV by air		NA
	- for professional healthcare facility environment •± 8 kV by contact •± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV by air	 ± 8 kV (contact) ± 15 kV (air)	 P P
*	2) Conducted disturbances induced by RF fields (IEC 61000-4-6)	For tests see Annex 6 from this TR.	
	- for home healthcare environment: • 3 V • 6 V in ISM bands (6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz) • 6 V in amateur radio bands (1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz) • 0,15 MHz – 80 MHz • 80 % AM at 1 kHz		NA

Clause	Requirement according to SR EN 60601-1-2:2016 + A1:2021	Results	Fulfilling the requirement
	- for professional healthcare facility environment • 3 V	U_{test} = 3 V, for 0,15 MHz – 80 MHz frequency range, except ISM bands (see 8.1 from this TR for used U_{test} = 6 V, for amateur radio bands)	P
	• 6 V in ISM bands (6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz)	U_{test} = 6 V, for ISM bands	P
	• 6 V in amateur radio bands (1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz)	U_{test} = 6 V, for amateur radio bands (1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz)	P
	• 0,15 MHz – 80 MHz • 80 % AM at 1 kHz	Frequencies : 0,15 MHz – 80 MHz Modulation signal: 1 kHz Degree of modulation : 80 % AM	P P
	Level for signal input/output parts port (Table 8)		
	1) Electrostatic discharge (IEC 61000-4-2)	For test see Annex 2 from this TR.	
	- for home healthcare environment •± 8 kV by contact •± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV by air		NA
	- for professional healthcare facility environment •± 8 kV by contact •± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV by air	± 8 kV (contact) ± 15 kV (air)	P P
	2) Electrical fast transients/bursts (IEC 61000-4-4)	Without SIP/SOP I/O ports provided with a cables longer than 3 m	NA
	- for home healthcare environment		
	• ± 1 kV		
	• 100 kHz repetition frequency		
	- for professional healthcare facility environment		
	• ± 1 kV		
	• 100 kHz repetition frequency		
	3) Surges (line–to–ground) (IEC 61000-4-5)	Class II equipment	NA
	- for home healthcare environment		
	• ± 2 kV		
	- for professional healthcare facility environment		
	• ± 2 kV		
	4) Conducted disturbances induced by RF fields (IEC 61000-4-6)	Without SIP/SOP I/O ports provided with a cables longer than 3 m	NA
8.10	**Immunity to proximity fields from RF wireless communications equipment**		
	The enclosure port of ME equipment and ME systems shall be tested as specified in Table 9 using the test methods specified in IEC 61000-4-3.	The tests were performed using the test methods specified in SR EN 61000-4-3 and levels specified in Table 9 from SR EN 60601-1-2:2016	P
Replace A1	**Test specifications for enclosure port immunity to RF wireless communications equipment (Table 9)**	For tests see Annex 6 from this TR, with modifications specified at 5.2.1.1 and 8.6.	
	Test frequency: 385 MHz (Band 380 MHz – 390 MHz) • Modulation: pulse modulation 18 Hz • Maxim power : 1,8 W • Distance : 0.3 m • Level : 27 V/m	The test frequency (385 MHz) was applied with following conditions: - with 18 Hz pulse modulation - 1 W RF output power - 0.22 m distance to equipment - the achieved level of immunity : 27 V/m	P

Clause	Requirement according to SR EN 60601-1-2:2016 + A1:2021	Results	Fulfilling the requirement
	Test frequency: 450 MHz (Band 430 MHz – 470 MHz) • Modulation: frequency modulation ± 5 kHz deviation; 1 kHz sine • Maxim power : 2 W • Distance : 0.3 m • Level : 28 V/m	The test frequency (450 MHz) was applied with following conditions: - with 1 kHz modulation signal and frequency modulation with ± 5 kHz deviation - 1 W RF output power - 0.21 m distance to equipment - the achieved level of immunity : 28 V/m	P
	Test frequency: 710 MHz; 745 MHz; 780 MHz (Band 704 MHz – 787 MHz) • Modulation: pulse modulation 217 Hz • Maxim power : 0.2 W • Distance : 0.3 m • Level : 9 V/m	The test frequencies (710 MHz; 745 MHz; 780 MHz) were applied with following conditions: - with 217 Hz pulse modulation - 0.2 W RF output power - 0.3 m distance to equipment - the achieved level of immunity : 9 V/m	P
	Test frequency: 810 MHz; 870 MHz; 930 MHz (Band 800 MHz – 960 MHz) • Modulation: pulse modulation 18 Hz • Maxim power : 2 W • Distance : 0.3 m • Level : 28 V/m	The test frequencies (810 MHz; 870 MHz; 930 MHz) were applied with following conditions: - with 18 Hz pulse modulation - 1 W RF output power - 0.21 m distance to equipment - the achieved level of immunity : 28 V/m	P
	Test frequency: 1720 MHz; 1845 MHz; 1970 MHz (Band 1700 MHz – 1990 MHz) • Modulation: pulse modulation 217 Hz • Maxim power : 2 W • Distance : 0.3 m • Level : 28 V/m	The test frequencies (720 MHz; 1845 MHz; 1970 MHz) were applied with following conditions: - with 217 Hz pulse modulation - 2 W RF output power - 0.3 m distance to equipment - the achieved level of immunity : 28 V/m	P
	Test frequency: 2450 MHz (Band 2400 MHz – 2570 MHz) • Modulation: pulse modulation 217 Hz • Maxim power : 2 W • Distance : 0.3 m • Level : 28 V/m	The test frequency (2450 MHz) was applied with following conditions: - with 217 Hz pulse modulation - 2 W RF output power - 0.3 m distance to equipment - the achieved level of immunity : 28 V/m	P
8.11 *Addition A1*	**Immunity to proximity fields in the frequency range 9 kHz to 13,56 MHz**	Not contain magnetically sensitive components or circuitry.	NA

Fulfilling the requirement:

P - The requirement is met (PASS)
NA - The requirement is not applicable to this product type (NOT APPLICABLE)

NOTE : *The tests marked with (*) are not covered by the RENAR accreditation but have been performed in accordance with the requirements of SR EN ISO/IEC 17025 and comply with applicable LICPE documents and RENAR policies and regulations.*

For information about accredited tests, please refer to the Accreditation Certificate LI 911 and Annex 1 to the Accreditation Certificate LI 911 on site www.oicpe.ro

Anexa 1 - Emisii RF conduse (Perturbaţii electromagnetice radiate)

Test according to the requirements of subclauses 7.1.1 and 7.3 from this TR.
Power supply according to subclause 4.3.3 from this TR.
Test method according to SR EN 55011:2016 + A1:2017+A11:2020+A2:2021, clause 7 and clause 8 (subclause 8.3).
Allowable limits according to SR EN 55011:2016 + A1:2017+A11:2020+A2:2021, clause 6 (subclause 6.2.1, table 7).
Used apparatus according to Annex 7 to this TR .
Ambient RF emissions was measured for the 30 MHz... 1000 MHz ranges, for horizontal and vertical polarization (Figure 1, Figure 2).
Measurements were resumed under normal operating conditions (Figure 3, Figure 4).

Note: Because the measurement was made in the electromagnetic free space (open area test site), signals for 88-108 MHz and 174-182 MHz (terrestrial transmissions), 390 MHz (data transmission), 420-460 MHz (mobile telephony), 730-790 MHz (terrestrial digital television) and 920-960 MHz (GSM mobile telephony) ranges, will not be considered.

1) 30 MHz ÷ 1000 MHz range ambient RF emissions, horizontal polarization

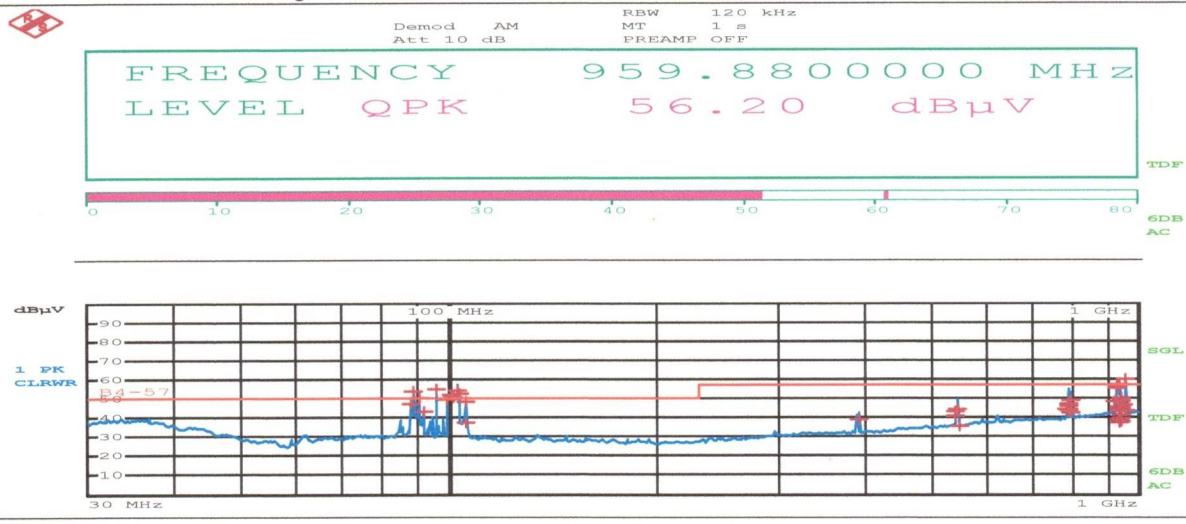

Figure 1

EDIT PEAK LIST (Final Measurement Results)

Trace1: B4-57
Trace2: ---
Trace3: ---

TRACE		FREQUENCY	LEVEL dBµV		DELTA LIMIT dB
1	Quasi Peak	88.48 MHz	47.09	L1	-2.90
1	Quasi Peak	89.04 MHz	53.66	L1	3.66
1	Quasi Peak	90.84 MHz	50.25	L1	0.25
1	Quasi Peak	92.08 MHz	43.01	L1	-6.98
1	Quasi Peak	96.12 MHz	54.74	L1	4.74
1	Quasi Peak	99.32 MHz	49.60	L1	-0.39
1	Quasi Peak	100.6 MHz	51.74	L1	1.74
1	Quasi Peak	101.84 MHz	50.84	L1	0.84
1	Quasi Peak	102.72 MHz	54.20	L1	4.20
1	Quasi Peak	103.84 MHz	52.25	L1	2.25
1	Quasi Peak	105.8 MHz	48.43	L1	-1.56
1	Quasi Peak	106.16 MHz	37.36	L1	-12.63
1	Quasi Peak	394 MHz	39.06	L1	-17.93
1	Quasi Peak	543.8 MHz	40.90	L1	-16.09
1	Quasi Peak	545.04 MHz	42.91	L1	-14.08
1	Quasi Peak	546.88 MHz	43.88	L1	-13.11
1	Quasi Peak	548.72 MHz	35.42	L1	-21.57
1	Quasi Peak	791.68 MHz	43.92	L1	-13.07
1	Quasi Peak	791.96 MHz	44.04	L1	-12.95
1	Quasi Peak	793.36 MHz	46.54	L1	-10.45

Clause	Requirement according to SR EN 60601-1-2:2016 + A1:2021	Results	Fulfilling the requirement

EDIT PEAK LIST (Final Measurement Results)

Trace1: B4-57
Trace2: ---
Trace3: ---

TRACE	FREQUENCY	LEVEL dBµV		DELTA LIMIT dB
1 Quasi Peak	794.2 MHz	43.60	L1	-13.40
1 Quasi Peak	794.52 MHz	43.96	L1	-13.03
1 Quasi Peak	794.84 MHz	45.95	L1	-11.04
1 Quasi Peak	795.48 MHz	47.08	L1	-9.91
1 Quasi Peak	796.32 MHz	48.94	L1	-8.05
1 Quasi Peak	800.12 MHz	42.24	L1	-14.75
1 Quasi Peak	926.44 MHz	48.50	L1	-8.50
1 Quasi Peak	931.6 MHz	55.18	L1	-1.81
1 Quasi Peak	933.44 MHz	56.66	L1	-0.33
1 Quasi Peak	935.64 MHz	43.34	L1	-13.65
1 Quasi Peak	936.08 MHz	56.95	L1	-0.04
1 Quasi Peak	936.88 MHz	44.37	L1	-12.62
1 Quasi Peak	937 MHz	43.22	L1	-13.77
1 Quasi Peak	937.08 MHz	42.85	L1	-14.14
1 Quasi Peak	937.16 MHz	45.42	L1	-11.57
1 Quasi Peak	937.4 MHz	44.79	L1	-12.20
1 Quasi Peak	937.6 MHz	43.56	L1	-13.43
1 Quasi Peak	937.76 MHz	38.77	L1	-18.22
1 Quasi Peak	937.92 MHz	37.73	L1	-19.26
1 Quasi Peak	938.28 MHz	37.60	L1	-19.39

EDIT PEAK LIST (Final Measurement Results)

Trace1: B4-57
Trace2: ---
Trace3: ---

TRACE	FREQUENCY	LEVEL dBµV		DELTA LIMIT dB
1 Quasi Peak	938.76 MHz	36.97	L1	-20.02
1 Quasi Peak	938.96 MHz	37.45	L1	-19.54
1 Quasi Peak	941.6 MHz	43.02	L1	-13.97
1 Quasi Peak	942.16 MHz	41.22	L1	-15.77
1 Quasi Peak	942.32 MHz	41.32	L1	-15.67
1 Quasi Peak	942.88 MHz	44.10	L1	-12.89
1 Quasi Peak	943.28 MHz	48.49	L1	-8.50
1 Quasi Peak	943.56 MHz	49.32	L1	-7.67
1 Quasi Peak	945.72 MHz	50.21	L1	-6.78
1 Quasi Peak	946.28 MHz	41.05	L1	-15.94
1 Quasi Peak	946.44 MHz	43.57	L1	-13.42
1 Quasi Peak	946.56 MHz	39.67	L1	-17.32
1 Quasi Peak	947.72 MHz	37.67	L1	-19.32
1 Quasi Peak	947.96 MHz	43.84	L1	-13.15
1 Quasi Peak	948.2 MHz	45.25	L1	-11.74
1 Quasi Peak	948.28 MHz	44.69	L1	-12.31
1 Quasi Peak	948.48 MHz	44.37	L1	-12.62
1 Quasi Peak	952.36 MHz	46.70	L1	-10.29
1 Quasi Peak	958.2 MHz	43.42	L1	-13.57
1 Quasi Peak	959.88 MHz	59.69	L1	2.69

2) 30 MHz ÷ 1000 MHz range ambient RF emissions, vertical polarization

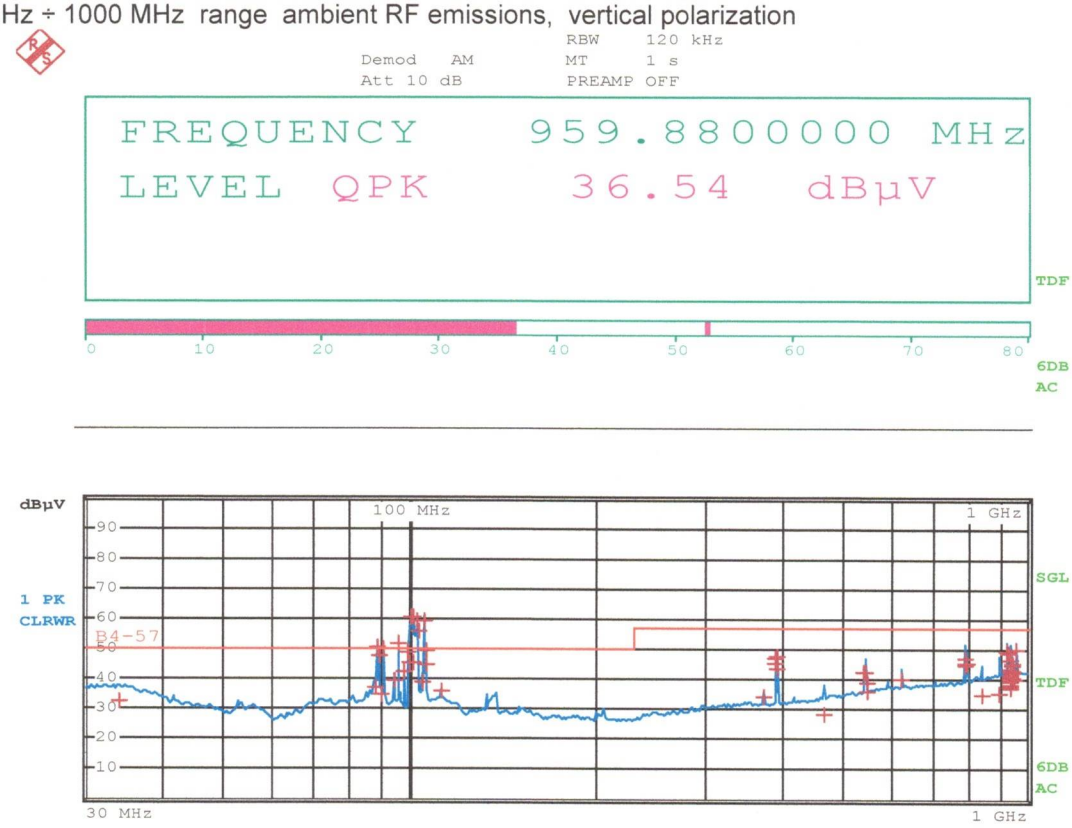

Figure 2

EDIT PEAK LIST (Final Measurement Results)

Trace1: B4-57
Trace2: ---
Trace3: ---

TRACE		FREQUENCY	LEVEL dBµV		DELTA LIMIT dB
1	Quasi Peak	33.92 MHz	32.68	L1	-17.32
1	Quasi Peak	88 MHz	36.96	L1	-13.03
1	Quasi Peak	89.04 MHz	50.75	L1	0.75
1	Quasi Peak	89.44 MHz	47.51	L1	-2.48
1	Quasi Peak	90.2 MHz	34.65	L1	-15.34
1	Quasi Peak	90.76 MHz	49.96	L1	-0.03
1	Quasi Peak	94.88 MHz	39.37	L1	-10.62
1	Quasi Peak	96.16 MHz	51.83	L1	1.83
1	Quasi Peak	98.32 MHz	42.30	L1	-7.69
1	Quasi Peak	99.32 MHz	49.02	L1	-0.97
1	Quasi Peak	100.24 MHz	45.17	L1	-4.82
1	Quasi Peak	100.64 MHz	60.27	L1	10.27
1	Quasi Peak	101.32 MHz	45.38	L1	-4.61
1	Quasi Peak	101.88 MHz	60.42	L1	10.42
1	Quasi Peak	102.88 MHz	59.37	L1	9.37
1	Quasi Peak	103.76 MHz	56.02	L1	6.02
1	Quasi Peak	105.32 MHz	39.15	L1	-10.84
1	Quasi Peak	105.8 MHz	59.25	L1	9.25
1	Quasi Peak	106.28 MHz	49.54	L1	-0.45
1	Quasi Peak	106.72 MHz	44.74	L1	-5.25

EDIT PEAK LIST (Final Measurement Results)

Trace1: B4-57
Trace2: ---
Trace3: ---

TRACE		FREQUENCY	LEVEL dBµV		DELTA LIMIT dB
1	Quasi Peak	931.6 MHz	48.90	L1	-8.09
1	Quasi Peak	935.92 MHz	46.72	L1	-10.27
1	Quasi Peak	936.44 MHz	41.58	L1	-15.41
1	Quasi Peak	937.52 MHz	37.51	L1	-19.48
1	Quasi Peak	937.8 MHz	43.79	L1	-13.20
1	Quasi Peak	938.04 MHz	43.00	L1	-13.99
1	Quasi Peak	938.28 MHz	38.36	L1	-18.63
1	Quasi Peak	938.48 MHz	40.08	L1	-16.91
1	Quasi Peak	938.64 MHz	39.68	L1	-17.31
1	Quasi Peak	938.92 MHz	37.23	L1	-19.77
1	Quasi Peak	939.4 MHz	46.70	L1	-10.29
1	Quasi Peak	942.16 MHz	41.14	L1	-15.85
1	Quasi Peak	942.32 MHz	40.75	L1	-16.24
1	Quasi Peak	945.88 MHz	44.50	L1	-12.49
1	Quasi Peak	946.84 MHz	40.64	L1	-16.35
1	Quasi Peak	948.24 MHz	42.18	L1	-14.82
1	Quasi Peak	948.36 MHz	45.20	L1	-11.79
1	Quasi Peak	948.52 MHz	43.26	L1	-13.74
1	Quasi Peak	956.24 MHz	40.19	L1	-16.80
1	Quasi Peak	959.88 MHz	49.84	L1	-7.15

EDIT PEAK LIST (Final Measurement Results)

Trace1: B4-40-47
Trace2: ---
Trace3: ---

TRACE		FREQUENCY	LEVEL dBµV		DELTA LIMIT dB
1	Quasi Peak	936.44 MHz	53.71	L1	6.71
1	Quasi Peak	936.6 MHz	53.38	L1	6.38
1	Quasi Peak	937.04 MHz	53.87	L1	6.87
1	Quasi Peak	937.16 MHz	54.08	L1	7.08
1	Quasi Peak	937.56 MHz	55.37	L1	8.37
1	Quasi Peak	937.8 MHz	53.71	L1	6.71
1	Quasi Peak	939.48 MHz	51.20	L1	4.20
1	Quasi Peak	941.4 MHz	46.65	L1	-0.34
1	Quasi Peak	941.48 MHz	45.83	L1	-1.16
1	Quasi Peak	941.68 MHz	45.04	L1	-1.96
1	Quasi Peak	941.84 MHz	49.07	L1	2.07
1	Quasi Peak	942.16 MHz	47.29	L1	0.29
1	Quasi Peak	942.32 MHz	45.75	L1	-1.24
1	Quasi Peak	942.4 MHz	45.98	L1	-1.01
1	Quasi Peak	943.36 MHz	45.83	L1	-1.16
1	Quasi Peak	943.56 MHz	48.40	L1	1.39
1	Quasi Peak	946.68 MHz	42.93	L1	-4.06
1	Quasi Peak	952.48 MHz	54.28	L1	7.28
1	Quasi Peak	956.44 MHz	41.78	L1	-5.21
1	Quasi Peak	959.88 MHz	58.79	L1	11.79

3) 30 MHz ÷ 1000 MHz range RF emissions, horizontal polarization, operational

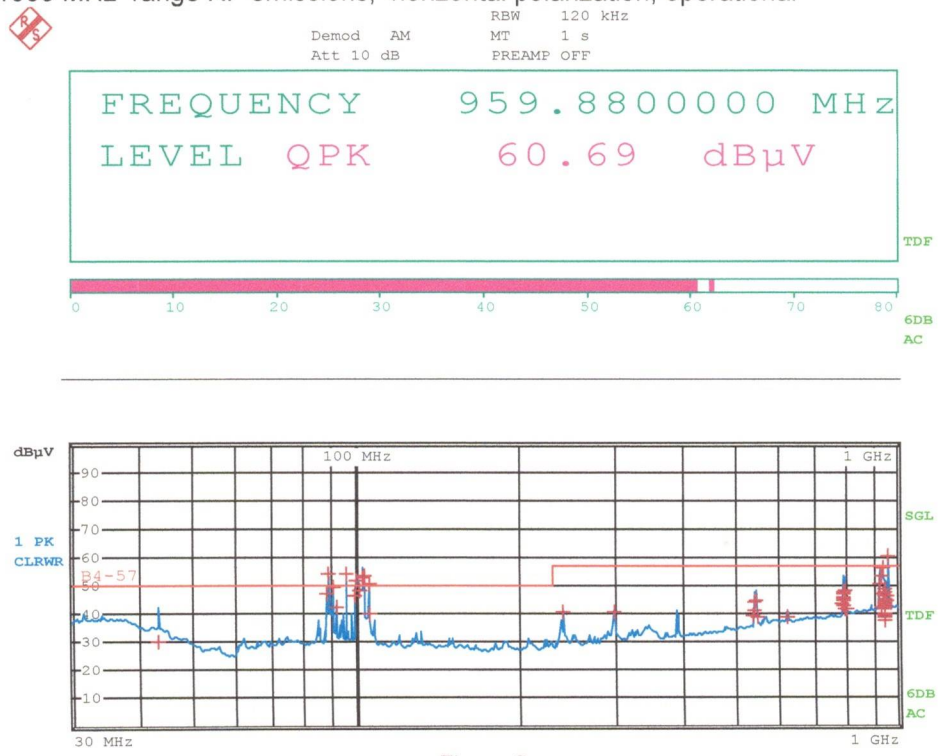

Figure 3

Clause	Requirement according to SR EN 60601-1-2:2016 + A1:2021	Results	Fulfilling the requirement

EDIT PEAK LIST (Final Measurement Results)

Trace1: B4-57
Trace2: ---
Trace3: ---

TRACE		FREQUENCY	LEVEL dBµV		DELTA LIMIT dB
1	Quasi Peak	43.24 MHz	29.84	L1	-20.15
1	Quasi Peak	88.48 MHz	47.32	L1	-2.67
1	Quasi Peak	89 MHz	53.87	L1	3.87
1	Quasi Peak	90.84 MHz	49.28	L1	-0.71
1	Quasi Peak	92.04 MHz	42.34	L1	-7.65
1	Quasi Peak	96.16 MHz	53.84	L1	3.84
1	Quasi Peak	99.28 MHz	46.26	L1	-3.73
1	Quasi Peak	100.52 MHz	51.75	L1	1.75
1	Quasi Peak	101.84 MHz	48.13	L1	-1.86
1	Quasi Peak	102.72 MHz	52.96	L1	2.96
1	Quasi Peak	103.84 MHz	53.59	L1	3.59
1	Quasi Peak	105.88 MHz	50.47	L1	0.47
1	Quasi Peak	106.16 MHz	40.01	L1	-9.98
1	Quasi Peak	240.04 MHz	40.36	L1	-16.63
1	Quasi Peak	300.04 MHz	40.55	L1	-16.44
1	Quasi Peak	542.24 MHz	39.34	L1	-17.65
1	Quasi Peak	543.68 MHz	41.46	L1	-15.53
1	Quasi Peak	545.08 MHz	44.13	L1	-12.86
1	Quasi Peak	546.96 MHz	44.70	L1	-12.29
1	Quasi Peak	549.44 MHz	39.03	L1	-17.96

EDIT PEAK LIST (Final Measurement Results)

Trace1: B4-57
Trace2: ---
Trace3: ---

TRACE		FREQUENCY	LEVEL dBµV		DELTA LIMIT dB
1	Quasi Peak	625 MHz	39.02	L1	-17.97
1	Quasi Peak	791.68 MHz	43.60	L1	-13.39
1	Quasi Peak	792 MHz	43.20	L1	-13.80
1	Quasi Peak	792.8 MHz	44.75	L1	-12.24
1	Quasi Peak	792.96 MHz	45.56	L1	-11.43
1	Quasi Peak	794.24 MHz	45.94	L1	-11.05
1	Quasi Peak	794.56 MHz	46.06	L1	-10.93
1	Quasi Peak	795.32 MHz	47.22	L1	-9.78
1	Quasi Peak	795.52 MHz	47.83	L1	-9.16
1	Quasi Peak	796.32 MHz	48.03	L1	-8.96
1	Quasi Peak	799.92 MHz	41.82	L1	-15.17
1	Quasi Peak	804.28 MHz	41.84	L1	-15.15
1	Quasi Peak	926.36 MHz	50.51	L1	-6.48
1	Quasi Peak	931.6 MHz	53.60	L1	-3.39
1	Quasi Peak	932 MHz	42.22	L1	-14.77
1	Quasi Peak	933.4 MHz	53.28	L1	-3.71
1	Quasi Peak	936.08 MHz	56.30	L1	-0.69
1	Quasi Peak	936.52 MHz	47.09	L1	-9.90
1	Quasi Peak	941.52 MHz	43.55	L1	-13.44
1	Quasi Peak	941.84 MHz	42.21	L1	-14.78

EDIT PEAK LIST (Final Measurement Results)

Trace1: B4-57
Trace2: ---
Trace3: ---

TRACE		FREQUENCY	LEVEL dBµV		DELTA LIMIT dB
1	Quasi Peak	43.24 MHz	29.84	L1	-20.15
1	Quasi Peak	88.48 MHz	47.32	L1	-2.67
1	Quasi Peak	89 MHz	53.87	L1	3.87
1	Quasi Peak	90.84 MHz	49.28	L1	-0.71
1	Quasi Peak	92.04 MHz	42.34	L1	-7.65
1	Quasi Peak	96.16 MHz	53.84	L1	3.84
1	Quasi Peak	99.28 MHz	46.26	L1	-3.73
1	Quasi Peak	100.52 MHz	51.75	L1	1.75
1	Quasi Peak	101.84 MHz	48.13	L1	-1.86
1	Quasi Peak	102.72 MHz	52.96	L1	2.96
1	Quasi Peak	103.84 MHz	53.59	L1	3.59
1	Quasi Peak	105.88 MHz	50.47	L1	0.47
1	Quasi Peak	106.16 MHz	40.01	L1	-9.98
1	Quasi Peak	240.04 MHz	40.36	L1	-16.63
1	Quasi Peak	300.04 MHz	40.55	L1	-16.44
1	Quasi Peak	542.24 MHz	39.34	L1	-17.65
1	Quasi Peak	543.68 MHz	41.46	L1	-15.53
1	Quasi Peak	545.08 MHz	44.13	L1	-12.86
1	Quasi Peak	546.96 MHz	44.70	L1	-12.29
1	Quasi Peak	549.44 MHz	39.03	L1	-17.96

4) 30 MHz ÷ 1000 MHz range RF emissions, vertical polarization, operational

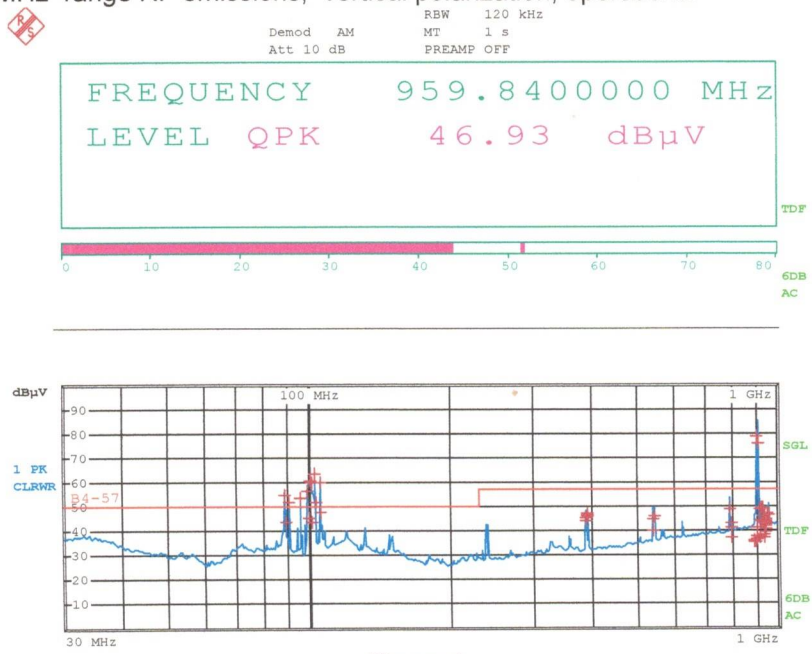

Figure 4

Clause	Requirement according to SR EN 60601-1-2:2016 + A1:2021	Results	Fulfilling the requirement

EDIT PEAK LIST (Final Measurement Results)

Trace1: B4-57
Trace2: ---
Trace3: ---

TRACE		FREQUENCY	LEVEL dBµV		DELTA LIMIT dB
1	Quasi Peak	89.04 MHz	54.90	L1	4.90
1	Quasi Peak	89.44 MHz	43.84	L1	-6.15
1	Quasi Peak	90.72 MHz	51.64	L1	1.64
1	Quasi Peak	96.12 MHz	53.23	L1	3.23
1	Quasi Peak	99.32 MHz	56.60	L1	6.60
1	Quasi Peak	100.24 MHz	45.49	L1	-4.50
1	Quasi Peak	100.64 MHz	60.56	L1	10.56
1	Quasi Peak	101.32 MHz	43.58	L1	-6.41
1	Quasi Peak	101.88 MHz	60.18	L1	10.18
1	Quasi Peak	102.84 MHz	63.37	L1	13.37
1	Quasi Peak	103.8 MHz	51.73	L1	1.73
1	Quasi Peak	105.8 MHz	60.20	L1	10.20
1	Quasi Peak	106.2 MHz	47.61	L1	-2.38
1	Quasi Peak	390.4 MHz	45.31	L1	-11.68
1	Quasi Peak	390.68 MHz	44.29	L1	-12.70
1	Quasi Peak	392.48 MHz	46.58	L1	-10.41
1	Quasi Peak	392.68 MHz	45.91	L1	-11.08
1	Quasi Peak	394 MHz	47.26	L1	-9.73
1	Quasi Peak	542.4 MHz	44.48	L1	-12.52
1	Quasi Peak	545.32 MHz	40.05	L1	-16.94

EDIT PEAK LIST (Final Measurement Results)

Trace1: B4-57
Trace2: ---
Trace3: ---

TRACE		FREQUENCY	LEVEL dBµV		DELTA LIMIT dB
1	Quasi Peak	548.76 MHz	45.78	L1	-11.21
1	Quasi Peak	792.32 MHz	48.83	L1	-8.16
1	Quasi Peak	795.04 MHz	43.02	L1	-13.98
1	Quasi Peak	796.28 MHz	41.13	L1	-15.86
1	Quasi Peak	798.04 MHz	37.34	L1	-19.65
1	Quasi Peak	894.4 MHz	35.57	L1	-21.42
1	Quasi Peak	895.68 MHz	35.62	L1	-21.37
1	Quasi Peak	896 MHz	35.70	L1	-21.30
1	Quasi Peak	896.6 MHz	35.66	L1	-21.33
1	Quasi Peak	897.2 MHz	35.63	L1	-21.37
1	Quasi Peak	897.56 MHz	35.66	L1	-21.33
1	Quasi Peak	907.4 MHz	36.38	L1	-20.61
1	Quasi Peak	907.56 MHz	37.78	L1	-19.21
1	Quasi Peak	907.72 MHz	41.33	L1	-15.67
1	Quasi Peak	910.32 MHz	78.83	L1	21.83
1	Quasi Peak	912.48 MHz	75.72	L1	18.72
1	Quasi Peak	914.84 MHz	37.29	L1	-19.70
1	Quasi Peak	914.92 MHz	44.08	L1	-12.91
1	Quasi Peak	915.08 MHz	48.81	L1	-8.18
1	Quasi Peak	926.44 MHz	49.48	L1	-7.51

Trace1: B4-57
Trace2: ---
Trace3: ---

TRACE		FREQUENCY	LEVEL dBµV		DELTA LIMIT dB
1	Quasi Peak	931.48 MHz	49.47	L1	-7.52
1	Quasi Peak	932 MHz	43.38	L1	-13.61
1	Quasi Peak	933.4 MHz	46.17	L1	-10.82
1	Quasi Peak	935.96 MHz	45.94	L1	-11.05
1	Quasi Peak	936.4 MHz	38.11	L1	-18.88
1	Quasi Peak	936.72 MHz	38.48	L1	-18.51
1	Quasi Peak	937.04 MHz	37.25	L1	-19.74
1	Quasi Peak	939.44 MHz	43.65	L1	-13.34
1	Quasi Peak	941.8 MHz	40.42	L1	-16.57
1	Quasi Peak	942.44 MHz	43.28	L1	-13.71
1	Quasi Peak	942.68 MHz	40.81	L1	-16.18
1	Quasi Peak	942.96 MHz	42.82	L1	-14.17
1	Quasi Peak	943.2 MHz	39.61	L1	-17.39
1	Quasi Peak	945.88 MHz	42.63	L1	-14.36
1	Quasi Peak	946.4 MHz	41.93	L1	-15.06
1	Quasi Peak	946.6 MHz	44.53	L1	-12.46
1	Quasi Peak	946.76 MHz	43.93	L1	-13.06
1	Quasi Peak	947 MHz	42.78	L1	-14.21
1	Quasi Peak	952.44 MHz	47.35	L1	-9.64
1	Quasi Peak	959.84 MHz	46.66	L1	-10.33

0 dB (µV/m) = 1 µV/m

The requirement is fulfilled

Annex 2 - Electrostatic discharge

Test according to the requirements of :

a) subclause 8.9 (table 4 – for equipment enclosure)
b) subclause 8.9 (table 7 – for patient connections)
c) subclause 8.9 (table 8 – for comunication connection with laptop, which also contains the power supply circuit)

Power supply according to subclause 4.3.3 from this TR.
Test method according to SR EN 61000-4-2:2009, clause 8.
Used apparatus according to Annex 7 to this TR

a) During application of electrostatic discharge through contact and air to the equipment enclosure, the equipment was normal operation.
b) During application of electrostatic discharge through contact and air to the equipment connectors for applied parts and on cables for connection to the patient (without simulation of the patient / artificial hand), the equipment was normal operation.
c) During application of electrostatic discharge through contact and air to the equipment USB connector for communication with the laptop and the power supply of the equipment , the equipment was normal operation

After the test, the operation of the equipment were checked.
Without errors.

The requirement is fulfilled

Clause	Requirement according to SR EN 60601-1-2:2016 + A1:2021	Results	Fulfilling the requirement

Annex 3 - Radiated RF electromagnetic fields

Test according to the requirements of subclause 8.9 (table 4) from this TR .
Power supply according to subclause 4.3.3 from this TR.
Test method according to SR EN 61000-4-3:2020, clause 8.
Used apparatus according to Annex 7 to this TR .

During application of the RF electromagnetic field with vertical and horizontal polarization, through a TEM open coplanare line, to the equipment, the equipment was normal operation.

After the test, the operation of the equipment were checked.
Without errors.

The requirement is fulfilled

Annex 4 - Proximity fields from RF wireless communications equipment

Test according to the requirements of subclause 8.9 (table 4) and subclause 8.10 (table 9) from this TR
Power supply according to subclause 4.3.3 from this TR.
Test method according to SR EN 61000-4-3:2006 + A1:2008 + A2:2011, clause 8.
Used apparatus according to Annex 7 to this TR

During application of the RF electromagnetic field with fixed test frequencies, through type λ / 2 antennas, to the equipment, the equipment was normal operation .

After the test, the operation of the equipment were checked.
Without errors.

The requirement is fulfilled

Annex 5 - Rated power frequency magnetic fields

Test according to the requirements of subclause 8.9 (table 4) from this TR .
Power supply according to subclause 4.3.3 from this TR.
Test method according to SR EN 61000-4-8:2010, clause 8.
Used apparatus according to Annex 7 to this TR

During application of the magnetic field at industrial frequency to the distribution head enclosure, the equipment was normal operation.

After the test, the operation of the equipment were checked.
Without errors.

The requirement is fulfilled

Annex 6 - Conducted disturbances induced by RF fields

Test according to the requirements of subclause 8.9 (table 7) from this TR .
Power supply according to subclause 4.3.3 from this TR.
Test method according to SR EN 61000-4-6:2014, clause 7.
Used apparatus according to Annex 7 to this TR

During application of conducted disturbances induced by RF fields , for each frequency range and its appropriate level, the equipment was normal operation.

After the test, the operation of the equipment were checked.
Without errors.

The requirement is fulfilled

Annex 7 - THE LIST OF USED MEASUREMENT AND TEST EQUIPMENTS

Nr. crt.	Denumire încercare	Aparatul de măsură /tip / serie sau inventar	Certificat de etalonare / emitent	Incertitudini
1	**Radiated RF emissions**	Test receiver (selective µV-meter for 9 kHz…3 GHz) type ESCI-3, serial 100611 Biconic logperiodical antenna HL-562 Rohde & Schwarz serial 100374	0001-3005589099/ 18.02.2021/ Rohde &Schwarz 4041.3000.02/29.03. 2019/ Rohde &Schwarz	Laborator: 9,4 dB
2	**Electrostatic discharges**	Electrostatic discharge generator Type DITO, serial CRO8423B	CR32293B / 04.2022	11,7 %
3	**Radiated RF EM fields**	Generator RF 250 kHz- 40 GHz, type G8257D, Serial MY45141301 RF amplifier 0,1 MHz … 1 GHz type 1W1000A, serial 21856 Amplifier RF 1 GHz - 18 GHz type ST181-50, serial S1772-1014 TEM open line with parallel plates type L-TEM-P, unique	- - - -	1,6 dB
4	**Proximity fields from RF wireless communications equipment**	Generator RF 250 kHz- 40 GHz, type G8257D, Serial MY45141301 RF amplifier 0,1 MHz … 1 GHz type 1W1000A, serial 21856 Amplifier RF 1 GHz - 18 GHz type ST181-50, serial S1772-1014 Antennes type λ/2 (table 9), uniques.	- - - -	2 %
5	**Rated power frequency magnetic fields**	Powermeter type Fluke 39, serial 6417029 Current clamp type Fluke 80i-110s, serial 6417029	1154/20.04.2021 / ARC BRAȘOV (LE 031)	9 %
6	**Conducted disturbances induced by RF fields**	Generator RF 9 kHz…1 GHz, type SML-01, serial 102763 RF amplifier 0,1 MHz…1 GHz type 1W1000A, serial 21856 Coupling/decoupling RF voltage network type CD –RF unique	03.05-131/24.08.2020 INM - BV 35 20.08.2020	3 dB
-	**Environment conditions**	Electronic hygrometer HTC-2 Serial M200545	CE 23885-11.22 / METROMAT (LE 008)	2 %

Note: Uncertainty is attributed to the expanded uncertainty obtained by multiplying the standard uncertainty with expansion factor k = 2 , and was estimated in accordance with SR ISO / IEC Guide 98-3: 2010. Measurand value is within the range designated with a probability of 95.45%
