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LABORATORUL DE ÎNCERCĂRI PENTRU CERTIFICAREA PRODUSELOR ELECTRICE

Testing Laboratory for Electrical Products Certification

accredited for
TESTING

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RAPORT DE ÎNCERCĂRI

TEST REPORT

No. 177 / 2023.03.20
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Exemplar no. 5 from 6

ÎNCERCAREA SOLICITATĂ Required Test	**Tests according to** **SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015** **SR EN 60601-2-10:2015 + A1:2017** **SR EN 60601-2-26:2015**
PRODUSUL Equipment	**UNIVERSAL ELECTROPHYSIOLOGICAL BIOFEEDBACK SYSTEM model 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**
DIRECTOR TEHNIC OICPE OICPE Technical Director	**Eng. Dragoş ROSMETENIUC**

ELECTRIC PRODUCTS CERTIFICATION INDEPENDENT BODY
ICPE
SOCIETATE cu RASPUNDERE LIMITATA

PRODUCT DATASHEET:
UNIVERSAL ELECTROPHYSIOLOGICAL BIOFEEDBACK SYSTEM model ED.X

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)
- Depression therapy, through neurofeedback (relaxation)

Serial	: 1EX230103 (ED.X module) CND137C22J (HP laptop, model 15-dw3043nq)
Product type	: sample
Product Receipt	: 2023.01.30
Tests period	: 2023.01.30 ÷ 2023.03.16
Sampling mode	: Unknown . The product was presented for tests by the client
Number of products tested	: one system

Responsible for tests	**eng. Victor POPESCU**	

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
4	**GENERAL REQUIREMENTS**		
4.1	**Conditions for application to ME equipment or ME systems**		
	Unless otherwise specified, the requirements of this standard shall apply in normal use and reasonably foreseeable misuse	Requirements of this standard are applied: - in normal use - in reasonably foreseeable misuse.	P
4.2 *Replace A1*	**Risk management process for ME equipment or ME systems**		
4.2.1 *Adding A1* *Modification A2*	**Introduction to risk management**		
	This risk management process is intended to serve the following purposes: a) To identify whether the normative requirements specified in Clauses 5 to 17 of this standard, together with the requirements of applicable collateral and particular standards, address all the hazards associated with the particular ME equipment or ME system under consideration b) To identify the way in which some particular tests specified in this standard should be applied to a particular ME equipment or ME system under consideration c) To identify whether particular hazards or hazardous situations for which this standard does not provide specific acceptance criteria result in any risks for a particular ME equipment or ME system and to establish acceptable risk levels and evaluate the residual risks d) To evaluate the acceptability of alternative risk control strategies by comparing residual risk with that achieved by applying the full requirements of this standard	The manufacturer have settled: - acceptable levels of risk; - risk management process; - acceptable residual risks	P
4.2.2 *Adding A1* *Modification A2*	**General requirement for RISK MANAGEMENT**		
	A risk management process complying with ISO 14971:2019 shall be performed, except: - the planning for and execution of production and post-production monitoring; - periodic reviews of the suitability of the risk management process	The manufacturer has established the management of risks in the document "Risk management report for Universal Electrophysiological Biofeedback Amplifier with Electrotherapy Function", code F-RD-002/2 of January 11, 2023	P
4.2.3 *Adding A1*	**Evaluating risk**		
4.2.3.1 *Adding A1*	**Hazards identified in the IEC 60601-series**		
	The requirements of this standard shall be applied when evaluating risk: a) Where this standard or its collateral or particular standards specify requirements addressing particular hazards or hazardous situations, that the residual risks have been reduced to acceptable levels b) Where this standard or its collateral or particular standards specify requirements addressing particular hazards or hazardous situations but do not provide specific acceptance criteria, the manufacturer shall provide the acceptance criteria defined in the risk management plan	The manufacturer has established the management of risks in the document "Risk management report for Universal Electrophysiological Biofeedback Amplifier with Electrotherapy Function", code F-RD-002/2 of January 11, 2023	P NA

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
	c) Where this standard or its collateral or particular standards identify particular hazards or hazardous situations that have to be investigated without providing specific technical requirements: - the manufacturer shall determine whether such hazards or hazardous situations exist for the particular ME equipment or ME system, - where such hazards or hazardous situations exist for the particular ME equipment or ME system, the manufacturer shall evaluate and (if necessary) control these risks following the risk management process specified in 4.2.2	The manufacturer has established the management of risks in the document "Risk management report for Universal Electrophysiological Biofeedback Amplifier with Electrotherapy Function", code F-RD-002/2 of January 11, 2023	P
4.2.3.2 *Adding A1*	**Hazards not identified in the IEC 60601-series**		
	For hazards or hazardous situations that are identified for the particular ME equipment or ME system, but are not specifically addressed in this standard or its collateral or particular standards, manufacturer shall address those hazards in the risk management process as specified in 4.2.2		NA
4.3 *Replace A1*	**Essential performance**		
	During risk analysis, the manufacturer shall identify the performance of the clinical function(s) of the ME equipment or ME system, other than that related to basic safety, that is necessary to achieve its intended use or that could affect the safety of the ME equipment or ME system The manufacturer shall then specify performance limits between fully functional and total loss of the identified performance in both normal condition and single fault condition, and shall then evaluate the risk beyond this limits If the resulting risk is unacceptable, then the identified performance constitutes an essential performance.	The manufacturer has established essential performance of the ED.X equipment in „User manual for ED.X MEDICAL DEVICE - Universal Electrophysiological Biofeedback System", No. 002.00-EN, January 2023	P
4.4	**Expected service life**		
	The manufacturer shall state the expected service life of the ME equipment or ME system	The manufacturer estimated service life of the "Universal Electrophysiological Biofeedback System" type ED.X at 10 years	P
4.5 *Replace A1*	**Alternative risk control measures or test methods for ME equipment or ME systems**		
	An alternative risk control measure or test method is acceptable, if the residual risk that results from applying the alternative risk control measure or test method remains acceptable and is comparable to the residual risk that results from applying the requirements of this standard		NA
4.6 *Replace A1*	**ME equipment or ME system parts that contact the patient**		
	The risk management process shall include an assessment of whether parts that can come into contact with the patient, are considered parties applied to patient and need to be subject to the requirements for applied parts (except that 7.2.10).	The equipment parts that come into contact with patients (parties applied to arms and legs) are considered part applied to the patient. See also 7.2.10 from this TR.	P
4.7	**Single fault condition for ME equipment**		
	ME equipment is considered single fault safe if: a) it employs a means for reducing a risk, or	The ED.X module is supplied at 5 V_{dc} (from the laptop USB port)	P

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
	b) in the single fault condition we have: - the initial fault will be detected during the expected service life of the ME equipment and before a second means for reducing a risk fails; or - the probability that the second means of reducing the risk will fail during the expected service life of the ME equipment is negligible	Maximum current at the USB port is 0.9 A (for USB 3.0 port) During the expected service life of the equipment, the probability that additional protection systems (power supply from the laptop and the internal circuits of the laptop) to malfunction is negligible.	P P
4.8	**Components of ME equipment**		
	The components used in ME equipment must: - the applicable safety requirements of a relevant standards ; or - where there is no relevant standards, the requirements of this standard have to be applied	The safety function components used are certified. See Table 5 from this TR. The other components used, but uncertified, have high ratings characteristics and are tested simultaneously with the product. See Table 5 from this TR.	P P
4.9	**Use of components with high-integrity characteristics in ME equipment**		
	A component with high-integrity characteristics shall be used when a fault in a particular component can generate an unacceptable risk.	No unacceptable risks can occur	NA
4.10	**Power supply**		
4.10.1	**Source of power for ME equipment**		
	ME equipment shall be suitable for connection to a supply mains, to a separate power supply or be powered by an internal electrical power source	Power supply: - for ED.X module from laptop USB port : 5 V_{dc} - for laptop: internal battery - for laptop (via adapter): mains AC single phase, U_{rated} = 230 V_{ac}, f = 50 Hz	P
4.10.2	**Supply mains for ME equipment and ME systems**		
	The mains supply voltage does not exceed: - 250 V for hand-held ME equipment		NA
	- 250 V (d.c. or single-phase a.c.) sau 500 V (polyphase a.c.) for ME equipment with $P_{rated} \leq 4$ kVA	During processing of the date (unconnected to the patient) the laptop may be powered on AC single phase (230 V_{ac}, 50 Hz), via adapter	P
	- 500 V all other ME equipment and ME systems		NA
4.11	**Power input**		
Modification A1	The input power of the ME equipment or ME system must be ust be within 110% P_{rated}	ME system supply condition: AC single phase (U_{rated} = 230 V_{ac}, f= 50 Hz) Measured (with charging the battery): max. 54 VA For ED.X module (U_{rated} = 5 V_{dc}) Measured: max. 495 mA Required : max. 500 mA ($I_{USB\ 3.0\ port}$ = max. 900 mA)	P
5	**GENERAL REQUIREMENTS FOR TESTING ME EQUIPMENT**		
5.1	**Type tests**		
	The tests described in this standard are type tests A test need not be performed if analysis shows that the condition being tested has been adequately evaluated by other tests or methods	Examinations and applicable tests were performed.	P P

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
Replace A1	The combination of simultaneous independent faults that could result in a hazardous situation shall be documented in the risk management file If tests is necessary, hey should be performed only for the worst case situations.		NA
5.2	**Number of samples**		
	Type tests are performed on a representative sample or multiple samples simultaneously	The tests were performed on a EM complete system (ED.X module, applied parts BF-type and laptop with the adapter).	P
5.3	**Ambient temperature, humidity, atmospheric pressure**		
	Tests must be performed în: - the environmental conditions for testing must be in the range declared by the manufacturer in the technical description, for normal usage	According to User Manual (temperature within 10 ° C to 40 °C) The ambient temperature during the tests was maximum 25 ° C	P
	- if not possible, then you have made the necessary corrections	The equipment was not subjected to disruptive environmental factors.	P
	- ME equipment is protected from disruptive external factors	The equipment was not subjected to disruptive environmental factors.	NA
5.4	**Other conditions**		
	The tests conditions must be :		
Replace A1	a) unless otherwise specified in this standard, the tests must be performed încercările under the least favourable working conditions	The tests were performed under conditions specified in this standard (SR EN 60601-1: 2007 as amended), taking into account the specifications of the manufacturer	P
	b) if provided with settings accessible to any persons other than service personnel, tests must be performed under the least favorable adjustment declared	Adjustments accessible only to operator from the laptop keyboard.	P
	c) if the test results are influenced by the inlet pressure and flow or chemical composition of a cooling liquid, the test is performed within the limits for these characteristics as prescribed in the technical description	Without liquid cooling circuits.	NA
	d) where cooling water is required, potable water is used	Without water cooling circuits.	NA
5.5	**Supply voltages, type of current, nature of supply, frequency**		
Replace A1	a) influence of deviations of the supply voltage from its rated value	The deviations of the supply voltage (207 V_{ac} ÷ 253 V_{ac}) not affect equipment operation (during processing of the date (unconnected to the patient)).	P
Modification A1	b) frequency of the mains supply	The deviations of the frequency : 49,5 Hz ÷ 50,5 Hz Required: 50 Hz ± 1%	P
Replace A1	c) EM equipment with multiple power supply, for both a.c. and d.c or for both external power and an internal electrical power source	General power supply of the ME system from AC mains (during processing of the date (unconnected to the patient)), and from internal d.c. supply of the laptop (during treatment (connected to the patient)).	P
	d) EM equipment connected to d.c. supply mains	General power supply of the ME system from AC mains (during processing of the date (unconnected to the patient)) General power supply of the ME system from internal d.c. supply of the laptop (during treatment (connected to the patient)).	NA P
	e) alternative accessories or components	Without alternative accessories or components	NA
	f) separate power supply	During processing of the date (unconnected to the patient) the laptop may be powered on AC single phase (230 V_{ac}, 50 Hz), via adapter	P

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
5.6	**Repairs and modifications**		
	If faults occur during the tests, repairs and necessary changes are made and all the relevant tests are performed again, under an agreement between the test laboratory and manufacturer	No need repairs or modifications.	NA
5.7	**Humidity preconditioning treatment**		
	Prior to the tests of 8.7.4 and 8.8.3, all ME equipment shall be subjected to a humidity preconditioning treatment, under the following conditions:	Prior to the tests of 8.7.4 and 8.8.3 was performed preconditioning of the ED.X module (IP40) under the following conditions:	
Replace A1	- prior conditioning treatment (without humidity): • temperature : T ..... T + 4 °C (T= humidity conditioning temperature) • duration : minim 4 h - during conditioning treatment (with humidity): • temperature: 20...30°C,maintained with ± 2°C • relative humidity: 93 % ± 3 % • duration: 48 h for IPX0 enclosures 168 h for other enclosures	Preconditioning without humidity: - temperature: 25 °C - duration: 4 h Conditioning with humidity: - temperature: 25 °C - relative humidity : 94 … 96 % - duration: 48 h	P P P P P NA
5.8	**Sequence of tests**		
	Unless stated otherwise, the tests are sequenced in such a way that the results of any test do not influence the results of a subsequent test It is recommended the sequence of the tests given in Annex B	According to Annex B of SR EN 60601-1: 2007 and Table 1 from this TR.	P
5.9	**Determination of applied parts and accessible parts**		
5.9.1	**Applied parts**		
	Applied parts are identified by inspection and by reference to the accompanying documents of the ME equipment. See also 4.6.	The ED.X module is provided with applied parts in contact with patients (parties applied to arms and legs). See figure 1 from this TR.	P
5.9.2	**Accessible parts**		
5.9.2.1	**Test finger**		
	In case of doubt, accessibility is determined by a test with the standard test finger. Except: EM equipment to be used on the floor having mass > 45 kg, which are not tilted	Is not required the test (after examination of the system).	NA NA
5.9.2.2	**Test hook**		
Modification A1	Apertures in the ME equipment shall be tested with test hook.	Conditions: The test hook (figure 7 from SR EN 60601-1:2007) Force: 20 N Duration : 10 s Applied to the joining area of the enclosure of the ED.X module. During the test no deterioration occurred.	P
5.9.2.3	**Actuating mechanisms**		
Replace A1	Conductive parts of actuating mechanisms of electrical controls that are accessible after the removal of actuating parts (buttons, levers, etc.) are regarded as accessible parts Conductive parts of actuating mechanisms are not considered accessible parts if removal of actuating parts requires the use of a tool Compliance is checked by tests according to 5.9.2.1 and 15.4.6.1		NA

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
6	**CLASSIFICATION OF ME EQUIPMENT AND ME SYSTEMS**		
6.1	**General**		
	ME equipment or their parts are classified according to 6.2 ... ..6.6	ME equipment (ED.X module). ME system (ED.X module with laptop). See 6.2 , 6.3 and 6.6 from this TR	P
6.2	**Protection against electric shock**		
	ME equipment energized from an external electrical power source shall be classified as class I or class II	Class II – ED.X module Class I - ME system (ED.X module with laptop and adapter).	P
	Other ME equipment shall be classified as internally powered	Internal power supply - ME system (ED.X module with laptop without adapter). ME equipment (ED.X module) is TFJS powered (5 V_{dc}) from the laptop USB port	P
6.3 *Modification A2*	**Protection against harmful ingress of water or particulate matter**		
	Enclosures shall be classified according to : - protection against harmful ingress of particulate matter - protection against harmful ingress of water	IP40 provided by enclosure of the ED.X module.	P
6.4	**Methods of sterilization**		
	ME equipment or its parts shall be classified according to the method(s) of sterilization: - by ethylene oxide gas - by irradiation (gamma ray , etc.) - by moist heat (autoclave) - by other methods validated by the manufacturer.	Without sterilization	NA
6.5	**Suitability for use in an oxygen rich environment**		
	ME equipment and ME systems intended for use in an oxygen rich environment shall be classified for such use (see 11.2.2)		NA
6.6	**Mode of operation**		
	ME equipment shall be classified for either continuous operation or non-continuous operation	Continuous operation during the cycle of the biofeedback treatment	P
7	**ME EQUIPMENT IDENTIFICATION, MARKING AND DOCUMENTS**		
7.1	**General**		
7.1.1	**Usability of the identification, marking and documents**		
Replace A1	See 12.2	See 12.2	P
7.1.2	**Legibility of markings**		
	The markings required by 7.2.....7.6 shall be clearly legible under the following conditions:		
Modification A2	- for warning statements, instructive statements, safety signs and drawings on the outside of ME equipment: from the intended position of the person performing the related function	Warnings are shown on the display of the laptop (during the run of the program) and on the ED.X module label	P
	- for fixed ME equipment : when the ME equipment is mounted in its position of normal use		NA
	- for transportable ME equipment and for stationary, not fixed, ME equipment : in normal use or after dislodging from a wall against which it has been positioned, or after turning from its position of normal use and, in the case of dismountable rack units, after their removal from the rack.	On the ED.X module label	P
	- for markings on the inside of ME equipment or ME equipment parts: when viewed from the intended position of the person performing the related function		NA
Replace A1	Compliance for clear legibility is checked by the tests.	See 7.1.3 from this TR.	P

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
7.1.3	**Durability of markings**		
	The markings required by 7.2…..7.6 shall be clearly legible under the following conditions:		
	The markings required by 7.2…7.6 shall be removable only with a tool or by appreciable force and sufficiently durable to remain clearly legible during the expected service life		
	Compliance:		
	a) After all the tests of this standard have been performed as specified in 5.8		
	- markings are tested to the requirements of 7.1.2; and	All markings remained legible	P
	- adhesive labels are not to have worked loose or become curled at the edges	Self-adhesive label has not been removed and has not been deteriorated.	P
Modification A1	b) For markings required by 7.2 and 7.4….7.6, additional test with washing agents, by rubbing with cloth moistened with: - distilled water for 15 s - ethanol for 15 s - isopropyl alcohol for 15 s	After tests, all markings remained legible and self-adhesive label has not been removed and has not been deteriorated	P
7.2	**Marking on the outside of ME equipment or ME equipment parts (see also Table C.1)**		
7.2.1	**Minimum requirements for marking on ME equipment and on interchangeable parts**		
	If the size of the ME equipment, an ME equipment part or an accessory, or the nature of its enclosure, does not allow affixation of all markings specified in 7.2.2 to 7.2.20 (inclusive), then at least the markings as indicated in 7.2.2, 7.2.5, 7.2.6 (except permanently installed me equipment), 7.2.10 and 7.2.13 (if applicable) shall be affixed and the remaining markings shall be recorded in full in the accompanying documents.	The label with the characteristics is on the enclosure of the ED.X module and the informations with functions of the terminals are in user manual	P
	Where no marking of the ME equipment is practicable, these markings may be affixed to the individual packaging		NA
Replace A1	Any material, component, accessory or ME equipment that is intended for a single use or its packaging shall be marked "Single Use Only", "Do Not Reuse" or with symbol ⊗		NA
7.2.2	**Identification**		
Replace A1	ME equipment shall be marked with: - the name or trademark and contact information of the manufacturer - a model or type reference	See figure 1 from this TR. QUANTUM MEDICAL ED.X	P P
	- a serial number or lot or other unique identifier - the date of manufacture or use by date, if applicable	1EX230103 2023	P P
Replace A1	Detachable components of the ME equipment shall be marked with (unless misidentification does not result in an unacceptable risk): - the name or trademark and contact information of the manufacturer - a model or type reference	The applied parts are only for this type of product. Color identification for each applied part.	NA
Modification A1	The identification of the software need not be on the outside of the ME equipment. The identification shall be available to designated persons (e.g. service personnel)	The software used is implemented on the laptop used with the ED.X module. The user manual specifies minimum recommended characteristics of the laptop for efficient use.	P

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
7.2.3	**Consult accompanying documents**		
Replace A2	When the manufacturer uses consulting the accompanying documents as a primary risk control measure for a specific risk and the usability engineering process determines that marking the ME equipment is required for the effectiveness of the risk control, the ME equipment shall be marked with the refer to instruction manual/booklet mandatory action symbol  Otherwise, symbol 🕮 may be used to advise the operator of the location of the instructions for use or to consult the accompanying documents.	The equipment is dedicated for use by qualified persons (medical personnel) who are warned with the symbol  about the risks of use. See also 7.2.5 from this TR.	P NA
7.2.4	**Accessories**		
Replace A1	Accessories shall be marked with: - the name or trademark and contact information of the manufacturer - a model or type reference - a serial number or lot or other unique identifier - the date of manufacture or use by date, if applicable Where no marking of the accessories is practicable, these markings may be affixed to the individual packaging	The BF-type applied parts are identified by colour (see user manual) Standardized USB cable (laptop – ED.X module)	P
7.2.5	**ME equipment intended to receive power from other equipment**		
Replace A1 Modification A2	If ME equipment is intended to receive its power from other electrical equipment in an ME system and compliance with the requirements of this standard is dependent on that other equipment, one of the following shall be provided:	The ED.X module is powered via the USB port of the laptop which form the system The laptop can be used powered by AC mains via adapter (during processing of the data (not connected to the patient)) or from internal source (from the laptop battery)	P
	- the name or trademark of the manufacturer of the other electrical equipment with a model or type reference of the specified other equipment adjacent to the relevant connection point	The user manual specifies minimum recommended characteristics of the laptop for efficient use. The USB port is standardized	NA
	- placing safety sign  adjacent to the relevant connection point and listing of the required details in the instructions for use	Marking on the label of the recommendation on mandatory reading of the instructions before use 	P
	- using a special connector style that is not commonly available on the market and listing of the required details in the instructions for use	Standardized connector for USB port	P
	See also 7.9.2.3, 8.2.1 and 16.3	See also 7.9.2.3, 8.2.1 and 16.3 from this TR.	P
7.2.6	**Connection to the supply mains**		
	ME equipment shall be marked with the following information:		
	- the rated supply voltage or rated voltage range	100 - 240 V_{ac} for adapter 19,5 V_{dc} for laptop (adapter output) 5 V_{dc} for ED.X module (USB port)	P P P
Modification A1	- nature of supply (number of phases, type of current) using the recommended symbols:		
	~ (alternating current)	~ (for the laptop adapter)	P
	3~ (three-phase alternating current)		NA
	3N~ (three-phase alternating current with neutral) ⎓ (direct current)	For the adapter output and input supply connector for laptop and ED.X module	NA P

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
	⎓ (both direct and alternating current)		NA
	- the rated supply frequency or rated frequency range	50 Hz - 60 Hz (for laptop adapter)	P
Modification A1	- for class II ME equipment should be used symbol ⧈		NA
	Except for permanently installed ME equipment, these markings shall appear on the outside of the part that contains the supply mains connection and preferably adjacent to the connection point		NA
Modification A1	For permanently installed ME equipment, the markings must placed on the inside or the outside of the ME equipment, preferably adjacent to the supply mains connection		NA
7.2.7	**Electrical input power from the supply mains**		
Replace A1	The rated input shall be given in: - amperes or volt-amperes, or - amperes, volt-amperes or watts (if the power factor exceeds 0,9)	ED.X: max. : maxim 0,5 A Adapter : P_{output} = max. 45 W (19,5 V_{dc}, 2,31 A)	P
7.2.8	**Output connectors**		
7.2.8.1	**Mains power output**		
	For multiple socket-outlets that are integral with ME equipment, see 16.9.2.1 b)		NA
7.2.8.2	**Other power sources**		
	With the exception of multiple socket-outlets or connectors intended only for specified equipment, equipment parts or accessories, the connectors shall be marked with the following information : - rated output voltage - rated current or power - output frequency		NA
7.2.9	**IP classification**		
	ME equipment must be marked with the degree of protection IP according to IEC 60529		NA
Replace A2	Except: ME equipment unclassified, or classified IP00, IPX0 or IP0X need not be marked as such	IP40 – the enclosures of the ED.X module IP20 – the laptop and adapter	P
7.2.10	**Applied parts**		
	Except: to parts that have been identified according to 4.6	See 4.6	P
Modification A1	The degree of protection against electric shock as classified in 6.2 must be marked with: For all applied parts:		
	- for type B - for type BF - for type CF	marking	P NA NA
	For defibrillation-proof applied parts - for parts type B - for parts type BF - for parts type CF		NA

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
	The relevant symbol shall be marked adjacent to or on the connector for the applied part, unless either there is no such connector or the connector is used for more than one applied part and the different applied parts have different classifications, in which case each applied part shall be marked	Symbol is marking on the ED.X module label (all applied parts are the same type - BF)	P
	For clear differentiation with symbol  , symbol  shall not be applied in such a way as to give the impression of being inscribed within a square		NA
Modification A2	If the protection against the effect of the discharge of a cardiac defibrillator is partly in the patient cable, safety sign  , shall be placed near the relevant outlet. The instructions for use shall explain that protection of the ME equipment against the effects of the discharge of a cardiac defibrillator is dependent upon the use of appropriate cables.		NA
7.2.11	**Mode of operation**		
	ME equipment intended for continuous operation need not be marked. ME equipment intended for non-continuous operation need marked with the maximum activation (on) time and the minimum deactivation (off) time	Continuous operation during the cycle of the biofeedback treatment Continuous operation during the cycle of the biofeedback treatment	P NA
7.2.12	**Fuses**		
	Where the fuse-holder is an accessible part, the type and full rating of the fuse (voltage, current, operating speed and breaking capacity) shall be marked adjacent to the fuse-holder		NA
7.2.13 *Modification A2*	**Physiological effects (safety signs and warning statements)**		
Modification A2	ME equipment producing physiological effects that are not obvious to the operator and can cause harm to the patient or operator shall bear a suitable safety sign, appear in a prominent location so that it will be clearly legible IN normal use after instalation. The instructions for use shall describe the nature of the hazard and the precautions for avoiding it or minimising the associated risk	The user manual specifies that the system can be operated only by licensed practicing physicians with the right to practice, or used in the hospitals.	NA
7.2.14	**High voltage terminal devices**		
Modification A1	High voltage terminal devices on the outside of ME equipment that are accessible without the use of a tool shall be marked with symbol 		NA
7.2.15	**Cooling conditions**		
	Requirements for cooling provisions for ME equipment shall be marked.	Without cooling.	NA
7.2.16	**Mechanical stability**		
	For requirements on ME equipment with a limited stability, see 9.4		NA
7.2.17	**Protective packaging**		
	If special handling measures have to be taken during transport or storage, the packaging shall be marked accordingly (see ISO 780).	For the laptop, the ED.X module, the applied parts and the USB-USB cable – in special bag	P

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
	The permissible environmental conditions for transport and storage shall be marked on the outside of the packaging (see 7.9.3.1 and ISO 15223).		
Modification A2	Where premature unpacking of ME equipment or its parts could result in an unacceptable risk, the packaging shall be marked with a suitable safety sign (see 7.5)		NA
Replace A1	The packaging of ME equipment or accessories supplied sterile shall be marked as sterile and indicate the method of sterilization (see ISO 15223-1)		NA
7.2.18	**External pressure source**		
Replace A1	Adjacent to each input connector, the ME equipment shall be marked with: - the rated maximum supply pressure from an external source, and - the rated flow rate if required to maintain basic safety or essential performance		NA
7.2.19	**Functional earth terminals**		
Modification A1	A functional earth terminal shall be marked with symbol ⏚		NA
7.2.20	**Removable protective means**		
	If an application that require the removal of a protective means to use a particular function, the protective means shall be marked to indicate the necessity for replacement when the relevant function is no longer needed. Except: No marking is required when an interlock is provided		NA
7.2.21	**Mass of mobile ME equipment**		
Adding A1	Mobile ME equipment shall be marked with its mass including its safe working load in kilograms, separate from maximum loads of drawers, containers, shelves		NA
7.3	**Marking on the inside of ME equipment or ME equipment parts**		
	Marking on the inside of ME equipment or ME equipment parts must comply with the requirements of C2, Annex C.		NA
7.3.1	**Heating elements or lampholders**		
	The maximum power loading of heating elements or lampholders designed for use with heating lamps shall be marked near the heater or in the heater itself For heating elements or lampholders designed for use with heating lamps that can be changed only by service personnel with the use of a tool, an identifying marking referring to information stated in the accompanying documents is sufficient		NA
7.3.2	**High voltage parts**		
Modification A1 *Modification A2*	The presence of high voltage parts shall be marked with symbol ϟ or ⚠ See also 7.5	The symbol ⚠ used on the laptop adapter.	P
7.3.3	**Batteries**		
	The type of battery and the mode of insertion (if applicable) shall be marked (see 15.4.3.2)	The laptop is provided with its own battery pack	P
	For batteries intended to be changed only by service personnel with the use of a tool, an identifying marking referring to information stated in the accompanying documents is sufficient	The ED.X module without batteries.	NA

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
Replace A2	Where lithium batteries or fuel cells are incorporated and where incorrect replacement would result in a hazardous situation, a warning indicating that replacement by inadequately trained personnel could result in a hazardous situation shall be given in addition to the identifying marking referring to information stated in the accompanying documents		NA
7.3.4	**Fuses, thermal cut-outs and over-current releases**		
Replace A1	Fuses and replaceable thermal cut-outs and over-current releases that are accessible only by the use of a tool shall be identified either by specification (voltage, current, operating speed, size, breaking capacity) adjacent to the component, or by a reference to information in the accompanying documents		NA
7.3.5	**Protective earth terminals**		
Modification A1	Protective earth terminals shall be marked with symbol ⏚, unless the protective earth terminal is in an appliance inlet	The symbol ⏚ is provided on the plug-connector on the adapter. The plug of the detachable power cord is provided with protective earth contacts.	P
	Markings that are on or adjacent to protective earth terminals shall not be affixed to parts that have to be removed to make the connection. They shall remain visible after the connection has been made		P NA
7.3.6	**Functional earth terminals**		
Modification A1	Functional earth terminals shall be marked with symbol ⏚		NA
7.3.7	**Supply terminals**		
Modification A1 *Modification A2*	Terminals for supply conductors shall be marked adjacent to the terminals	Detachable power cord (for adapter) for supply from AC mains. Special plug-connector for laptop at the output of the adapter Special connector USB for the ED.X module.	P
	If ME equipment is so small that the terminal markings cannot be affixed, they shall be included in the accompanying documents Terminals that are provided exclusively for the connection of the neutral supply conductor in permanently installed ME equipment shall be marked with the appropriate code from IEC 60445 (N) Marking for connection to a three-phase supply shall be according to IEC 60445 Markings that are on or adjacent to electrical connection points shall not be affixed to parts that have to be removed to make the connection. They shall remain visible after the connection has been made		NA NA NA P P
7.3.8	**Temperature of supply terminals**		
	If any point within a terminal box or wiring compartment intended for connection of the power supply conductors for permanently installed ME equipment (including such conductors themselves), attains a temperature of more than 75 °C during normal use and normal condition at the maximum ambient operating temperature as indicated in the technical description (see 7.9.3.1), the ME equipment shall be marked with the following or an equivalent statement:		NA

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
	"For supply connections, use wiring materials suitable for at least X °C." where "X" is greater than the maximum temperature measured in normal use and normal condition. This statement shall be located at or near the point where the supply connections are to be made and shall be clearly legible after the connections have been made		
7.4	**Marking of controls and instruments (see also Table C.3)**		
7.4.1	**Power switches**		
Modification A2	Switches used to control power to ME equipment, including mains switches, shall have their "ON" and "OFF" positions marked as follows :		
Modification A1	- with symbols | and ○; or	On the ED.X module 	P
	- indicated by an adjacent indicator light; or		NA
	- indicated by other unambiguous means	On the ED.X module display. See figure 5 from this TR.	P
	If a push button with bistable positions is used:		NA
Modification A1	- it shall be marked with symbol ⏀; and		
	- the status shall be indicated by an adjacent indicator light; or		
	- the status shall be indicated by other unambiguous means		
	If a push button with momentary on position is used:		NA
Modification A1	- it shall be marked with symbol ⊖; and		
	- the status shall be indicated by an adjacent indicator light; or		
	- the status shall be indicated by other unambiguous means		
	Switches used to control power to parts of ME equipment shall have their "ON" and "OFF" positions:		NA
	– marked with symbols as specified above; or		
	– with symbols ⊙ and ○; or		
	– indicated by an adjacent indicator light; or		
	– indicated by other unambiguous means		
7.4.2	**Control devices**		
Modification A1 *Modification A2*	Different positions of control devices and different positions of switches on ME equipment shall be indicated by figures, letters or other visual means	The visual signalisation for ON/OFF state on the displays (the laptop and ED.X module).	P
	If in normal use, the change of setting of a control could result in an unacceptable risk to the patient, such controls shall be provided with either: - an associated indicating device, e.g. instruments or scale, or - an indication of the direction in which the magnitude of the function changes. See also 15.4.6.2.	They can not be modified after setting the parameters of biofeedback cycle.	NA

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
7.4.3 *Replace A1*	**Units of measurement**		
Modification A1	Numeric indications of parameters on ME equipment shall be expressed in SI units Except : the base quantities listed in Table 1 may be expressed in the indicated units, which are outside the SI units system		P
7.5 *Modification A2*	**Safety signs**		
Modification A2	The markings used to convey a warning, prohibition or mandatory action that mitigates a risk that is not obvious to the operator shall be a safety sign selected from ISO 7010.	The optical signaling of the status on the laptop and the ED.X module displays	P
Adding A1 Modification A2	If a safety sign with an established meaning is appropriately used, the use of the general warning sign  is not required.		NA
Modification A2	Where a safety sign is not available to indicate a particular desired meaning, the meaning may be obtained by one of the following methods :		
	a) Constructing a safety sign according to ISO 3864-1:2002, Clause 7 (for the templates, see safety signs  ,  and )		NA
	b) Using the general warning sign () placed together with a supplementary symbol or text. The text associated with the general warning sign shall be an affirmative statement (i.e., a safety notice) describing the principal risk foreseen (e.g. “Causes burns”, “Risk of explosion”, etc.)	The symbol  is used for general warning.	P
	c) Using the general prohibition sign () placed together with a supplementary symbol or text. The text associated with the general prohibition sign shall be a statement (i.e. a safety notice) describing what is prohibited (e.g. “Do not open”, “Do not drop”, etc.)		NA
	d) Using the general mandatory action sign () placed together with a supplementary symbol or text. The text associated with the general mandatory action sign shall be a command (i.e. a safety notice) describing required action (e.g. “Wear protective gloves”, “Scrub before entering”, etc.).		NA
	If there is insufficient space to place the affirmative statement together with the safety sign on the ME equipment, it may be placed in the instructions for use		P
	Safety signs, including any supplementary symbol or text, shall be explained in the instructions for use (see 7.9.2)		
Adding A1 Modification A2	When supplementary text is placed together with safety signs, the supplementary text shall be in a language that is acceptable to the intended operator		NA

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
7.6	**Symbols**		
7.6.1	**Explanation of symbols**		
	The meanings of the symbols used for marking shall be explained in the instructions for use	The used symbols are explained in the user manual.	P
7.6.2	**Symbols from Annex D**		
	Symbols required by this standard shall conform to the requirements in the referenced IEC or ISO publication. Annex D provides the symbol graphic and description for these symbols.	The used symbols in accordance with Annex D of this standard.	P
7.6.3	**Symbols for controls and performance**		
Modification A1	Symbols used for controls and performance shall conform to the requirements of the IEC or ISO publication where the symbol is defined, when applicable. See also 7.2.13	The graphical symbols, special for this application, on the laptop display.	P
7.7	**Colours of the insulation of conductors**		
7.7.1	**Protective earth conductor**		
	A protective earth conductor shall be identified throughout its length by green and yellow coloured insulation	The protective earth conductor is provided in the detachable power cord of the adapter.	P
7.7.2	**Protective earth connections**		
	Any insulation on conductors inside ME equipment that form protective earth connections shall be identified by the colours green and yellow at least at the termination of the conductors.	The protective earth connections in the adapter (on the PCB).	P
7.7.3	**Green and yellow insulation**		
	Identification by green and yellow insulation shall be used only for the following conductors: - to connect to the earth circuit protection	Green and yellow insulation used only for conductors specified at: 7.7.1 (in the detachable power cord)	P
Modification A1	- as specified in 7.7.2		NA
	- for potential equalization - pentru functional earth		NA NA
7.7.4	**Neutral conductor**		
	Conductors in power supply cords intended to be connected to the neutral conductor of the supply system shall be coloured "light blue" as specified in IEC 60227-1 or in IEC 60245-1	The system is provided with detachable power cord for adapter. The plug of the power cord can be insert in any position in the outlet-socket.	NA
7.7.5	**Power supply cord conductors**		
	Colours of conductors in power supply cords shall be in accordance with IEC 60227-1 or with IEC 60245-1	Colors are: brown, light blue (for L and N), and green and yellow for PE.	P
7.8	**Indicator lights and controls**		
7.8.1 *Modification A2*	***Colours of indicator lights**		
	The colours of indicator lights shall comply with Table 2	Without indicator lights.	NA
Replace A2	Table 2 - Colours meanings of indicator lights and alarm indicator lights for ME equipment		
	Warning - on when : hazardous situation is to be avoided - indicator light : **red**, not flashing - alarm indicator light :- - accompanied by sound: - - operator requirement : avoidance of a hazardous situation which could cause death or serious injury		

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
	Caution - on when : hazardous situation is to be avoided - indicator light : **yellow**, not flashing - alarm indicator light :- - accompanied by sound: - - operator requirement : avoidance of a hazardous situation which could cause minor or moderate injury or equipment damage		
	Ready to use - on when : ME equipment is ready for use - indicator light : **green** - alarm indicator light : - - accompanied by sound: - - operator requirement : -		
	High priority alarm condition - on when : interruption of current workflow is needed - indicator light : - - alarm indicator light : **red**, flashing - accompanied by sound : typically - operator requirement : immediate action to prevent injury		
	Medium priority alarm condition - on when : re-planning of current workflow is needed - indicator light : - - alarm indicator light : **yellow**, flashing - accompanied by sound : typically - operator requirement : prompt action to prevent injury		
	Low priority alarm condition - on when : planning of future workflow is needed - indicator light : - - alarm indicator light : **yellow** or **cyan**, not flashing - accompanied by sound : optional - operator requirement : awareness for future action		
	Other - on when : situations other than that of red, yellow or green - indicator light : any colour other than red, yellow, cyan or green - alarm indicator light : - - accompanied by sound : - - operator requirement : -		
	Dot-matrix and other alphanumeric displays are not considered to be indicator lights	The system status informations provided on the displays	P
7.8.2	**Colours of controls**		
	The colour red shall be used only for a control by which a function is interrupted in case of emergency	Red color of the program icons for STOP.	P

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
7.9	**Accompanying documents**		
7.9.1	**General (see also Table C.4)**		
	ME equipment shall be accompanied by documents containing at least the instructions for use and a technical description. The accompanying documents shall be regarded as a part of the ME equipment The accompanying documents shall identify the ME equipment by including, as applicable, the following:	It is delivered together with - user manual (paper), - warranty statement - declaration of conformity - software (on the laptop)	P
Replace A1	- name or trade-name of the manufacturer and contact information	**QUANTUM MEDICAL S.R.L.** Str. Rândunelelor nr. 19, 440049, Satu Mare, Romania	P
	- a model or type reference (see 7.2.2)	ED.X	P
Replace A1	Accompanying documents may be provided electronically(CD or DVD). If the accompanying documents are provided electronically, the usability engineering process shall include consideration of which information also needs to be provided as hard copy or as markings on the ME equipment (see 12.2).	The User Manual can also be available in paper format on request	P
	The accompanying documents must specify the training and skills of the operator and any environment or location restrictions for using ME equipment		P
	The accompanying documents shall be written at a level consistent with the education, training and any special needs of the personel for whom they are intended		P
Replace A1	Compliance is checked by inspection of the accompanying documents, and, when provided electronically, as specified in IEC 60601-1-6		P
7.9.2	**Instructions for use (see also Table C.5)**		
7.9.2.1	**General**		
Replace A1	The instructions for use shall document: - the use of the ME equipment as intended by the manufacturer; - the frequently used functions; - any known contraindications to the use of the ME equipment - those parts of the ME equipment that shall not be serviced or maintained while in use with a patient	The user manual specifies how to use, the functions, contraindications and contain classification, marking and control, and optional meanings.	P
	Where the patient is an intended operator, the instructions for use shall indicate: - the patient is an intended operator - a warning against servicing and maintenance while the ME equipment is in use - which functions the patient can safely use and, where applicable, which functions the patient cannot safely use; - which maintenance the patient can perform		NA
	The instructions for use shall indicate: - name or trade-name and address of the manufacturer - a model or type reference	**QUANTUM MEDICAL S.R.L.** Str. Rândunelelor nr. 19, 440049, Satu Mare, Romania ED.X	P P

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
Modification A2	The instructions for use shall include all applicable classifications specified in Clause 6, all markings specified in 7.2, and the explanation of safety signs and symbols (marked on the ME equipment)		P
	The instructions for use shall be in a language that is acceptable to the intended operator.	Romanian and English	P
Adding A1	In some countries, more than one language is required	Romanian and English	P
7.9.2.2	**Warning and safety notices**		
	The instructions for use shall include all warning and safety notices	The user manual specifies the specific safety warnings and alerts.	P
	For class I ME equipment, the instructions for use shall include a warning statement to the effect: **WARNING** **To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.**	The user manual specified the location of the equipment near an electrical outlet easily accessible and provided with protective earth for supply of the adapter for the laptop.	P
	The instructions for use shall provide the operator or responsible organization with warnings regarding any significant risks of reciprocal interference posed by the presence of the ME equipment during specific investigations or treatments	The user manual specify restrictions for the patiens	P
	The instructions for use shall include information regarding potential electromagnetic or other interference between the ME equipment and other devices together with advice on ways to avoid or minimize such interference	The user manual specify the restrictions for the used environement	P
	If the ME equipment is provided with an integral multiple socket-outlet, the instructions for use shall provide a warning statement that connecting electrical equipment to the multiple socket-outlet effectively leads to creating an ME system and the result can be a reduced level of safety		NA
7.9.2.3	**ME equipment specified for connection to a separate power supply**		
	If ME equipment is intended for connection to a separate power supply, either the power supply shall be specified as part of the ME equipment or the combination shall be specified as an ME system. The instructions for use shall state this specification	During processing of data (unconnected to the patient) the system is powered on AC single phase (230 V, 50 Hz). During processing of data (unconnected to the patient) or the treatments and investigations (connected to the patient) the system is powered from internal power supply (battery) of the laptop. The ED.X module (ME equipment) is supplied with 5 V_{dc} (via USB port of the laptop).	P
7.9.2.4	**Electrical power source**		
	For mains-operated ME equipment with an additional power source not automatically maintained in a fully usable condition, the instructions for use shall include a warning statement referring to the necessity for periodic checking or replacement of such an additional power source If leakage from a battery would result in an unacceptable risk, the instructions for use shall include a warning to remove the battery if the ME equipment is not likely to be used for some time If an internal electrical power source is replaceable, the instructions for use shall state its specification		NA

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
	If loss of the power source would result in an unacceptablerisk, the instructions for use shall contain a warning that the ME equipment must be connected to an appropriate power source		
7.9.2.5	**ME equipment description**		
	The instructions for use shall include: - a brief description of the ME equipment - how the ME equipment functions - the significant physical and performance characteristics of the ME equipment	The user manual describes the equipment, how to use, the functions, the performance and physical characteristics, the patients group for which it is recommended and for which is contraindicated	P
	If applicable, this description shall include the expected positions of the operator, patient and other persons near the ME equipment in normal use (see 9.2.2.3)	The equipment is placed near the patient	P
	The instructions for use shall include information on the materials or ingredients to which the patient or operator is exposed if such exposure can constitute an unacceptable risk (see 11.7)		NA
	The instructions for use shall specify any restrictions on other equipment coupled, other than those forming part of the ME system		NA
	The instructions for use shall indicate any applied part	The user manual describe the applied parts, type and where will be placed on the patient.	P
7.9.2.6	**Installation**		
	If installation of the ME equipment or its parts is required, the instructions for use shall contain: - a reference to where the installation instructions are to be found (e.g. the technical description), or - contact information for persons designated by the manufacturer as qualified to perform the installation	The user manual specifies minimum recommended characteristics of the laptop for efficient use.	P
7.9.2.7	**Isolation from the supply mains**		
Modification A1	If an appliance coupler or mains plug or other separable plug is used as the isolation means, the instructions for use shall contain an instruction not to position the ME equipment so that it is difficult to operate the disconnection device.	The user manual specified the location near an soket-outlet easily accessible and provided with protective earth for supply of the adapter for the laptop (processing of data (unconnected to the patient). The ED.X module is provided with a switch on the back panel	P
7.9.2.8	**Start-up procedure**		
	The instructions for use shall contain the necessary information for the operator to bring the ME equipment into operation including such items as any initial control settings, connection to or positioning of the patient, etc The instructions for use shall detail any treatment or handling needed before the ME equipment, its parts, or accessories can be used	The user manual shows the sequence for starting and stopping of the system and how to select the biofeedback cycle.	P
7.9.2.9	**Operating instructions**		
	The instructions for use shall contain all information necessary to operate the ME equipment in accordance with its specification, include explanation of the functions of controls, displays and signals, the sequence of operation, and connection and disconnection of detachable parts and accessories, and replacement of material that is consumed during operation	The user manual shows how to use the system.	P

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
	The meanings of figures, symbols, warning statements, abbreviations and indicator lights on ME equipment shall be explained in the instructions for use	The user manual explains the used symbols, meaning of the images on the laptop display, the warning statements and the abbreviations.	P
7.9.2.10	**Messages**		
	The instructions for use shall list all system messages, error messages and fault messages that are generated, unless these messages are self-explanatory Also provided for each message explaining them, cause of condition that causes thereof and action is necessary to resolve the situation indicated in the message	The user manual explains the meaning of the images on the laptop display.	P
7.9.2.11	**Shutdown procedure**		
	The instructions for use shall contain the necessary information for the operator to safely terminate the operation of the ME equipment	The user manual shows the sequence for stopping of the system.	P
7.9.2.12	**Cleaning, disinfection and sterilization**		
	For ME equipment parts or accessories that can become contaminated through contact with the patient or with body fluids or expired gases during normal use, the instructions for use shall contain: - details about cleaning and disinfection or sterilization methods that may be used; and - list the applicable parameters such as temperature, pressure, humidity, time limits and number of cycles that such ME equipment parts or accessories can tolerate. See also 11.6.6 and 11.6.7 This requirement does not apply to any material, component, accessory or ME equipment that is marked as intended for a single use unless the manufacturer specifies that the material, component, accessory or ME equipment is to be cleaned, disinfected or sterilized before use (see 7.2.1).	User manual specify how to clean and to disinfect the ED.X module and its applied parts.	P
7.9.2.13	**Maintenance**		
	The instructions for use shall instruct the operator or responsible organization in sufficient detail concerning preventive inspection, maintenance and calibration to be performed by them, including the frequency of such maintenance The instructions for use shall provide information for the safe performance of such routine maintenance necessary to ensure the continued safe use of the ME equipment Additionally, the instructions for use shall identify the parts on which preventive inspection and maintenance shall be performed by service personnel, including the periods to be applied, but not necessarily including details about the actual performance of such maintenance For ME equipment containing rechargeable batteries that are intended to be maintained by anyone other than service personnel, the instructions for use shall contain instructions to ensure adequate maintenance	User manual specify how to check the system before use. The repairs are provided by the manufacturer.	P
7.9.2.14	**Accessories, supplementary equipment, used material**		
	The instructions for use shall include a list of accessories, detachable parts and materials that the manufacturer has determined are intended for use with the ME equipment	The user manual specify how to make interconnection of system components and of the applied parts to the ED.X module.	P

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
Modification A1	If ME equipment is intended to receive its power from other equipment in an ME system, the instructions for use shall sufficiently specify such other equipment to ensure compliance with the requirements of this standard (e.g. part number, rated voltage, maximum or minimum power, protection class, intermittent or continuous service)	The user manual specify how to connect the ED.X module to the laptop (with USB-USB cable)	P
7.9.2.15	**Environmental protection**		
Replace A1	The instructions for use shall provide advice on the proper disposal of waste products, residues, etc. and of the ME equipment and accessories at the end of their expected service life	The user manual specify how to protect the environment on residual waste (*Waste Electrical and Electronic Equipment* Directive - WEEE). The components meet the requirements of RoHS.	P
7.9.2.16	**Reference to the technical description**		
	The instructions for use shall contain the information specified in 7.9.3 or a reference to where the material is to be found (e.g. in a service manual)	See 7.9.3 from this TR.	P
7.9.2.17	**ME equipment emitting radiation**		
Adding A1	For ME equipment emitting radiation for medical purposes, when appropriate, the instructions for use shall indicate the nature, type, intensity and distribution of this radiation		NA
7.9.2.18	**ME equipment and accessories supplied sterile**		
Adding A1	The instructions for use for ME equipment or accessories supplied sterile shall indicate that they have been sterilized and indicate the method of sterilization The instructions for use shall indicate the necessary instructions in the event of damage to the sterile packaging, and where appropriate, details of the appropriate methods of resterilization (see also 7.9.2.12)		NA
7.9.2.19	**Unique version identifier**		
Adding A1	The instructions for use shall contain a unique version identifier such as its date of issue	Ref. 002.00-RO, Ianuarie 2023 Ref. 002.00-EN, January 2023	P
7.9.3	**Technical description (see also Table C.6)**		
7.9.3.1	**General**		
	The technical description shall provide all data that is essential for safe operation, transport and storage, and measures or conditions necessary for installing the ME equipment , and preparing it for use.	The equipment is accompanied by "User Manual" which presents the configuration and interconnection of the system parts, the operating mode, allowed operations and specific warnings.	P
	This shall include:		
	- the information required in 7.2		P
	- the permissible environmental conditions of use including conditions for transport and storage. See also 7.2.17		P
	- all characteristics of the ME equipment , including range(s), accuracy, and precision of the displayed values or an indication where they can be found		P
	- any special installation requirements such as the maximum permissible apparent impedance of supply mains		P
	- if liquid is used for cooling, the permissible range of values of inlet pressure and flow, and the chemical composition of the cooling liquid		NA
	- a description of the means of isolating the ME equipment from the supply mains, if such means is not incorporated in the ME equipment (see 8.11.1 b));		P
	- if applicable, a description of the means for checking the oil level in partially sealed oil-filled ME equipment or its parts (see 15.4.9)		NA

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
	- a warning statement that addresses the hazards that can result from unauthorized modification of the ME equipment , e.g. a statement to the effect: • " WARNING: No modification of this equipment is allowed." • " WARNING: Do not modify this equipment without authorization of the manufacturer." • " WARNING: If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment."		
Adding A1	- information pertaining to essential performance and any necessary recurrent essential performance and basic safety testing including details of the means, methods and recommended frequency		P
	if the technical description is separable from the instructions for use, it shall contain: - the information required in 7.2 - all applicable classifications specified in Clause 6, any warning and safety notices and the explanation of safety signs (marked on the ME equipment);	In the user manual.	NA
Replace A1	- a brief description of the ME equipment , how the ME equipment functions and its significant physical and performance characteristics; and - a unique version identifier such as its date of issue		
	The manufacturer may designate the minimum qualifications for service personnel. If present, these requirements shall be documented in the technical description.		
7.9.3.2	**Replacement of fuses, power supply cords and other parts**		
	The technical description shall contain, as applicable, the following: - for permanently installed ME equipment: the required type and full rating of fuses used in the external supply mains, if the type and rating of these fuses are not apparent from the information concerning rated current and mode of operation of ME equipment - for ME equipment having a non-detachable power supply cord: instructions for correct connection and anchoring if if replacement is not performed by service personnel - for interchangeable or removable components and parts of ME equipment: instructions for correct replacement of interchangeable or detachable parts that the manufacturer specifies as replaceable by service personnel -where replacement of a component could result in an unacceptable risk, appropriate warnings that identify the nature of the hazard and, if the manufacturer specifies the component as replaceable by service personnel, all information necessary to safely replace the component.	The repaires are provided by the manufacturer. Without components replaced by the user (fuses, power supply cords and other parts)	NA

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
7.9.3.3	**Circuit diagrams, component part lists, etc**		
	The technical description shall contain a statement that the manufacturer will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist service personnel to repair those parts of ME equipment that are designated by the manufacturer as repairable by service personnel.	The equipment is accompanied by "User Manual" which presents the configuration and interconnection of the system parts, and specific warnings. The repaires are provided by the manufacturer.	P NA
7.9.3.4	**Mains isolation**		
	The technical description shall clearly identify any means used to comply with the requirements of 8.11.1	Disconnect from the AC mains supply is ensured by the plug of the detachable power cord. The bipolar switch for the ED.X module	P
8	**PROTECTION AGAINST ELECTRICAL HAZARDS FROM ME EQUIPMENT**		
8.1	**Fundamental rule of protection against electric shock**		
	The limits specified in 8.4 shall not be exceeded for accessible parts and applied parts in normal condition or single fault condition For other hazardous situations in single fault condition, see 13.1 a) normal condition includes all of the following simultaneously: - the presence on any signal input/output part of any voltage or current from other electrical equipment that is permitted to be connected according to the accompanying documents as specified in 7.9. if the accompanying documents place no restrictions on such other electrical equipment, the presence of the maximum mains voltage as specified in 8.5.3. - transposition of supply connections, for ME equipment intended for connection to a supply mains by means of a mains plug - partial or total short circuit of any or all insulation that does not comply with the requirements of 8.8 - short circuit of any or all creepage distances or air clearances that do not comply with the requirements of 8.9 - open circuit of any or all earth connections that do not comply with the requirements of 8.6, including functional earth connections b) single fault condition includes: - short circuit of any one insulation that complies with the requirements for one means of protection as specified in 8.8 - short circuit of any one creepage distances or air clearances that complies with the requirements for one means of protection as specified in 8.9 - short circuit and open circuit of any component other than a component with high- integrity characteristics that is connected in parallel with insulation, with an air clearance or with a creepage distance unless shorting can be shown not to be a failure mode for the component (see also 4.8 and 4.9) - open circuit of any one protective earth conductor or internal protective earth connection that complies with the requirements of 8.6, except for the permanently installed ME equipment - interruption of any one supply conductor, except for the neutral conductor of polyphase ME equipment or permanently installed ME equipment.	The equipment provides protection against electrical hazards in normal use and single fault condition. See applicable tests from clause 8. See also 13.1 from this TR.	P

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
Replace A1	- interruption of any one power-carrying conductor between ME equipment parts in separate enclosures, if this condition might cause permitted limits to be exceeded - unintended movement of a component (see 8.10.1);		
	- accidental detachment of conductors and connectors where breaking free could lead to a hazardous situation. See also 8.10.2 Determination of which parts are accessible parts is performed in accordance with 5.9 Leakage currents are measured in accordance with 8.7		
8.2	**Requirements related to power sources**		
8.2.1	**Connection to a separate power source**		
	If ME equipment is specified for connection to a separate power source, other than the supply mains, either the separate power source shall be considered as part of the ME equipment or the combination shall be considered as an ME system.	The ED.X module is powered from the laptop (via USB 3.0 port).	P
8.2.2	**Connection to an external d.c. power source**		
Replace A1	If ME equipment is specified for power supplied from an external d.c. power source, then a connection with the wrong polarity shall not lead to the hazardous situations described in 13.1 The ME equipment, when connection is subsequently made with the correct polarity, shall maintain basic safety and essential performance. Protective devices that can be reset by anyone without the use of a tool are acceptable provided the ME equipment returns to normal condition on reset See also 11.8	The ED.X module is powered from the laptop (via USB 3.0 port). The USB connectors are standardized, with the guide	P NA NA
8.3	**Classification of applied parts**		
Modification A1	a) an applied part that is specified in the accompanying documents as suitable for direct cardiac application shall be a type CF applied part b) an applied part that includes a patient connection that is intended to deliver electrical energy or an electrophysiological signal to or from the patient shall be a type BF applied part or type CF applied part c) an applied part not covered by a) or b) shall be a type B applied part, type BF applied part or type CF applied part	Without applied parts CF-type Applied parts BF-type	NA P NA
8.4	**Limitation of voltage, current or energy**		
8.4.1	**Patient connections intended to deliver current**		
	The limits specified in 8.4.2 do not apply to currents that are intended to flow through the body of the patient to produce a physiological effect during normal use		NA
8.4.2 *Replace A1*	**Accessible parts and applied parts**		
	a) the currents from, to or between patient connections shall not exceed the limits for patient leakage current and patient auxiliary current specified in Table 3 and Table 4 when measured as specified in 8.7.4	See 8.7.4 from this TR	P
Replace A1	b) the leakage currents from, to or between accessible parts shall not exceed the limits for touch current specified in 8.7.3 c) when measured as specified in 8.7.4	See 8.7.4 from this TR	P

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
	c) the limits specified in b) above do not apply to the following parts if the probability of a connection to a patient, either directly or through the body of the operator, through which a current exceeding the allowable touch current could flow, is negligible in normal use, and the instructions for use instruct the operator not to touch the relevant part and the patient simultaneously: - accessible contacts of connectors - contacts of fuseholders that are accessible during replacement of the fuse - contacts of lampholders that are accessible after removal of the lamp - parts inside an access cover that can be opened without the use of a tool, or where a tool is needed but the instructions for use instruct any operator other than service personnel to open the relevant access cover For such parts, the voltage to earth or to other accessible parts shall not exceed 42,4 V peak a.c. or 60 V d.c. in normal condition or in single fault condition		P
Modification A1 *Modification A2*	The energy shall not exceed 240 VA for longer than 60 s or the stored energy available shall not exceed 20 J at a potential of 2 V or more.		P
Replace A1	Compliance is checked by inspection of the instructions for use and by measurement.		P
Adding A2	If the ME equipment has SIP/SOP connectors or separate power supply output connectors, measure the voltage of all conductive accessible parts of the SIP/SOP connectors or power output connectors to earth: – connect a resistor of 10 kΩ ± 500 Ω between the SIP/SOP-pin (or other output connector) to earth – connect in parallel to the 10 kΩ resistor a peak voltmeter or an oscilloscope to measure the voltage	Connectors without conductive accessible parts.	NA
	If the voltage measured above is less than or equal to 60 V d.c. or 42,4 V peak a.c., a subsequent leakage current test is not necessary.		NA
	If the voltage measurement above exceeds the specified levels, then the touch current from SIP/SOP connectors to earth and from any separate power supply output connectors to earth shall be measured.		NA
	Measure the touch current derived from the supply mains by applying the limits in 8.7.3 c) from the connectors described above in:		NA
	– normal condition including open functional earth conductor (if applicable); and		
	– single fault condition (respectively open neutral conductor; open protective earth conductor (if applicable)).		
	d) the voltage and energy limits specified in c) above also apply to: - internal parts, other than contacts of plugs, connectors and socket-outlets, that can be touched by the test pin inserted through an opening in an enclosure; and	The system enclosures are not provided with openings or holes for pre-settings.	NA

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
Replace A1	- internal parts that can be touched by a metal test rod with a diameter of $4^{+0}_{-0.05}$ mm and a length of $100^{+0.5}_{-0}$ mm, inserted through any opening in the top of an enclosure orthrough any opening provided for the adjustment of pre-set controls that can be adjusted by the responsible organization in normal use by using a tool		NA
	e) where an access cover that can be opened without the use of a tool gives access to parts that are at voltages above the levels permitted by this subclause, but these parts are automatically de-energized when the access cover is opened, components used to provide this protection must comply with 8.11.1 for mains isolating switches, and must remain effective in single fault condition		NA
8.4.3	**ME equipment intended to be connected to a power source by a plug**		
Modification A1	For the ME equipment or its parts intended to be connected to a power source by means of a plug shall be so designed that 1 s after disconnection of the plug the voltage between the pins of the plug and between either supply pin and the enclosure does not exceed 60 V. If this value is exceeded, the stored charge does not exceed 45 µC.	The ED.X module is powered from the laptop (via USB 3.0port).	NA
		During the treatments and investigations (connected to the patient) the system is powered from internal power supply (battery) of the laptop	NA
		During processing of data (unconnected to the patient) the system is powered on AC single phase (230 V, 50 Hz). $U_{residual}$ = 10,8 V_{ac} (after 1 s).	P
8.4.4	**Internal capacitive circuits**		
	Conductive parts of capacitive circuits that become accessible after ME equipment has been de-energized and access covers as present in normal use have been removed immediately thereafter, shall not have a residual voltage exceeding 60 V. If this value is exceeded, the stored charge does not exceed 45 µC If automatic discharging is not reasonably possible and access covers can be removed only with the aid of a tool, a device that is included and which permits manual discharging is acceptable		NA
Modification A1	The capacitor or the connected circuitry shall then be marked with symbol ↯ and the non-automatic discharging device shall be specified in the technical description.		
8.5	**Separation of parts**		
8.5.1	**Means of protection (MOP)**		
8.5.1.1	**General**		
	ME equipment shall have two means of protection to prevent applied parts and other accessible parts from exceeding the limits specified in 8.4	Provided with basic insulation and supplimentary insulation	P
Replace A2	Each means of protection shall be categorized in relation to the me equipment part(s) which it protects from exceeding permitted limits. It is a means of patient protection if it protects applied parts or parts that are identified according to 4.6 as needing to be subject to the same requirements as applied parts. Otherwise the requirements for either MOPP or MOOP shall be used as shown in figure 40.	One MOOP / two MOOP Two MOPP	P

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
Modification A1	Varnishing, enamelling, oxidation and similar protective finishes, as well as covering with sealing compounds that can replasticize at temperatures to be expected during operation (including sterilization), shall not be regarded as a means of protection	Without protective finishing (varnishing, enamelling, oxides, etc.) used as a means of protection.	P
	Components and wiring forming a means of protection shall comply with the relevant requirements of 8.10	See 8.10 from this TR.	P
	Any insulation, creepage distance, air clearances, component or earth connection that does not comply with the requirements of 8.5.1.2 and 8.5.1.3 shall not be considered as a means of protection. Failure of any or all such parts shall be regarded as normal condition		NA
Adding A1	Compliance is checked by the test in 8.5.1.3	See 8.5.1.3 from this TR.	P
Adding A2	Figure 40 – Identification of means of patient protection (MOPP) and means of operator protection (MOOP)		P
8.5.1.2 *Replace A1*	**Means of patient protection (MOPP)**		
	Solid insulation forming a means of patient protection shall comply with the dielectric strength test according to 8.8 at the test voltage specified in Table 6	See 8.8 from this TR.	P
Modification A2	Creepage distances and air clearances forming a means of patient protection shall comply with the limits specified in Table 12		P
	Protective earth connections forming a means of patient protection shall comply with the requirements and tests of 8.6	Without connection to the AC mains supply during the treatments and investigations	NA
Replace A1	A Y capacitor (Y1 or Y2) complying with IEC 60384-14 is considered equivalent to one means of patient protection. Where two capacitors are used in series, they shall be identical in type (either both Y1 or both Y2) and shall have the same nominal capacitance. The capacitor(s) shall meet the dielectric strength for the type of protection for which they are being used Where the working voltage across a barrier forming a means of patient protection is less than 42,4 V peak a.c. or 60Vd.c., a single Y1 capacitor is acceptable for two means of patient protection Compliance is checked by the test in 8.5.1.3		NA P
Adding A2	Opto-couplers complying with IEC 60747-5-5:2007, or a later edition, are considered equivalent to the requirements of 8.8.2 and 8.9.3. All of the following apply: – air clearance at the outside of the opto-coupler; – creepage distance at the outside of the opto-coupler; and – dielectric strength across the opto-coupler	Without connection to the AC mains supply during the treatments and investigations	NA
8.5.1.3	**Means of operator protection (MOOP)**		
	Solid insulation forming a means of operator protection shall be: - comply with the dielectric strength test according to 8.8 at the test voltage specified in Table 6; or	See 8.8 from this TR	P

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
Replace A2	- comply with the requirements of IEC 60950-1:2005, IEC 60950-1:2005/AMD1:2009 and IEC 60950-1:2005/AMD2:2013 for insulation co-ordination, or - comply with the requirements of IEC 62368-1:2018 for insulation co-ordination	The laptop adapter is marked The laptop is marked	P
	Creepage distances and air clearances forming a means of operator protection shall be: - comply with the limits specified in Table 13 to Table 16; or	See 8.9 from this TR	P
Replace A2	- comply with the requirements of IEC 60950-1:2005, IEC 60950-1:2005/AMD1:2009 and IEC 60950-1:2005/AMD2:2013 for insulation co-ordination, or - comply with the requirements of IEC 62368-1:2018 for insulation co-ordination	The laptop adapter is marked The laptop is marked	P
	Protective earth connections forming a means of operator protection shall be : - comply with the requirements of 8.6; or		NA
Replace A2	- comply with the requirements of IEC 60950-1:2005, IEC 60950-1:2005/AMD1:2009 and IEC 60950-1:2005/AMD2:2013 for protective earthing, or - comply with the requirements of IEC 62368-1:2018 for protective earthing	The laptop adapter is marked	P
Replace A1	A Y capacitor (Y1 or Y2) complying with IEC 60384-14 is considered equivalent to one means of operator protection. Where two capacitors are used in series, they shall be identical in type (either both Y1 or both Y2) and shall have the same nominal capacitance. The capacitor(s) shall meet the dielectric strength for the type of protection for which they are being used A single Y1 capacitor is acceptable for two means of operator protection	The laptop adapter is marked.	P
Adding A2	Opto-couplers complying with IEC 60747-5-5:2007, or a later edition, are considered equivalent to the requirements of 8.8.2 for distances through solid insulation and 8.9.3 for spaces filled by insulating compound. All of the following apply: – air clearance at the outside of the opto-coupler; – creepage distance at the outside of the opto-coupler; and – dielectric strength across the opto-coupler	The laptop adapter is marked (with opto-coupler)	P
Replace A1 Modification A2	Compliance is checked by examination of the physical and electrical configuration of the ME equipment to identify points that ensure that the accessible parts or applied parts from exceeding the limits specified in 8.4	Examination of the system.	P
	For each such point, it is determined: - whether solid insulation: • complies with the dielectric strength test according to 8.8 or		
Replace A2	- comply with the requirements of IEC 60950-1:2005, IEC 60950-1:2005/AMD1:2009 and IEC 60950-1:2005/AMD2:2013 or IEC 62368-1:2018 for insulation co-ordination (for a means of operator protection)		
	-whether creepage distances and air clearances are • as specified in 8.9, or		

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
Replace A2	- comply with the requirements of IEC 60950-1:2005, IEC 60950-1:2005/AMD1:2009 and IEC 60950-1:2005/AMD2:2013 or IEC 62368-1:2018 for insulation co-ordination (for a means of operator protection)		
	- if the components that are connected in parallel with an insulation, comply with 4.8 and 8.10.1 - if protective earth connections: • comply with the requirements of 8.6, or		
Replace A2	- comply with the requirements of IEC 60950-1:2005, IEC 60950-1:2005/AMD1:2009 and IEC 60950-1:2005/AMD2:2013 or IEC 62368-1:2018 for protective earthing (for a means of operator protection)		
Replace A1	The voltage, current or energy that can appear between any accessible part or applied part and any other accessible part, applied part or earth in normal condition and in single fault condition is determined by inspection or calculation or, where necessary, by measurement in the relevant conditions		
8.5.2	**Separation of patient connections**		
8.5.2.1	**F-type applied parts**		
	The patient connection of any F-type applied part shall be separated from all other parts, including the patient connection(s) of other applied parts, by means equivalent to one means of patient protection for a working voltage equal to the maximum mains voltage and shall comply with the specified limit for patient leakage current with 110 % of the maximum mains voltage applied A single F-type applied part may include multiple functions, in which case separation between such functions is not required If there is no electrical separation between patient connection(s) of the same or another function, then these patient connection(s) are treated as one applied part Whether multiple functions are to be considered as all within one applied part or as multiple applied parts is as defined by the manufacturer The classification as type BF, type CF or defibrillation-proof applies to the whole of one applied part	BF-type applied parts.	NA
	Compliance is checked by inspection, by the leakage current tests of 8.7.4, by the dielectric strength test of 8.8.3 and by measurement of relevant creepage distances and air clearances	See 8.7.4, 8.8.3 and 8.9 from this TR	P
8.5.2.2	**B-type applied parts**		
	The patient connection(s) of a type B applied part that is not protectively earthed shall be separated by one means of patient protection from metal accessible parts that are not protectively earthed, unless: - the metal accessible part is physically contiguous with the applied part and can be regarded as a part of the applied part; and - the risk that the metal accessible part will make contact with a source of voltage or leakage current above permitted limits is acceptably low	BF-type applied parts.	P NA NA

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
Adding A2	In this case, the test in 8.7.4.7 d) does not apply		NA
	Compliance is checked by inspection, by the leakage current tests of 8.7.4, by the dielectric strength test of 8.8.3, by measurement of relevant creepage distances and air clearances, and by reference to the risk management file	Examination of the system. Leakage currents measurement . Dielectric strength test. Creepage distances measurement Air clearances measurement. Examination of the "Risk management report for Universal Electrophysiological Biofeedback Amplifier with Electrotherapy Function", code F-RD-002/2 of January 11, 2023	P
8.5.2.3 *Replace A1*	**Patient leads or patient cables**		
Replace A1	Any connector for electrical connections on a patient lead that:	Without direct electrical connections on the patient.	NA
Replace A1 *Modification A2*	- is at the end of the lead or cable that is remote from the patient; and		
	- contains a conductive part that is not separated from any patient connection by one means of patient protection for a working voltage equal to the maximum mains voltage		
8.5.3	**Maximum mains voltage**		
	Maximum mains voltage:		
Modification A2	-for single-phase or d.c. supply mains powered ME equipment, including internally powered ME equipment that also has a means of connection to a supply mains, the maximum mains voltage is the highest rated supply voltage; unless this is less than 100 V, in which case the maximum mains voltage is 240 V	U_{rated} = 230 V_{ac} (according to SR EN 50160:2011) U_{maxim} = 110 % U_{rated} = 253 V_{ac} The laptop has a mixed power supply (internal from the battery during therapy use) and from the mains (U_{rated} = 230 V_{ac}) during data processing (not connected to the patient)	P
	-for polyphase ME equipment, the maximum mains voltage is the highest rated phase to neutral supply voltage		NA
Modification A2	-for other internally powered ME equipment, the maximum mains voltage is 240 V	The laptop has a mixed power supply (internal from the battery during therapy use) and from the mains (U_{rated} = 230 V_{ac}) during data processing (not connected to the patient)	P
8.5.4	**Working voltage**		
	The working voltage for each means of protection shall be determined as follows :		
Adding A2	-for working voltage measurement, all circuits shall be connected to earth with the exception of floating parts providing at least one means of protection to earth in which case the highest measured voltage on either side of the barrier is the working voltage		P
	- the highest measured value of the input supply voltage to the ME equipment; For d.c. voltages with superimposed ripple, the working voltage is the average value if the peak-to-peak ripple does not exceed 10 % of the average value or the peak voltage if the peak-to-peak ripple exceeds 10 % of the average value - for means of protection forming double insulation is the voltage to which the double insulation as a whole is subjected; - for a patient connection not connected to earth, the situation in which the patient is earthed (intentionally or accidentally) is regarded as a normal condition;	For the laptop adapter: U_{rated} = 230 V_{ac} U_{maxim} = 110 % U_n = 253 V_{ac} 19,5 V_{dc} – the laptop adapter output 5 V_{dc} –USB port The laptop adapter with fully insulated enclosure.	P P P P

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
	- between the patient connections of an F-type aplied part and the enclosure is taken as the highest voltage appearing across the insulation in normal use; - for defibrillation-proof applied parts, the working voltage is determined without the presence of defibrillation voltages; - for motors provided with capacitors where a resonance voltage can occur, shall be equal to the resonance voltage.		NA NA NA
8.5.5	**Defibrillation-proof applied parts**		
8.5.5.1 *Modification A1* *Modification A2*	**Defibrillation protection**	Without defibrillation-proof applied parts	NA
8.5.5.2 *Modification A1* *Modification A2*	**Energy reduction test**		
8.6	**Protective earthing, functional earthing and potential equalization of ME equipment**		
8.6.1	**Applicability of requirements**		
Modification A2	The requirements of 8.6.2 to 8.6.8 (inclusive) apply unless the parts concerned comply with the requirements and tests of IEC 60950-1:2005 and IEC 60950-1:2005/AMD1:2009 and IEC 60950-1:2005/AMD2:2013 or IEC 62368-1:2018 for protective earthing and serve as means of operator protection but not as means of patient protection	The laptop adapter is marked, class I.	NA
8.6.2	**Protective earth terminal**	See 8.6.1 from this TR.	NA
8.6.3	**Protective earthing of moving parts**		
8.6.4 *Modification A1* *Modification A2*	**Impedance and current-carrying capability**		
8.6.5	**Surface coatings**		
8.6.6	**Plugs and sockets**		
8.6.7 *Modification A1*	**Potential equalization conductor**		
8.6.8	**Functional earth terminal**		
8.6.9	**Class II ME equipment**		
	If class II ME equipment with isolated internal screens is supplied with a power supply cord having three conductors, the third conductor (connected to the protective earth contact of the mains plug) shall be used only as the functional earth connection to a functional earth terminal for these screens and shall be coloured green and yellow	The system is class I (if it is supplied from AC mains, through the adapter) only for processing of the data.	NA
		During the treatments and investigations (connected to the patient), or for processing of the data, the system is powered from internal power supply (the laptop battery)	
		The ED.X module it is supplied via the laptop USB port	
Adding A1	In such a case, the accompanying documents shall state that the third conductor in the power supply cord is only a functional earth		NA
Replace A1	The insulation between internal screens, including internal wiring connected to them and accessible parts, shall provide two means of protection		
8.7	**Leakage currents and patient auxiliary currents**		
8.7.1	**General requirements**		
	a) the electrical isolation providing protection against electric shock shall be of such quality that currents flowing through it are limited to the values specified in 8.7.3	Earth leakage currents are below the limit values specified in 8.7.3	P

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
	b) the specified values of the earth leakage current, the touch current, the patient leakage current and the patient auxiliary current apply in any combination of the following conditions: - at operating temperature and following the humidity preconditioning treatment, as described in 5.7	The test was performed before and after humidity conditioning (5.7)	P
Adding A1	- after any required sterilization **procedure** (see 11.6.7)		NA
	- in normal condition and in the single fault conditions specified in 8.7.2 - with ME equipment energized in stand-by condition and fully operating and with any switch in the mains part in any position - with the highest rated supply frequency	In the normal conditions and the single fault conditions. In stand-by condition and fully operating conditions. 50 Hz (according SR EN 50160:2011) for supply from the AC mains	P P P
	- with a supply equal to 110 % of the highest rated mains voltage	Supply voltage: 110 % U_{rated} =253 V~ for supply from the AC mains	P
8.7.2	**Single fault conditions**		
	The allowable values specified in 8.7.3 apply in the single fault conditions specified in 8.1 b) except that: - where insulation is used in conjunction with a protective earth connection, short circuit of the insulation applies only in the circumstances specified in 8.6.4 b) - the only single fault condition for the earth leakage current is the interruption of one supply conductor at a time - leakage currents and patient auxiliary current are not measured in the single fault condition of short circuiting of one constituent part of double insulation	 The interruption of one supply conductor at a time The system is powered from the laptop internal battery during the cycle of biofeedback.	NA P P
8.7.3	**Allowable values**		
	a) the allowable values specified in 8.7.3 b), c) and d) apply to currents measured with the network of Figure 12 a)	Leakage currents were measured with the network from figure 12 a) from SR EN 60601-1:2007	P
	b) the allowable values of the patient leakage currents and patient auxiliary currents are stated in Table 3 and Table 4	See Table 2 and Table 3 from this TR	P
	c) the allowable values of the touch current are: - in normal condition: 100 µA - in single fault condition: 500 µA	See Table 4 from this TR	P
	d) the allowable values of the earth leakage current are: - in normal condition: 5 mA - in single fault condition: 10 mA	Measured (for system): Max. 1,5 mA (before 5.7) Max. 1,8 mA (after 5.7) Max. 2,6 mA (before 5.7) Max. 3,4 mA (after 5.7)	P P
	Except : for permanently installed ME equipment connected to a supply circuit that supplies only this ME equipment, a higher value of earth leakage current is allowed	The system is provided with detachable power cord	NA
Replace A2	e) additionally, regardless of waveform and frequency, no leakage current shall exceed 10 $mA_{r.m.s.}$ in normal condition or in single fault condition when measured with a non-frequency-weighted device;		NA
Adding A1	f) the allowable values of leakage currents that can flow in a functional earth conductor in a non-permanently installed ME equipment are 5 mA in normal condition and 10 mA in single fault condition		NA

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
8.7.4	**Measurements**		
8.7.4.1	**General**		
Modification A1	The leakage current and patient auxiliary current test figures referenced in 8.7.4.5 to 8.7.4.8 (Figure 13 to Figure 19 inclusive):	Schemes used for measurement are: - for earth leakage current : figure 13 of this standard - for touch current: figure 14 of this standard - for the patient leakage current: figure 15 of this standard - for the patient leakage current for F –type applied part : figure 16 of this standard - for patient auxiliary current: figure 19 of this standard - for the total patient leakage current: figure 20 of this standard	P P P P P P
	a) the earth leakage current, the touch current, the patient leakage current and the patient auxiliary current are measured after the ME equipment has been brought up to operating temperature in accordance with the requirements of 11.1.3 c)	Measurement of the currents was performed after reaching thermal stability.	P
Modification A1	b) Where examination of the circuit arrangement and the arrangement of components and material of the ME equipment shows no possibility of any hazardous situation described in 13.1, the number of tests can be reduced	Without hazardous situations as specified in 13.1	P
8.7.4.2	**Measuring supply circuits**		
Replace A2	a) ME equipment specified for connection to a supply mains is connected to an appropriate power source For single-phase ME equipment, the polarity of the supply is reversible and tests are conducted at both polarities	The power supply circuit comply with figure F.1 of this standard (SR EN 60601-1:2007). Provided with the commutator switch (S5) for reverse the polarity of the mains supply for the system.	P P
	b) Internally powered ME equipment is tested without any connection to a measuring supply circuit.	For the system powerded from internal battery, without connection to a measuring supply circuit	P
8.7.4.3	**Connection to the measuring supply circuit**		
	a) ME equipment provided with a power supply cord is tested using this cord		NA
	b) ME equipment provided with an appliance inlet is tested while connected to the measuring supply circuit via a detachable power supply cord having a length of 3 m or a length and type specified in the instructions for use	Connection to the power supply circuit has been made with the supplied detachable power cord	P
	c) permanently installed ME equipment is tested while connected to the measuring supply circuit by the shortest possible connection		NA
	d) measuring arrangement: 1) applied parts and patient cables are placed on an insulating surface at 200 mm above an earthed metal surface	The applied parts placed at 205 mm from the protective earth plane.	P
	2) if an isolating transformer is not used for leakage current measurements, the reference earth of the measuring circuits is connected to protective earth of the supply mains	With isolating transformer.	NA
8.7.4.4	**Measuring device (MD)**		
	a) the measuring device loads the source of leakage current or patient auxiliary current with a resistive impedance of approximately 1000 Ω for frequencies up to and including 1 MHz	According to Fig.12 a) of this standard (SR EN 60601-1: 2007).	P
	b) measuring device according to Figure 12 a) allows for the direct measurement of the leakage current value		P
	c) the voltage measuring instrument as shown in Figure 12 a) has an input resistance of at least 1 MΩ and input capacitance of no more than 150 pF, with an indicating error not exceeding ± 5 % of the indicated value within frequencies up to and including 1 MHz		P

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
8.7.4.5 *Replace A1*	**Measurement of the earth leakage current and current in functional earth connection**		
Replace A1	a) class I ME equipment is tested according to Figure 13. Class II ME equipment with a functional earth connection according to 8.6.9 is tested as if it were Class I ME equipment	According to Fig. 13 of this standard (SR EN 60601-1: 2007) (for system powered from AC mains).	P
	b) for class I ME equipment has more than one protective earth conductor; c) For fixed ME equipment that can have connections to earth through the building structure		NA NA
8.7.4.6	**Measurement of the touch current**		
	a) ME equipment is tested according to Figure 14, using an appropriate measuring supply circuit: - measure with MD between earth and each part of the enclosure that is not protectively earthed;	The system enclosures are from insulating material. See Table 4 from this TR	P
	- measure with MD between parts of the enclosure that is not protectively earthed - measure with MD between parts of the enclosure that is normally protectively earthed and in the single fault condition of interruption of any one protective earth conductor	The system enclosures are from insulating material. See Table 4 from this TR The adapter with fully insulated enclosure	P NA
	- measure with MD between parts of the enclosure for internally powered ME equipment, not between the enclosure and earth unless 8.7.4.6 c) applies		NA
	b) for ME equipment has an enclosure or a part of the enclosure made of insulating material: - in normal condition - in single fault condition	The system enclosures from insulating material. See Table 4 from this TR	P
	c) for ME equipment with a signal input/output part - in normal condition - in single fault condition	The exchange of information within the system via USB cable, under internal power supply conditions.	NA
8.7.4.7	**Measurement of the patient leakage current**		
	a) ME equipment with an applied part is tested according to Figure 15	According to Fig. 15 of this standard (SR EN 60601-1: 2007) (for system powered from the internal battery).	P
	b) ME equipment with an F-type applied part is additionally tested according to Figure 16	According to Fig. 16 of this standard (SR EN 60601-1: 2007) (for system powered from the internal battery).	P
	c) ME equipment with an applied part and a signal input/output part is additionally tested according to Figure 17		NA
	d) ME equipment with a patient connection of a type B applied part that is not protectively earthed or a type BF applied part and with metal accessible parts that are not protectively earthed is additionally tested according to Figure 18		NA
Modification A2	This test need not be conducted if it can be demonstrated that there is adequate separation of the parts involved or if the risk is acceptably low according to 8.5.2.2		NA
	e) An applied part consisting of a surface made of insulating material is tested using metal foil as mentioned under 8.7.4.6		P
	f) where the patient connection is formed by a fluid which contacts the patient, the fluid is replaced by saline solution		NA
Replace A1	g) The patient leakage current is measured:		
	- for type B applied parts, from all patient connections connected directly together		NA
	- for type BF applied parts, from and to all patient connections of a single function either connected directly together or loaded as in normal use.		P

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
	- for type CF applied parts, from and to every patient connection in turn.		NA
Modification A1	If the instructions for use specifies alternatives for a detachable part of the applied part the patient leakage current measurements are made with the least favourable specified detachable part. (See also 7.9.2.14)		NA
	h) the total patient leakage current is measured from and to all patient connections of all applied parts of the same type connected together		P
	i) if the patient connections of the applied part are loaded in normal use, the measuring device is connected to each patient connection in turn.		P
8.7.4.8	**Measurement of the patient auxiliary current**		
	ME equipment with an applied part is tested according to Figure 19, using an appropriate measuring supply circuit unless the ME equipment has only a single patient connection	According to Fig. 19 of this standard (SR EN 60601-1: 2007) (for system powered from the internal battery).	P
8.7.4.9	**EM equipment with multiple patient connections**		
	EM equipment with multiple patient connections is investigated to ensure that the patient leakage current and the patient auxiliary current do not exceed the allowable values for normal condition while one or more patient connections are: - disconnected from the patient - disconnected from the patient and earthed	See Table 2 from this TR	P
8.8	**Isolation**		
8.8.1	**General**		
Replace A1 Modification A1	Only insulation that is relied upon as a means of protection, including reinforced insulation, shall be subject to testing		NA
	Except: insulation forming means of operator protection complies with the requirements and tests of IEC 60950-1:2005 and IEC 60950-1:2005/AMD1:2009 and IEC 60950-1:2005/AMD2:2013 or IEC 62368-1:2018 for insulation co-ordination	The laptop adapter is marked. (conformity with IEC 60950-1).	P
8.8.2	**Distance through solid insulation or use of thin sheet material**		
	Solid insulation for a peak working voltage greater than 71 V shall either : a) have a distance through insulation of at least 0.4 mm, or b) not form part of an enclosure and not be subject to handling or abrasion during normal use, and comprise: - at least two layers of material, each of which will pass the appropriate dielectric strength test; or - three layers of material, for which all combinations of two layers together will pass the appropriate dielectric strength test c) wire that has solid insulation, other than solvent based enamel, complying with a) above; d) wire that has multi-layer extruded or spirally wrapped insulation (where the layers can be individually tested for dielectric strength) complying with b) above and passes the tests of Annex L e) wire that has multi-layer extruded or spirally wrapped insulation (where only the finished wire can be tested) and passes the tests of Annex L.	Only for laptop adapter. See 8.8.1 from this TR.	NA

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
	The minimum number of constructional layers applied to the conductor shall be as follows: - for basic insulation: two wrapped layers or one extruded layer - for supplementary insulation: two layers, wrapped or extruded - for reinforced insulation: three layers, wrapped or extruded		
8.8.3	**Dielectric strength**		
Modification A1 *Modification A2*	Compliance is checked by applying the test voltage specified in Table 6 for 1 min, only insulation with a safety function need be subject to testing (see 8.8.1):		
	- immediately after the humidity preconditioning treatment	After the humidity preconditioning treatment (according to 5.7): a) was applied 1500 V_{rms}, 50 Hz for 1 min. between mains supply terminals shorted and earth protection terminal (one MOOP) No breakdowns and flashovers occurred.	P
		b) was applied 3000 V_{rms}, 50 Hz for 1 min. between mains supply terminals shorted and a metal foil over the adapter insulated enclosure (two MOOP) No breakdowns and flashovers occurred.	P
		c) was applied 3000 V_{rms}, 50 Hz for 1 min. between mains supply terminals shorted and a metal foil over the laptop keyboard (two MOOP) No breakdowns and flashovers occurred.	P
		d) was applied 3000 V_{rms}, 50 Hz for 1 min. between mains supply terminals shorted and a metal foil over the ED.X module enclosure (two MOOP) No breakdowns and flashovers occurred.	P
		e) was applied 3000 V_{rms}, 50 Hz for 1 min. between mains supply terminals shorted and a metal foil over the applied parts connected to the ED.X module (two MOOP) No breakdowns and flashovers occurred.	P
		f) was applied 4000 V_{rms}, 50 Hz for 1 min. between mains supply terminals shorted and a metal foil over the applied parts connected to the ED.X module (two MOPP) (used mode non-recommended by the manufacturer) No breakdowns and flashovers occurred.	P
		g) was applied 1000 V_{rms}, 50 Hz for 1 min. between the supply terminals shorted of the ED.X module and a metal foil over the applied parts connected to the ED.X module (two MOPP). No breakdowns and flashovers occurred.	P
	- after any required sterilization procedure		NA
	- after reaching a steady state operating temperature during the heating test of 11.1.1	After thermal stabilization (according 11.1.1):	
		a) was applied 1500 V_{rms}, 50 Hz for 1 min. between mains supply terminals shorted and earth protection terminal (one MOOP) No breakdowns and flashovers occurred.	P

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
		b) was applied 3000 V_{rms}, 50 Hz for 1 min. between mains supply terminals shorted and a metal foil over the adapter insulated enclosure (two MOOP) No breakdowns and flashovers occurred.	P
		c) was applied 3000 V_{rms}, 50 Hz for 1 min. between mains supply terminals shorted and a metal foil over the laptop keyboard (two MOOP) No breakdowns and flashovers occurred.	P
		d) was applied 3000 V_{rms}, 50 Hz for 1 min. between mains supply terminals shorted and a metal foil over the ED.X module enclosure (two MOOP) No breakdowns and flashovers occurred.	P
		e) was applied 3000 V_{rms}, 50 Hz for 1 min. between mains supply terminals shorted and a metal foil over the applied parts connected to the ED.X module (two MOOP) No breakdowns and flashovers occurred.	P
		f) was applied 4000 V_{rms}, 50 Hz for 1 min. between mains supply terminals shorted and a metal foil over the applied parts connected to the ED.X module (two MOPP) (used mode non-recommended by the manufacturer) No breakdowns and flashovers occurred.	P
		g) was applied 1000 V_{rms}, 50 Hz for 1 min. between the supply terminals shorted of the ED.X module and a metal foil over the applied parts connected to the ED.X module (two MOPP). No breakdowns and flashovers occurred.	P
8.8.4	**Insulation other than wire insulation**		
8.8.4.1	**Mechanical strength and resistance to heat**		
	The resistance to heat shall be retained by all types of insulation, including insulating partition walls, during the expected service life of the ME equipment	The ED.X module and the adapter enclosures is made from insulating material	P
Replace A1	Compliance is checked by inspection of the ME equipment and the design documentation, and, if necessary, inspection of the risk management file in conjunction with the following tests:		P
	- resistance to moisture (11.6) - dielectric strength (8.8.3) - mechanical strength (15.3)	See 11.6.5 and 11.6.6 from this TR See 8.8.3 from this TR See 15.3.2, 15.3.6 and 15.3.7 from this TR	P P P
8.8.4.2	**Resistance to environmental stress**		
	The insulating characteristics and mechanical strength of any means of protection shall be so designed or protected that it is not likely to be impaired by environmental stresses including deposition of dirt or by dust resulting from wear of parts within the ME equipment to such an extent that creepage distances and air clearances are reduced below the values specified in 8.9	The marked laptop adapter with bonded enclosure. Marked laptop. The ED.X module with degree of protection IP40. The ED.X module without parts that can produce dust by abrasion.	P
8.9	**Creepage distances and air clearances**		
8.9.1	**Values**		
8.9.1.1	**General**		
Replace A1	Creepage distances and air clearances of ME equipment shall be equal to or greater than the values of:		

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
	- for insulation between parts of opposite polarity of the mains part on the supply mains side of any mains fuse or over-current release, one means of operator protection in accordance with Table 13, Table 14 and Table 16; and - for insulation providing at least a means of protection, in accordance with Table 12 to Table 16, except as specified in 8.9.1.2 to 8.9.1.15. See also 8.9.2 to 8.9.4	See 8.9.1.2 for the laptop adapter. For secondary circuits of the ED.X module provided for ensuring the means of protection of: a)patient (MOPP) ➢ air clearances : Measured : 4.1 mm Required : min. 1.6 mm ➢ creepage distances : Measured : 7.9 mm Required : min. 3.4 mm b)operator (MOOP) ➢ air clearances : Measured : 4.9 mm Required : min. 1.4 mm ➢ creepage distances : Measured : 6.1 mm Required : min. 2.4 mm	P P
8.9.1.2 *Modification A2*	**Creepage distances and air clearances complying with IEC 60950-1 or IEC 62368-1**		
Replace A2	The values of Table 12 to Table 16 do not apply to creepage distances and air clearances forming means of operator protection that comply with the requirements of IEC 60950-1:2005, IEC 60950-1:2005/AMD1:2009 and IEC 60950-1:2005/AMD2:2013 or IEC 62368-1:2018	Marked laptop adapter (according to IEC 60950-1).	P
	Equipment/sub-assemblies/components complying with IEC 62368-1:2018 designed specifically for use with transient-free supply mains shall additionally comply with the applicable requirements of Table 13 to Table 16 (inclusive)		NA
8.9.1.3	**Creepage distances across glass, mica, ceramic and similar materials**		
	For creepage distances across glass, mica, ceramic and other inorganic insulating materials with similar tracking characteristics, the specified minimum value of air clearance shall be applied as the minimum creepage distance	Without support from inorganic material type glass, mica, ceramic or similar for electrical circuits.	NA
8.9.1.4	**Minimum creepage distance**		
Modification A1	If the minimum creepage distance derived from Table 12 to Table 16 is less than the applicable minimum air clearance, that value of minimum air clearance shall be applied as the minimum creepage distance		NA
8.9.1.5	**ME equipment rated for high altitudes**		
Modification A1 *Modification A2*	Where ME equipment is intended to be operated at high altitude (over 2000 m), the air clearance is then multiplied by the multiplication factor from Table 8.		NA
8.9.1.6	**Interpolation**		
Modification A1	For intermediate values of working voltages specified in Table 12 to Table 16 is allowed interpolation		NA
8.9.1.7	**Material groups classification**		
	Material groups are classified as shown in Table 9: - material group I, with 600 < CTI - material group II, with 400 < CTI < 600 - material group IIIa, with 175 < CTI < 400 - material group IIIb, with 100 < CTI < 175	PCB (printed circuit board).	NA NA P NA

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
8.9.1.8	**Pollution degree classification**		
	Pollution degree 1 is used to describe a micro-environment that is sealed so as to exclude dust and moisture		NA
	Pollution degree 2 is used to describe a micro-environment where only non-conductive pollution occurs except that occasionally a temporary conductivity caused by condensation is to be expected	Pollution degree 2 – with occasionally conductivity.	P
	Pollution degree 3 is used to describe a micro-environment that is subject to conductive pollution, or to dry non-conductive pollution that could become conductive due to expected condensation		NA
	Pollution degree 4 is used to describe a micro-environment where continuous conductivity occurs due to conductive dust, rain or other wet conditions		NA
Adding A1	Annex M specifies measures that may be used to reduce the pollution degree		NA
8.9.1.9	**Overvoltage category classification**		
	The applicable value of the mains transient voltage shall be determined from the overvoltage category according to IEC 60664-1 and the nominal a.c. mains voltage (see Table 10)	Mains supply with overvoltage category II for powered the system.	P
8.9.1.10	**Air clearance for mains parts**		
	For mains parts operating on rated mains voltages up to 300 V, the required air clearance shall be the value in Table 13 for the r.m.s. or d.c. rated mains voltage plus the additional air clearance in Table 14 for the peak working voltage	See 8.9.1.2 from this TR	P
8.9.1.11	**Supply mains overvoltage**		
	The values of overvoltage from the mains supply in function the main voltage and overvoltage category	AC mains supply overvoltage 2500 V~	P
8.9.1.12	**Secondary circuits**		
	A secondary circuit derived from a supply mains will normally be overvoltage category I according to IEC 60664-1 if the mains part is overvoltage category II; the maximum transients for various supply mains voltages in overvoltage category I are shown in the column headings of Table 15.	See exceptions.	NA
	Where the secondary circuit is earthed or the ME equipment is internally powered, Table 15 applies		
	Where a secondary circuit is not earthed and is derived from a supply mains, the circuit shall be subjected to the requirements for primary circuits in Table 13 and Table 14		
	If the secondary circuit is separated from the mains part by a functionally earthed or protectively earthed metal screen or transients in the secondary circuit are below the levels expected for overvoltage category I, (for example due to being attenuated by connecting a component, such as a capacitor, between the secondary circuit and earth), the values in Table 15 apply.		
	The column for circuits not subject to transient overvoltages applies to:		
Modification A2	– d.c. secondary circuits that are reliably connected to earth and have capacitive filtering which limits the peak-to-peak ripple to 10 % of the d.c. voltage;		NA
Modification A2	– circuits in internally powered ME equipment, or		P
Addition A2	- the means of protection required by 15.4.3.5 and 15.5.1.1	See 15.4.3.5 and 15.5.1.1 from this TR	P

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
8.9.1.13	**Peak working voltages above 1 400 V peak or d.c**		NA
8.9.1.14	**Minimum creepage distances for two means of operator protection**		
	Minimum creepage distances for two means of operator protection are obtained by doubling the values shown in Table 16 for one means of operator protection	Marked laptop adapter (according to IEC 60950-1)	P
8.9.1.15	**Creepage distances and air clearances for defibrillation-proof applied parts**		
Modification A1	Creepage distances and air clearances needed to satisfy 8.5.5.1 for defibrillation-proof applied parts shall not be less than 4 mm	Without defibrillation-proof applied parts	NA
8.9.1.16	**Conductive surface coatings**		
Adding A2	When conductive coatings are applied to non-metallic surfaces, it shall be established that flaking or peeling does not result in the reduction of any air clearance or creepage distance Compliance is checked by examination of the construction and of the available data. If such data is not available, compliance is checked by application of an appropriate coating test standard		NA
8.9.2	**Application**		
Modification A1	a) for insulation in the mains part between parts of opposite polarity, the minimum creepage distances and air clearances are not required if short circuiting of each single one of these creepage distances and air clearances in turn does not result in a hazardous situation described in 13.1	Marked laptop adapter (according to IEC 60950-1)	P
Modification A2	b) for the creepage distances in the space of the channels smaller than 1 mm are ignored		P
	c) design for air clearance which provides a means of protection should be taken to providing mechanical rigidity such that there is no reduction of the creepage distances and air clearances	The air clearance are not considered means of protection.	NA
8.9.3	**Spaces filled by insulating compound**		
8.9.3.1	**General**	Without spaces filled by insulating compound	NA
8.9.3.2	**Insulating compound forming solid insulation between conductive parts**		
8.9.3.3	**Insulating compound forming a cemented joint with other insulating parts**		
8.9.3.4	**Thermal cycling**		
8.9.4	**Measurement of creepage distances and air clearances**		
Replace A1 *Modification A2*	Compliance is checked by measurement taking into account the rules in Figure 22 to Figure 31		P
	The mobile parts shall be in their least favourable positions	Without mobile parts which may affect the insulation distances	NA
Modification A1	If creepage distances or air clearances for one or two means of protection are interrupted by one or more floating conductive parts, the minimum values specified in Table 12 to Table apply to the sum of the sections		NA
	Creepage distances or air clearances through slots or openings in external parts are measured after applied of the standard test finger with a 30 N force. For bare conductors, the force is 2 N.	Without slots or openings which may affect the insulation distances Without bare conductors	NA
8.10	**Components and wiring**		
8.10.1	**Fixing of components**		
	Components of ME equipment, the unwanted movement of which could result in an unacceptable risk, shall be mounted securely to prevent such movement	The components of the subassemblies of system are mounted on PCB (printed circuit board).	P

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
8.10.2	**Fixing of wiring**		
Modification A1	Conductors and connectors of ME equipment shall be so secured or insulated that accidental detachment shall not result in a hazardous situation described in 13.1	The components of the subassemblies of system are mounted on PCB (printed circuit board).	P
	Stranded conductors shall not be solder-coated if they are affixed by any clamping means and poor contact could result in a hazardous situation described in 13.1		NA
Replace A1	Compliance is checked by inspection of the ME equipment		P
8.10.3	**Connections between different parts of ME equipment**		
	Flexible cords detachable without the use of a tool that are used for interconnection of different parts of ME equipment shall be provided with means for connection such that compliance is not compromised when a connection is loosened or broken	Cables for interconnect between parts of the system. One enclosure for the ED.X module. The applied parts connected to the ED.X module by conductors provided with connectors.	NA
8.10.4	**Cord-connected hand-held parts and cord-connected foot-operated control devices**		
8.10.4.1	**Limitation of operating voltages**	Without cord-connected hand-held parts and cord-connected foot-operated control devices	NA
8.10.4.2 *Modification A1*	**Connection cords**		
8.10.5	**Mechanical protection of wiring**		
Modification A1	a) internal cables and wiring shall be adequately protected against contact with a moving part or from friction at sharp corners and edges where damage to insulation could result in a hazardous situation described in 13.1	The components of the subassemblies of system are mounted on PCB (printed circuit board).	P
Modification A1	b) ME equipment shall be so designed that wiring, cord forms or components are not likely to be damaged during assembly or the opening or closing of access covers where such damage could result in a hazardous situation described in 13.1	The components of the subassemblies of system are mounted on PCB (printed circuit board).	P
8.10.6	**Guiding rollers for insulated conductors**		
	Guiding rollers of insulated conductors of ME equipment shall be constructed in such a manner that movable insulated conductors in normal use are not bent round a radius of less than five times the outer diameter of the lead concerned	Without guiding rollers.	NA
8.10.7	**Insulation of internal wiring**		
	a) With insulating sleeving b) the sheath of a flexible cord shall not be used as a means of protection if it is subject to mechanical or thermal stresses outside its rated characteristics c) insulated conductors of ME equipment that in normal use are subject to temperatures exceeding 70 °C shall have insulation of heat-resistant material		NA NA NA
8.11	**Mains parts, components and layout**		
8.11.1	**Isolation from the supply mains**		
	a) ME equipment shall have means to isolate its circuits electrically from the supply mains on all poles simultaneously.	The plug of the detachable power cord (for the system)	P
	Permanently installed ME equipment connected to a polyphase supply mains may be provided with a device that does not interrupt the neutral conductor		NA
Adding A1	For permanently installed ME equipment, the means provided to isolate its circuits electrically from the supply mains shall be capable of being locked in the OFF position if:	Detachable power cord (for the system)	NA

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
	- reconnection would result in a hazardous situation; or - any operator including service personnel is unable to view the means of isolation from their intended position The locking mechanism may be in a supply mains switch provided by the responsible organization The requirements for the isolation device shall be specified in the accompanying documents		
	b) means for isolation either shall be incorporated in ME equipment or, if external, shall be described in the technical description	The plug of the detachable power cord (for system, without connection to patient)	P
	c) the supply mains switch that is used to comply with 8.11.1 a) shall comply with the creepage distances and air clearances as specified in IEC 61058-1 for a mains transient voltage of 4 kV	Without mains switch	NA
	d) a supply mains switch shall not be incorporated in a power supply cord or any other external, flexible lead	Without mains switch	NA
Replace A1	e) the actuator of a supply mains switch that is used to comply with 8.11.1 a) shall comply with IEC 60447	Without mains switch	NA
Replace A1	f) in non-permanently installed ME equipment that has no supply mains switch, a suitable plug device shall be considered as complying with the requirements of 8.11.1 a). An appliance coupler or a flexible cord with a mains plug may be used	See 8.11.1 a) from this TR	
	g) a fuse or a semiconductor device shall not be used as an isolating means		P
	h) ME equipment shall not include a device that causes disconnection of the ME equipment from the supply mains by producing a short circuit that results in operation of an overcurrent protection device		P
	i) for ME equipment with part of the enclosure having a circuit voltage exceeding 42,4 V peak a.c. or 60 V d.c. that cannot be disconnected from its supply shall be provided with supplementary protection and warning	The ED.X module powered at 5 V_{dc} The system, used with patient, is powered from the laptop battery.	NA
8.11.2	**Multiple socket-outlets**		
	Multiple socket-outlets that are integral with ME equipment shall comply with the requirements of 16.2 d) and 16.9.2.1.		NA
8.11.3	**Power supply cords**		
8.11.3.1	**Application**		
	The mains plug of ME equipment shall not be fitted with more than one power supply cord	The detachable power cord with one plug	P
8.11.3.2	**Types**		
	The power supply cord of ME equipment shall be not less robust than: - ordinary tough rubber- sheathed comply with IEC 60245 code 53 - ordinary polyvinyl chloride sheathed comply with IEC 60227 code 53 A polyvinyl chloride insulated power supply cord shall not be used for ME equipment having external metal parts with a temperature exceeding 75 °C and which can be touched in normal use.	The detachable power cord, 3 x 0,75 mm^2, PVC sheathed	NA P NA

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
8.11.3.3	**Cross-sectional area of power supply cord conductors**		
	The nominal cross-sectional area of conductors of power supply cord of ME equipment shall be: For I < 6 A: minim 0,75 mm² For 6 A< I < 10 A: min. 1,0 mm² For 10 A< I < 16 A: min. 1,5 mm² For 16 A< I < 25 A: min. 2,5 mm² For 25 A< I < 32 A: min. 4,0 mm² For 32 A< I < 40 A: min. 6,0 mm² For 40 A< I < 63 A: min. 10,0 mm²	The cross-sectional area of conductors: 0,75 mm² Conductors number : 3	P NA NA NA NA NA NA
Adding A2	For ME equipment utilizing power supply cords and operating at currents greater than 63 A, apply the electrical regulations appropriate for the jurisdiction in which the ME equipment is to be used		NA
8.11.3.4	**Appliance couplers**		
	Appliance couplers complying with IEC 60320-1 are considered to comply with 8.11.3.5 and 8.11.3.6	The system is provided with detachable power cord with 2 P + PE plug (with protective earth contacts).	P
8.11.3.5	**Cord anchorage**	The detachable power cord.	NA
8.11.3.6	**Cord guards**	The detachable power cord.	NA
8.11.4	**Mains terminal devices**		
8.11.4.1	**General requirements for mains terminal devices**		
	Permanently installed ME equipment and ME equipment having a non-detachable power supply cord that is replaceable by service personnel shall be provided with mains terminal devices that ensure reliable connection	The detachable power cord.	NA
	Terminals of components may be used as terminals intended for external conductors if they comply with the requirements of this subclause and are properly marked according to 7.3.7	The detachable power cord.	NA
	Screws and nuts that clamp external conductors shall not serve to fix any other component, except that they may also clamp internal conductors if these are so arranged that they are unlikely to be displaced when fitting the supply conductors	The detachable power cord.	NA
8.11.4.2	**Arrangement of mains terminal devices**		
	a) for ME equipment with rewirable cords, the terminals are provided for the connection of external cords shall be closely grouped, so as to provide a convenient means of connection.	The detachable power cord.	NA
	b) for details of protective earth conductor connections, see 8.6	See 8.6 from this TR	P
	c) for marking of mains terminal devices, see 7.3	See 7.3 from this TR	P
	d) mains terminal devices shall not be accessible without the use of a tool	The detachable power cord.	NA
	e) mains terminal devices shall be so located or shielded that, if a wire of a stranded conductor escapes when the conductors are fitted, short circuiting a means of protection is unlikely	The detachable power cord.	NA

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
8.11.4.3	**Fixing of mains terminals**		
	Terminals shall be fixed such that, when the means for clamping the conductors are tightened or loosened, the internal wiring is not subjected to stress and creepage distances and air clearances are not reduced below the values specified in 8.9	The detachable power cord.	NA
8.11.4.4	**Connections to mains terminals**		
	Terminals with clamping means for a rewirable flexible cord shall not require special preparation of the conductors in order to effect correct connection, and they shall be so designed or placed that the conductors are not damaged and cannot slip out when the clamping means are tightened. See also 8.10.2	The detachable power cord.	NA
8.11.4.5	**Accessibility of the connection**		
	EM equipment designed for fixed wiring or rewiring power cables must be provided with sufficient space to perform wiring and inspected. See also 8.10.5	The detachable power cord.	NA
8.11.5	**Mains fuses and over-current releases**		
	A fuse or over-current release shall be provided in each supply lead for class I ME equipment and for class II ME equipment having a functional earth connection according to 8.6.9, and in at least one supply lead for other single-phase class II ME equipment, except that:	Marked laptop adapter (according to IEC 60950-1)	P
	- for permanently installed me equipment, the neutral conductor shall not be fused		NA
Modification A1	- if examination shows that two means of protection are present between all parts of opposite polarity within the mains part, and between all parts of the mains part and earth, then the fuses or over-current releases may be omitted	Marked laptop adapter (according to IEC 60950-1) (provided with in-built fuse)	P
	The effect of short-circuit fault conditions in other circuits shall be verified before eliminating fuses or over-current releases		NA
	A protective earth conductor shall not incorporate a fuse or over-current release		P
Replace A2	Protective devices shall have adequate breaking capacity to interrupt the maximum fault current which can flow	Marked adapter (according to IEC 60950-1) (provided with in-built fuse)	P
Replace A1	Justification for omission of fuses or over-current releases shall be documented	Marked adapter (according to IEC 60950-1) (provided with in-built fuse)	P
Replace A1	Compliance is checked by inspection of the ME equipment and the manufacturer's documentation		P
8.11.6	**Internal wiring of the mains part**		
Replace A1	a) internal wiring in a mains part between the mains terminal device or the appliance inlet and the protective devices shall have a cross-sectional area not less than the minimum required for the power supply cord as specified in 8.11.3.3	Marked laptop adapter (according to IEC 60950-1) (on PCB).	P
	b) the cross-sectional area of other wiring in the mains part and the sizes of tracks on printed wiring circuits of ME equipment shall be sufficient to prevent fire in case of possible fault currents		

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
9	**Protection against mechanical hazards of ME equipment and ME systems**		
9.1	**Mechanical hazards of ME equipment**		
	For general requirements on design and manufacture of ME equipment, see Clause 4 and 15.3	The system comply with the applicable requirements specified at 4 and 15.3	P
	The protective measures against mechanical hazards as specified in subsections:		
	Crushing hazard: 9.2, 9.4 and 9.8	Without crushing hazard. See 9.2, 9.4 and 9.8	P
	Shearing hazard: 9.2 and 9.8	Without shearing hazard. See 9.2 and 9.8	P
	Cutting or severing hazard: 9.2, 9.3 and 9.8	Without cutting or severing hazard:. See 9.2, 9.3 and 9.8	P
	Entanglement hazard: 9.2	Without entanglement hazard. See 9.2	P
	Trapping hazard: 9.2	Without trapping hazard See 9.2	P
	Stabbing or puncturing hazard: 9.2, 9.3 and 9.8	Without stabbing or puncturing hazard See 9.2, 9.3 and 9.8	P
	Friction or abrasion hazard: 9.2 and 9.3	Without friction or abrasion hazard See 9.2 and 9.3	P
	Expelled parts hazard: 9.5	Without expelled parts hazard. See 9.5	P
	High pressure fluid ejection hazard: 9.7	Without high pressure fluid ejection hazard. See 9.7	P
	Falling hazard: 9.8	Without falling hazard. See 9.8	P
	Instability hazard: 9.4	Without instability hazard See 9.4	P
	Impact hazard: 9.2 and 9.8	Without impact hazard See 9.2 and 9.8	P
	Moving and positioning of patient hazard: 9.2 and 9.4	Without moving and positioning of patient hazard. See 9.2 and 9.4	P
	Vibration and noise hazard: 9.6	Without vibration and noise hazard. See 9.6	P
9.2 *Replace A1* *Modification A1* *Modification A2*	**Mechanical hazards associated with moving parts**	Without moving accessible parts. The fan is incorporated into the laptop.	NA
9.3 *Replace A1*	**Mechanical hazard associated with surfaces, corners and edges**		
Replace A1	Rough surfaces, sharp corners and edges of ME equipment that could cause injury or damage shall be avoided or covered Compliance is checked by inspection of the ME equipment	Without the rough surfaces, sharp corners and edges that could cause injury for the patient or operator.	P
9.4	**Instability hazards**		
9.4.1	**Generalităţi**		
Replace A1	ME equipment and its parts, other than fixed ME equipment, intended to be placed on a surface such as a floor or a table in normal use shall not overbalance (tip over) or move unexpectedly	The ED.X module and the laptop are placed on a table near the patient.	P
	Compliance is checked by the tests in 9.4.2 to 9.4.4, performed separately.	See 9.4.2 ....9.4.4 from this TR	P
9.4.2	**Instability - overbalance**		
9.4.2.1	**Instability in transport position**		
Modification A1	ME equipment or its parts shall not overbalance when placed in any transport position of normal use on a plane inclined at an angle of 10° from the horizontal plane	The transportation is performed in original packaging	P

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
9.4.2.2 *Replace A1*	**Instability excluding transport position**		
	ME equipment or its parts shall not overbalance when placed in any position of normal use, excluding any transport positions, on a plane inclined at an angle of 5° from the horizontal plane	The ED.X module and the laptop were placed on a plane inclined at an angle of 5 ° from the horizontal plane and has been turn 360 °. There were not overbalanced.	P
	If the ME equipment or its parts shall not overbalance when placed in any position of normal use, excluding any transport positions, on a plane inclined at an angle of 10° from the horizontal plane, then it has provided a warning	The ED.X module and the laptop they were placed on a plane inclined at an angle of 10 ° from the horizontal plane and has been turn 360 °. There were not overbalanced.	NA
9.4.2.3	**Instability from horizontal and vertical forces**		
Replace A1 Modification A2	a) ME equipment or its parts having a mass of 25 kg or more other than fixed ME equipment that is intended to be used on the floor shall be permanently marked with a clearly legible warning of this risk by use of safety sign (), or it shall not overbalance due to being pushed, leaned, rested upon		NA
	The marking shall be visible during normal use, but not on surfaces for which pushing is associated with normal use. F = 15 % of ME equipment weight, but not more than 150 N, applied on the lateral sides, at not exceeding 1,5 m from the floor.		
Modification A2	b) ME equipment or its parts other than fixed ME equipment that is intended to be used on the floor shall be permanently marked with a clearly legible warning of this risk by use (sing  or ) or it shall not overbalance due to being sat or stepped upon		NA
	F = 800 N, applied at the point of maximum moment to any working surface, excluding patient support surfaces, at not exceeding 1 m from the floor		
9.4.2.4 *Modification A1*	**Castors and wheels**	Without castors and wheels	NA
9.4.3	**Instability from unwanted lateral movement (including sliding)**		
9.4.3.1 *Modification A1*	**Instability in transport**	The transportation is performed in original packaging	P
9.4.3.2 *Replace A1 + Modification A1*	**Instability excluding transport position**	Transportable system.	NA
9.4.4	**Grips and other handling devices**	The subassemblies system mass < 20 kg.	NA
9.5	**Expelled parts hazard**		NA
9.6	**Acoustic energy (including infra- and ultrasound) and vibration**		
9.6.1	**General**		
	ME equipment shall be designed so that human exposure to acoustic energy and vibration shall not result in an unacceptable risk	Without generated vibrations. The audio output level of the laptop according to IEC 60950-1.	P
Replace A1	Compliance is checked by the tests in 9.6.2 and 9.6.3, and, if necessary, by inspection of the risk management file	See 9.6.2 and 9.6.3 from this TR	P

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
9.6.2	**Acoustic energy**		
9.6.2.1	**Audible acoustic energy**		
Modification A1	In normal use, the patient, operator and other persons shall not be exposed to acoustic energy from ME equipment , except sound from auditory alarm signals, exceeding the levels specified below	The audio output level of the laptop according to IEC 60950-1.	P
	80 dBA for a cumulative exposure of 24 h over a 24 h period		
Modification A1	140 dB un-weighted sound pressure level for impulsive or impact acoustic energy (noise).		
Adding A2	Acoustic energy directly associated with the intended use of the ME equipment or ME systems is excluded. See subclauses 1.1 and 7.2.13		P
9.6.2.2	**Infrasound and ultrasound energy**		
	When applicable, the manufacturer shall address the risks associated with infrasound or ultrasound in the risk management process		NA
9.6.3	**Hand-transmitted vibration**	Without generated vibrations	NA
9.7 *Modification A1* *Modification A2*	**Pressure vessels and parts subject to pneumatic and hydraulic pressure**		NA
9.8 *Replace A1* *Modification A1* *Modification A2*	**Hazards associated with support systems**		NA
10	**Protection against unwanted and excessive radiation hazards**		
10.1	**X-Radiation**	The system does not generate or use dangerous radiation (microwave, X-radiation, alpha, beta, gamma, neutron and other types of electromagnetic radiation (in the visible, infrared or ultraviolet)).	NA
10.1.1 *Modification A1* *Modification A2*	**ME equipment not intended to produce diagnostic or therapeutic X-radiation**		
10.1.2 *Replace A1*	**ME equipment intended to produce diagnostic or therapeutic X-radiation**		
10.2	**Alpha, beta, gamma, neutron and other particle radiation**		
10.3 *Replace A1* *Modification A2*	**Microwave radiation**		
10.4 *Replace A1*	**Lasers**		
10.5	**Other visible electromagnetic radiation**		
10.6 *Modification A2*	**Infrared radiation**		
10.7 *Modification A2*	**Ultraviolet radiation**		
11	**PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER HAZARDS**		
11.1	**Excessive temperatures in ME equipment**		
11.1.1	**Maximum temperature during normal use**		
	When ME equipment is operated in worst-case normal use including the maximum ambient operating temperature specified in the technical description (see 7.9.3.1):	$T_{environment}$ = 22 ^{0}C	
Modification A2	– ME equipment parts shall not reach temperatures exceeding the values given in Table 22 and Table 23;		P
	– the ME equipment shall not cause the surfaces of the test corner to exceed 90 °C; and		P

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
	– thermal cut-outs shall not operate in normal condition		NA
	Table 22 – Allowable maximum temperatures of parts		
	For insulating, including windings with	Marked laptop adapter.	P
	- class A material: 105 °C		NA
	- class E material: 120 °C		NA
	- class B material::130 °C		NA
	- class F material: 155 °C		NA
	- class H material: 180 °C		NA
	Parts with T marking : T °C		NA
	Other components and materials: according with the characteristics of each material	25 °C (supply connector)	P
	Parts in contact with flammable liquid with flash-point of t : t – 25 °C		NA
	Wood : 90 °C		NA
	Table 23 – Allowable maximum temperatures for ME equipment parts that are likely to be touched		
	Surfaces that are likely to be touched for a t < 1s		NA
	- of metal and liquids: 74 °C		
	- of glass, porcelain, vitreous material: 80 °C		
	- of moulded material, plastic, rubber, wood: 86 °C		
	Surfaces that are likely to be touched for a 1 s ≤ t < 10 s	Operator	
	- of metal and liquids: 56 °C		NA
	- of glass, porcelain, vitreous material: 66 °C	28,2 °C (laptop display)	P
		26,8 °C (ED.X module display)	P
	- of moulded material, plastic, rubber, wood: 71 °C	26,5 °C (laptop keyboard)	P
		26,8 °C (ED.X module enclosure)	P
		33.9 °C (laptop enclosure)	P
		max 38 °C (laptop adapter enclosure)	P
	Surfaces that are likely to be touched for a 10 s ≤ t < 1 min	Operator	
	- of metal and liquids: 51 °C		NA
	- of glass, porcelain, vitreous material: 56 °C	28,2 °C (laptop display)	P
		26,8 °C (ED.X module display)	P
	- of moulded material, plastic, rubber, wood: 60 °C	26,5 °C (laptop keyboard)	P
		26,8 °C (ED.X module enclosure)	P
		33.9 °C (laptop enclosure)	P
		max 38 °C (laptop adapter enclosure)	P
	Surfaces that are likely to be touched for a 1 min ≤ t	The temperature of the applied parts depends on the patient's body temperature. See 11.1.2.2 from this TR	NA
	- of metal and liquids: 48 °C		
	- of glass, porcelain, vitreous material: 48 °C		
	- of moulded material, plastic, rubber, wood: 48 °C		
11.1.2	**Temperature of applied parts**		
11.1.2.1	**Applied parts intended to supply heat to a patient**		
	The temperature (hot or cold surfaces) or the clinical effects shall be determined and documented in the risk management file	Without applied parts with hot or cold surfaces.	NA
11.1.2.2	**Applied parts not intended to supply heat to a patient**		
Replace A1	The limits of Table 24 shall apply in both normal condition and single fault condition.		

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
	Table 24 – Allowable maximum temperatures for skin contact with ME equipment applied parts		
	Applied part having contact with patient for a t<1 min - of metal and liquids: 51 ^{0}C - of glass, porcelain, vitreous material: 56 ^{0}C - of moulded material, plastic, rubber, wood: 60 ^{0}C		NA
	Applied part having contact with patient for a 1 min ≤ t < 10 min	The temperature of the applied parts depends on the patient's body temperature ($T_{patient}$ + $\Delta t_{applied\ part}$).	
	- of metal and liquids: 48 ^{0}C	Metallic applied parts, without patient contact: 24,2 ^{0}C (Δt = 2,2 K)	P
	- of glass, porcelain, vitreous material: 48 ^{0}C		NA
	- of moulded material, plastic, rubber, wood: 48 ^{0}C	Insulated applied parts, without patient contact: 24,0 ^{0}C (Δt = 2,0 K)	P
	Applied part having contact with patient for a 10 min ≤ t	The temperature of the applied parts depends on the patient's body temperature ($T_{patient}$ + $\Delta t_{applied\ part}$).	
	- of metal and liquids: 43 ^{0}C	Metallic applied parts, without patient contact: 24,2 ^{0}C (Δt = 2,2 K)	P
	- of glass, porcelain, vitreous material: 43 ^{0}C		NA
	- of moulded material, plastic, rubber, wood: 43 ^{0}C	Insulated applied parts, without patient contact: 24,0 ^{0}C (Δt = 2,0 K)	P
	If the surface temperature of an applied part exceeds 41 °C: – the maximum temperature shall be disclosed in the instructions for use; – the conditions for safe contact, e.g. duration or condition of the patient, shall be disclosed; and – the clinical effects with respect to characteristics such as body surface, maturity of patients, medications being taken or surface pressure shall be determined and documented in the risk management file		NA
	Where 41 °C is not exceeded, no justification is required	Without excessive temperatures	P
	If analyses documented in the risk management file demonstrate that applied part temperatures cannot be affected by operation of the ME equipment including in single fault conditions, measurement of applied part temperature according to 11.1.3 is not required		P
11.1.3	**Measurements**		
	Where engineering judgement by the manufacturer indicates that temperature limits cannot be exceeded, no measurement is required. This judgement shall be documented in the risk management file	The used components have the electrical and thermal characteristics higher the normal operating conditions, which causes a negligible risk.	P
Modification A2	For accessible parts that are likely to be touched and for applied parts, the probability of occurrence of contact and of the duration of contact is determined and documented in the risk management file		
11.1.4	**Guards**		
	Guards intended to prevent contact with hot or cold accessible surfaces of ME equipment shall be removable only with the aid of a tool	The system not provided with hot or cold parts.	NA

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
11.2	**Fire prevention**		
11.2.1	**Strength and rigidity required to prevent fire in ME equipment**		
	Enclosures shall have the strength and rigidity necessary to avoid a fire that could occur as a result of a total or partial collapse caused by reasonably foreseeable misuse.	Marked adapter. Marked laptop. The ED.X module powered at 5 V_{dc}, (P_{input} = max. 2,5 W)	NA
11.2.2	**ME equipment and ME systems used in conjunction with oxygen rich**		
11.2.2.1 *Modification A1*	**Risk of fire in an oxygen rich environment**	Not for use in oxygen rich environment.	NA
11.2.2.2	**External exhaust outlets for oxygen rich environment**		
11.2.2.3	**Electrical connections in oxygen rich environments**		
11.2.3	**Single fault conditions related to oxygen rich environments in conjunction with ME equipment and ME systems**		
11.3	**Constructional requirements for fire enclosures of ME equipment**		
Modification A2	This subclause provides an alternative means of compliance with selected hazardous situations and fault conditions as identified in 13.1.2	Without excessive temperatures in normal use and in single fault condition. See 13.1.2 from this TR	NA
11.4	**ME equipment and ME systems intended for use with flammable anaesthetics**		
	ME equipment,ME systems or their parts described in the accompanying documents for use with flammable anaesthetics (category AP) or flammable anaesthetics with oxidants (category APG) shall meet the applicable requirements of Annex G	The system does not use flammable anesthetics.	NA
11.5	**ME equipment and ME systems intended for use in conjunction with flammable agents**		
	The manufacturer's risk management process shall address the possibility of fire and associated mitigations	Without the use of agents that can cause fire outbreaks	NA
11.6	**Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME equipment**		
11.6.1	**General**		
	The construction of ME equipment and ME systems shall ensure a sufficient degree of protection against overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection and sterilization as well as compatibility with substances used with the ME equipment	Without components that can produce approaches, floods, leaks, seepage of water or particulate matter.	NA
11.6.2	**Overflow in ME equipment**		
Replace A1	If ME equipment incorporates a reservoir or liquid storage chamber that is liable to be overfilled or to overflow in normal use, liquid overflowing from the reservoir or chamber shall not wet any means of protection that is liable to be adversely affected by such a liquid, nor result in the loss of basic safety or essential performance.		NA
11.6.3 *Replace A1*	**Spillage on ME equipment and ME systems**		
Replace A1	ME equipment and ME systems requiring the handling of liquids in normal use, including ME equipment and ME systems used in an environment where the process has determined that spillage on the ME equipment is likely to occur, shall be so constructed that spillage does not wet parts that are likely to result in the loss of basic safety or essential performance.		NA
11.6.4	**Leakage**		
	See 13.2.6		NA

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
11.6.5	**Ingress of water or particulate matter into ME equipment and ME systems**		
	Enclosures of ME equipment and ME systems designed to give a specified degree of protection against harmful ingress of water or particulate matter shall provide this protection in accordance with the classification of IEC 60529 See 7.2.9	ED.X module : IP40 Laptop (marked) : IP20 Laptop adapter (marked) : IP20 (the system subassemblies are not protected against water ingress - second characteristic digit 0) Verification of protection against access to hazardous parts indicated by the first characteristic numeral 4 According to 12 from SR EN 60529: 1995 + A1: 2003 + A2: 2015 + AC: 2017 + AC: 2019, test wire with 1.0 mm diameter was applied with 1 N force in all openings of the ED.X module enclosure, after connecting all cables. The test wire did not touch live parts Verification of protection against solid foreign objects indicated by the first characteristic numeral 4 According to 12 from SR EN 60529: 1995 + A1: 2003 + A2: 2015 + AC: 2017 + AC: 2019, test wire with 1.0 mm diameter was applied with 1 N force in all openings of the ED.X module enclosure, after connecting all cables and power cord. The test wire did not penetrate.	
Modification A1 *Modification A2*	After these procedures, the ME equipment is to show no signs of bridging of insulation (or electrical components) that is likely to result in the loss of basic safety or essential performance in normal condition or in combination with a single fault condition (based on a visual inspection) followed by the appropriate dielectric strength and leakage current tests		P
11.6.6	**Cleaning and disinfection of ME equipment and ME systems**		
	ME equipment, ME systems and their parts, including applied parts and accessories, shall be capable of withstanding, without damage or deterioration of safety provisions, the cleaning or disinfection processes specified in the instructions for use. See also 7.9.2.12	The subassemblies enclosures of the system are made from insulating material which not damaged during the cleaning. Applied parts are made from rubber (for limbs) and synthetic leather with rubber parts (for head).	P
Replace A1	The manufacturer shall evaluate the effects of multiple cleanings/disinfections during the expected service life of the ME equipment, ME systems , their parts and accessories and assure that no unacceptable risk will occur.	Without negative effects on basic safety or essential performance	P
11.6.7	**Sterilization of ME equipment and ME systems**		
Modification A1	ME equipment, ME systems and their parts or accessories intended to be sterilized shall be assessed and documented according to ISO 11135-1, ISO 11137-1 or ISO 17665-1 as appropriate. See also 7.9.2.12		NA
11.6.8	**Compatibility with substances used with the ME equipment**		
Replace A1	When applicable, the manufacturer shall address in the risk management process the risks associated with compatibility with substances used with the ME equipment		NA
	Such risks may be addressed through the application of appropriate ISO or IEC standards (giving the presumption of acceptable risk or through the manufacturer's own testing and risk control measures.		

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
11.7	**Biocompatibility of ME equipment and ME systems**		
	ME equipment, ME systems and their parts or accessories intended to come into direct or indirect contact with biological tissues, cells or body fluids shall be assessed and documented according to the guidance and principles given in the ISO 10993 series of standards	According to B.1 of the Annex B, these tests are subject to another Test Report.	
11.8	**Interruption of the power supply / supply mains to ME equipment**		
Replace A1	ME equipment shall be so designed that an interruption and restoration of the power supply shall not result in the loss of basic safety or essential performance	The system (without connection to the patient) was subjected to 10 sequences of the power ON / power OFF with duty time 5 min. ON and 10 min. OFF. Not occurred any hazardous situation (the system has worked without interruption with powered by internal supply of the laptop). The ED.X module was subjected to 10 sequences of the power ON / power OFF with duty time 5 min. ON and 10 min. OFF. After the test, the ED.X module remained operational.	P
12	**ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS**		
12.1	**Accuracy of controls and instruments**		
	When applicable, the manufacturer shall address in the risk management process the risks associated with accuracy of controls and instruments	The system is provided with screen's (the laptop and ED.X module displays) With the software installed on the laptop was established the treatment cycle, the parameters, sequences and working mode. The data records for treatment , for each patient, was stored in the laptop (working database without connection to patient). Adjusting of the parameters of the treatment cycle can be continuously, and on the display of the laptop a high level of the output signal were appearing the warnings.	P
12.2 *Replace A1*	**Usability of ME equipment**		
Replace A1 *Modification A2*	The manufacturer shall address the risks of poor usability, including those associated with identification, marking and documents, through a usability engineering process complying with IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020. Compliance is checked as specified in IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020.	The data from the accompanying documents, the labeling and marking of the system subassemblies ensure its proper use. For command it is used the laptop keyboard and, if applicable, attached mouse. On the laptop display the data are provided in descriptive form and ergonomic design.	P
12.3 *Replace A1*	**Alarm systems**		
Replace A1 *Modification A2*	If the manufacturer has implemented an alarm system, this alarm system shall comply with IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 Compliance is checked as specified in IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020		NA

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
12.4	**Protection against hazardous output**		
12.4.1	**Intentional exceeding of safety limits**		
	When applicable, the manufacturer shall address in the risk management process the risks associated with hazardous output arising from the intentional exceeding of safety limits	Without hazardous electrical output.. The excesive level generated at output over the normal level is signaled with warnings about higher levels during the treatment.	P
12.4.2 *Replace A1*	**Indications relevant to safety**		
Replace A1	When applicable, the manufacturer shall address in the risk management process the need to indicate any hazardous output	The manufacturer has established the management of risks in the document "Risk management report for Universal Electrophysiological Biofeedback Amplifier with Electrotherapy Function", code F-RD-002/2 of January 11, 2023	P
12.4.3	**Accidental selection of excessive output values**		
	Where ME equipment is a multi-purpose unit designed for providing both low-intensity and high-intensity outputs for different treatments, the manufacturer shall address in the risk management process the risks associated with accidental selection of excessive output values	The system is provided with outputs whose levels can be set at a minimum level to normal and maximum levels. The excesive level generated at output over the normal level is signaled with warnings about higher levels during the treatment.	P
12.4.4	**Incorrect output**		
	When applicable, the manufacturer shall address in the risk management process the risks associated with incorrect output.	The ED.X module has provided with outputs marked by color, and the applied parts have connections with marking by same color for correct interconnection to the patient.	P
12.4.5	**Diagnostic or therapeutic radiation**		
12.4.5.1	**Limits**		
	For ME equipment designed to produce radiation for diagnostic or therapeutic purposes, adequate provisions shall be made to protect patients, operators, other persons and sensitive devices in the vicinity, from unwanted or excessive radiation emitted by the ME equipment	Without X-ray, radio wave (RF), other radiations or acustic pressure.	NA
12.4.5.2	**Diagnostic X-ray equipment**		
Replace A1	ME equipment and ME systems designed to produce X-radiation for diagnostic imaging purposes shall comply with IEC 60601-1-3 Compliance is checked as specified in IEC 60601-1-3		NA
12.4.5.3	**Radiotherapy equipment**		
	When applicable, the manufacturer shall address in the risk management process the risks associated with radiotherapy		NA
12.4.5.4	**Other ME equipment producing diagnostic or therapeutic radiation**		
	When applicable, the manufacturer shall address in the risk management process the risks associated with ME equipment producing diagnostic or therapeutic radiation other than for diagnostic X-rays and radiotherapy.	The system generate the sequence with frequencies up to 100 kHz according to type of selected treatment.	P
12.4.6	**Diagnostic or therapeutic acoustic pressure**		
	When applicable, the manufacturer shall address in the risk management process the risks associated with diagnostic or therapeutic acoustic pressure		NA

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
13 *Replace A1*	**HAZARDOUS SITUATIONS AND FAULT CONDITIONS FOR ME EQUIPMENT**		
13.1	**Specific hazardous situations**		
13.1.1	**General**		
	When applying the single fault conditions as described in 4.7 and listed in 13.2, one at a time, none of the hazardous situations in 13.1.2 to 13.1.4 (inclusive) shall occur in the ME equipment	See 13.1.2 to 13.1.4 from this TR	P
13.1.2	**Emisii, deformări ale carcasei sau depăşirea temperaturii maxime**		
	The following hazardous situations shall not occur: - emission of flames, molten metal, poisonous or ignitable substance in hazardous quantities - deformation of enclosures to such an extent that compliance with 15.3.1 is impaired - temperatures of applied parts exceeding the allowed values identified in Table 24 when measured as described in 11.1.3	 Without emission of flames, molten metal, poisonous or ignitable substance. The isolated materials for enclosures. Without deformations. Not exceded the allowed limits of temperatures for the applied parts.	 P P P
Replace A2	- temperatures of ME equipment parts that are not applied parts but are likely to be touched, exceeding the allowable values in Table 34 when measured and adjusted as described in 11.1.3 - temperatures of ME equipment parts that are not applied parts but are likely to be touched, exceeding the allowable values in Table 23 when measured and adjusted as described in 11.1.3	Not exceded the allowed limits of temperatures for accessible parts. Not exceded the allowed limits of temperatures for accessible parts.	P NA
	- exceeding the allowable values for "other components and materials" identified in Table 22 times 1,5 minus 12,5 °C. Limits for windings are found in Table 26, Table 27 and Table 31. In all other cases, the allowable values of Table 22 apply		NA
Adding A2	Tabelul 34 – Allowable accessible parts maximum temperatures for that are likely to be touched, but not intended to be touched to operate the ME equipment External surfaces of accessible parts that are likely to be touched for a time $t < 1$ s - metal or liquids : 80 °C - glass, porcelain, vitreous material : 90 °C - moulded material, plastic, rubber : 104 °C - wood : 150 °C	 max 40 °C (laptop adapter enclosure)	 NA NA P NA
	The single fault conditions in 4.7, 8.1 b), 8.7.2 and 13.2.2, with regard to the emission of flames, molten metal or ignitable substances, shall not be applied to parts and components where:		
Modification A1	- the supply circuit limits the power dissipation in single fault condition to less than 15 W or the energy dissipation to less than 900 J, or	The ED.X module is powered at 5 V_{dc}, maxim 0,5 A (max. 2,5 W on USB port)	P
Adding A1	- secondary circuits meet all of the following conditions:		
	• mounted on material with a flammability classification of FV1 or better (IEC 60695-11-10)	FV1 class PCB (impregnated glass fiber PCB)	P
	• they are energized at a voltage of 60 $V_{d.c.}$ or 42,2 V_{peak} or less in normal and single fault condition	Marked adapter with 19.5 V_{dc} output, for the laptop external supply. The maximum voltage for ED.X module : 5,5 V_{dc} (maximum allowable output voltage for USB ports)	P

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
	• they are limited to 100 VA or are limited to 6 000 J in single fault condition	The adapter with 45 W maximum output power.	P
	• they employ wire insulation of types PVC, TFE, PTFE, FEP, polychloroprene or polybromide,	Wire insulation : PVC	P
	or		
	- the component is a component with high-integrity characteristics as described in 4.9, or	Laptop and adapter marked	P
	- they are completely contained within a fire enclosure		NA
13.1.3	**Exceeding leakage current or voltage limits**		
	In single fault condition: - exceeding the limits for leakage current in single fault condition as indicated in 8.7.3 - exceeding the voltage limits for the accessible parts including applied parts indicated in 8.4.2	 See 8.7.3 from this TR See 8.4.2 from this TR	 P P
13.1.4	**Specific mechanical hazards**		
	For specific mechanical hazards, see 9.1 to 9.8	See 9.1…9.8 drom this TR. Without mechanical hazards.	P
13.2	**Single fault conditions**		
13.2.1	**General**		
	During the application of the single fault conditions listed in 13.2.2 to 13.2.13, the normal conditions shall also be applied in the least favourable combination	The single fault conditions was applied in the least favourable combination of used normal condition.	P
Adding A2	If resistance to heat for insulation of thermoplastic materials that is used as supplementary insulation or reinforced insulation is established by performing the ball-pressure test in 8.8.4.1, the test is performed at a temperature 25 °C higher than the temperature of the insulation measured during the tests of 13.2.2 to 13.2.13 (inclusive).		NA
13.2.2	**Electrical single fault conditions**		
	For the tests conditions see 8.1	See 8.1 from this TR.	P
13.2.3	**Overheating of transformers in ME equipment**		
	For the tests conditions see 15.5	See 15.5 from this TR	P
13.2.4	**Failure of thermostats**		
	For the tests conditions see 13.2.13 and 15.4.2	Without thermostats	NA
13.2.5	**Failure of temperature limiting devices**		
	For the tests conditions see 13.2.13 and 15.4.2	Without temperature limiting devices	NA
13.2.6	**Leakage of liquid**		
	The leakage of liquid from the liquid reservoirs of ME equipment shall be not an unacceptable risk	Without liquid reservoirs.	NA
13.2.7 *Replace A1*	**Impairment of cooling that could result in a hazardous situation**		
	ME equipment shall be so designed that it remains single fault safe during the failure of cooling systems to operate as intended	The CPU cooling system (fan) is protected by the laptop enclosure.	P
13.2.8	**Locking of moving parts**		
	ME equipment shall be so designed that it remains single fault safe when moving parts become jammed	The CPU cooling system (fan) is protected by the laptop enclosure.	P
13.2.9	**Interruption and short circuiting of motor capacitors**		
	ME equipment shall be so designed that it remains single fault safe during the short circuit and open circuit of motor capacitors	Without motor capacitor.	NA
13.2.10	**Additional test criteria for motor operated ME equipment**	Marked laptop.	NA

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
13.2.11	**Failures of components in ME equipment used in conjunction with oxygen rich environments**		NA
13.2.12	**Failure of parts that might result in a mechanical hazard**		
	For the tests conditions see 9 and 15.3	See 9 and 15.3 from this TR. Without mechanical hazards.	P
13.2.13	**Overload**		
13.2.13.1	**General overload test conditions**		
	After the tests of 13.2.13.2 to 13.2.13.4, the ME equipment, when cooled down to within 3 °C of the temperature in the test environment, shall remain safe	See 13.2.13.2 … 13.2.13.4 from this TR.	NA
13.2.13.2	**ME equipment with heating elements**	Without heating elements.	NA
13.2.13.3	**ME equipment with motors**	Without motor on the ED.X module.	NA
13.2.13.4	**ME equipment rated for non-continuous operation**	The system it provided for continuos duty cycle during the treatment.	NA
14	**PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)**		
14.1	**General**		
Replace A1	The requirements in 14.2 to 14.12 shall apply to PEMS unless:		
	- none of the programmable electronic subsystem (PESS) provides functionality necessary for basic safety or essential performance; or	The system laptop is provided with complex software that communicates with ED.X module for ensure the treatment parameters.	P
	- the application of risk management as described in 4.2 demonstrates that the failure of any PESS does not lead to an unacceptable risk	The failure of the laptop or the ED.X module interrupt the treatment sequences to be generated.	P
	The requirements in 14.13 are applicable to any PEMS intended to be incorporated into an IT-network whether or not the requirements in 14.2 to 14.12 apply	See 14.13 from this TR.	NA
14.2 *Modification A1*	**Documentation**	See 14.1 from this TR.	NA
14.3 *Modification A1*	**Risk management plan**		
14.4	**PEMS development life-cycle**		
14.5	**Problem resolution**		
14.6	**Risk management process**		
14.6.1 *Replace A1*	**Identification of known and foreseeable hazards**		
14.6.2 *Modification A1*	**Risk control**		
14.7	**Requirement specification**		
14.8 *Modification A1*	**Architecture**		
14.9 *Modification A1*	**Design and implementation**		
14.10	**Verification**		
14.11 *Modification A1*	**PEMS validation**		
14.12 *Modification A1*	**Modification**		
14.13 *Replace A1*	**PEMS intended to be incorporated into an IT-network**	During operating with the patient (applied parts of the ED.X module connected to the patient), the system it is not connected to the telecomunication/IT network. During data processing, the system may be connected to ETHERNET network. Marked laptop.	NA

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
15	**CONSTRUCTION OF ME EQUIPMENT**		
15.1	**Arrangements of controls and indicators of ME equipment**		
Replace A1 Modification A2	When applicable, the manufacturer shall address the risks associated with the arrangement of controls and indicators of ME equipment in the usability engineering process. See 12.2 Compliance is checked as specified in IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020	Not applicable. All icons on the laptop display are logical placed and windows appared with full informations needed for function or the selection list, without the possibility of occurrence of the risks	NA
15.2	**Serviceability**		
	Parts of ME equipment subject to mechanical wear, electrical and environmental degradation or ageing that could result in an unacceptable risk if allowed to continue unchecked for too long a period shall be accessible for inspection, replacement and maintenance	The ED.X module design and execution allowed access, inspection and easy replacement of components by specialized personnel.	P
15.3	**Mechanical strength**		
15.3.1	**General**		
Replace A1	ME equipment or its parts shall have adequate mechanical strength and shall not result in loss of basic safety or essential performance due to moulding stress or when subjected to mechanical stress caused by pushing, impact, dropping, and rough handling	Enclosures of the system with adecvated mechanical strength (marked laptop and adapter, and ED.X module enclosure)	P
	The applicable tests for ME equipment type:		
	Hand-held - push (15.3.2) - drop (15.3.4.1) - moulding stress relief (15.3.6)	The system is intended for placement on a table near to the patient.	NA
Adding A1	Body-work - push (15.3.2) - impact (15.3.3) - drop (15.3.4.1) - moulding stress relief (15.3.6)	The system is intended for placement on a table near to the patient.	NA
	Portable - push (15.3.2) - impact (15.3.3) - drop (15.3.4.1) - moulding stress relief (15.3.6)	The system is intended for placement on a table near to the patient.	NA
	Mobile - push (15.3.2) - impact (15.3.3) - rough handling (15.3.5) - moulding stress relief (15.3.6)	The system is intended for placement on a table near to the patient.	NA
	Fixed or stationary - push (15.3.2) - impact (15.3.3) - moulding stress relief (15.3.6)	The system is intended for placement on a table near to the patient (transportable). Marked laptop and adapter. See 15.3.2 See 15.3.3 See 15.3.6	 P P P
15.3.2	**Push test**		
Modification A1	External parts of an enclosure are subject to a steady force of 250 N ± 10 N, for a period of 5 s.	Was applied a force of 250 N for 5 s on the ED.X module enclosure. No deformation of the enclosure ocurred.	P
	Except: the bottom of an enclosure of ME equipment having a mass of more than 18 kg		NA

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
15.3.3	**Impact test**		
Modification A1	Except for hand-held me equipment and ME equipment parts that are hand-held, enclosures and other external insulating parts, the deterioration of which could result in unacceptable risk, are tested as indicated below.	M_{ball} : 510 g Height : 1,3 m	
	For testing the lateral sides a ball with mass of 500 g ± 25 g falls from a 1,3 m height (like a pendulum)	Impact no. : One for each lateral side of the ED.X module. No damage occurred likely to generate hazards.	P
	For testing the orizontal sides the ball a mass of 500 g ± 25 g fall freely from a 1,3 m height	Not applicable. The orizontal side of ED.X module it is the display.	NA
15.3.4	**Drop test**		
15.3.4.1 *Replace A1*	**Hand-held ME equipment**	See 15.3.1 from this TR.	NA
15.3.4.2 *Replace A1*	**Portable ME equipment**		
15.3.5 *Modification A1*	**Rough handling test**		
15.3.6	**Mould stress relief test**		
	Enclosures of moulded or formed thermoplastic materials shall be so constructed that any shrinkage or distortion of the material due to release of internal stresses caused by the moulding or forming operation does not result in an unacceptable risk	Marked laptop and adapter. The ED.X module was conditioned at 70 °C during 7 h. No deformation of the enclosure after conditioning ocurred. The system remained functional.	P
15.3.7	**Environmental influences**		
	The materials used in the construction of ME equipment shall take account of the intended use, the expected service life and the conditions for transport and storage	The system operates under medical environment. Environmental conditions for storage, transportation and use do not cause damage during estimated lifetime.	P
15.4	**ME equipment components and general assembly**		
15.4.1	**Construction of connectors**		
	Design and construction of electrical, hydraulic, pneumatic and gas connection terminals and connectors of ME equipment shall be such that incorrect connection of accessible connectors, removable without the use of a tool, shall be prevented where an unacceptable risk	Interconnection between electrical circuits of the subassemblies system is performed by guiding connectors (eg USB, jack).	P
Replace A1	a) plugs for connection of patient leads or patient cables shall be so designed that they cannot be connected to outlets on the same ME equipment intended for other functions, unless it can be proven that no unacceptable risk can result Compliance is checked by inspection of ME equipment and of the risk management file	The connectors were marked and identified by color (ED.X module) for the part of human body where is applied The applied parts were provided with the cable connectors, identified by color.	P
	b) Medical gas connections on ME equipment for different gases to be operated in normal use shall not be interchangeable .		NA
Replace A1	Compliance is checked by inspection of all medical gas connectors		
15.4.2	**Temperature and overload control devices**		
15.4.2.1 *Modification A1*	**Application**	The ED.X module not provided with temperature and overload control devices	NA
15.4.2.2	**Temperature settings**		

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
15.4.3	**Batteries**		
15.4.3.1 *Replace A1*	**Housing**	Without batteries replaceable by the user. Marked laptop (provided with battery).	NA
15.4.3.2	**Connection**		
15.4.3.3	**Protection against overcharging**		
15.4.3.4 *Replace A1 Modification A2*	**Lithium batteries**		
15.4.3.5 *Modification A1*	**Excessive current and voltage protection**		
15.4.4	**Indicators**		
	Unless it is otherwise apparent to the operator from the normal operating position, indicator lights shall be provided to indicate that ME equipment is ready for normal use	The laptop display shows the status and options that can be selected. After pressing the switch ON/OFF on the ED.X module, its display show the message of status ON.	P
15.4.5	**Pre-set controls**		
	When applicable, the manufacturer shall address in the risk management process the risks associated with pre-set controls	System without preset components. Needed adjustments are performed by software.	NA
15.4.6	**Actuating parts of controls of ME equipment**		
15.4.6.1	**Fixing, prevention of maladjustment**		
	a) the actuating parts shall be so secured that they cannot be pulled off or work loose during normal use	Bipolare rocker switch (marked) to turn ON / OFF the ED.X module.	P
Replace A1	b) controls shall be so secured that the indication of any scale always corresponds with the position of the control	The positions of rocker switch are stable and properly marked.	P
	c) fixation of the indication element of controls must be firm.	Marked rocker switch .	P
15.4.6.2	**Limitation of movement**		
Replace A1	Stops of adequate mechanical strength shall be provided on rotating or movable parts of controls of ME equipment , where necessary to prevent an unexpected change from maximum to minimum, or vice-versa, of the controlled parameter.	The fixed positions of rocker switch accessible to the operator.	NA
15.4.7	**Cord-connected hand-held and foot-operated control devices**		
15.4.7.1	**Mechanical strength**	Not applicable. Without cord-connected hand-held and foot-operated control devices.	NA
15.4.7.2	**Accidental operation of ME equipment**		
15.4.7.3 *Modification A1*	**Entry of liquids**		
15.4.8	**Internal wiring of ME equipment**		
	Aluminium wires of less than 16 mm cross-section shall not be used in ME equipment	Wiring with copper conductors only. Internal PCB.	P
15.4.9	**Oil containers**		
	a) oil containers in portable ME equipment b) oil containers in mobile ME equipment c) partially sealed oil-filled ME equipment or its parts		NA
15.5	**Mains supply transformers of ME equipment and transformers providing separation in accordance with 8.5**		
15.5.1	**Overheating**	Marked adapter (switching power supply).	P
15.5.1.1 *Modification A1*	**Transformers**		
15.5.1.2 *Modification A1*	**Short-circuit test**		
15.5.1.3 *Modification A1*	**Overload test**		
15.5.2 *Modification A1*	**Dielectric strength**		
15.5.3 *Replace A1*	**Construction of transformers used to provide separation as required by 8.5**		

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
16	**ME SYSTEMS**		
16.1	**General requirements for the ME systems**		
	After installation or subsequent modification, an ME system shall not result in an unacceptable risk		P
	Only hazards arising from combining various equipment to constitute an ME system shall be considered		P
	An ME system shall provide:		
	- within the patient environment, the level of safety equivalent to ME equipment complying with this standard; and	The system is provided with a marked laptop used with internal supply within the patient environment.	P
	- outside the patient environment, the level of safety equivalent to equipment complying with their respective IEC or ISO safety standards		NA
	Tests shall be performed:		
	- in normal condition unless otherwise specified, and		NA
	- under the operating conditions specified by the manufacturer of the ME system	Under normal conditions of use specified by manufacturer in user manual.	P
	Safety tests that have already been performed on individual equipment of the ME system according to relevant standards shall not be repeated	Marked adapter. Marked laptop. The ED.X module was tested according to this standard.	P P NA
	Non-ME equipment, when used in an ME system, shall comply with IEC or ISO safety standards that are relevant to that equipment	Marked adapter and laptop, compliant with IEC 60950-1	P
	Equipment in which protection against electric shock relies only on basic insulation shall not be used in an ME system		P
16.2	**Accompanying documents of an ME system**		
	An ME system shall be accompanied by documents containing all the data necessary for the ME system to be used as intended by the manufacturer, and an address to which the responsible organization can refer.	The system is accompanied by the user manual. The contact address of the manufacturer is specified in user manual.	P
	The accompanying documents shall be regarded as a part of the ME system		P
	These documents shall include:		
Modification A2	a) the accompanying documents for each item of ME equipment that is provided by the manufacturer	The user manual contains information about the ED.X module.	P
	b) the accompanying documents for each item of non-ME equipment that is provided by the manufacturer	The user manual contains information on minimum requirements for the laptop that can connect to the ED.X module. The system was tested with a laptop type HP, model 15-dw3043nq.	P
	c) the following information: - the specification of the ME system, including the use as intended by the manufacturer and a listing of all of the items forming the ME system	The user manual contains information on system configuration and its usage mode	P
	- instructions for the installation, assembly and modification of the ME system to ensure continued compliance with this standard	The user manual contains information how to interconnect system components and minimum requirements for the laptop. Different models of laptop does not influence the ED.X module parameters	P

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
	- instructions for cleaning and, when applicable, disinfecting and sterilizing each item of equipment or equipment part forming part of the ME system (see 11.6.6 and 11.6.7)	The user manual contains information about cleaning and disinfecting. No sterilizing.	P
	- additional safety measures that should be applied, during installation of the ME system	The user manual contains information about the location of the system	P
	- which parts of the ME system are suitable for use within the patient environment	The user manual contains information about ME equipment within the patient environment (ED.X module)	P
	- additional measures that should be applied during preventive maintenance	The user manual contains information about the regular maintenance.	P
	- if a multiple socket-outlet is present and it is a separate item, a warning that it shall not be placed on the floor		NA
	- a warning that an additional multiple socket-outlet or extension cord shall not be connected to the ME system		NA
	- a warning to connect only items that have been specified as part of the ME system or that have been specified as being compatible with the ME system	The user manual contains information about minimum requirements for the laptop.	P
	- the maximum permitted load for any multiple socket-outlet(s) used with the ME system		NA
	- an instruction that multiple socket-outlets provided with the ME system shall only be used for supplying power to equipment that is intended to form part of the ME system		NA
	- an explanation of the risks of connecting non-ME equipment that has been supplied as a part of the ME system directly to the wall outlet when the non-ME equipment is intended to be supplied via a multiple socket-outlet with a separating transformer		NA
	- an explanation of the risks of connecting any equipment that has not been supplied as a part of the ME system to the multiple socket-outlet		NA
	- the permissible environmental conditions of use of the ME system including conditions for transport and storage; and	The user manual contains information about environmental conditions (for use, transportation, storage)	P
	- instructions to the operator not to touch parts referred to in 16.4 and the patient simultaneously d) advice to the responsible organization:		NA
Modification A2	- to carry out all adjustment cleaning, sterilization and disinfection procedures specified therein; and	The user manual contains information about cleaning and disinfecting, respective for regular maintenance.	P
	- that the assembly of ME systems and modifications during the actual service life require evaluation to the requirements of this standard	The ED.X module is not affected by the type of the laptop which forming the system.	NA
16.3	**Power supply**		
	If ME equipment is intended to receive its power from other equipment in an ME system, the instructions for use shall specify the other equipment sufficiently to ensure compliance with the requirements of this standard	The user manual contains information about powered of the ED.X module : USB 3.0 port of the laptop (5 V_{dc}, max. 0,9 A). Used of the ED.X module connected to the patient is allowed only if the laptop is powered by the internal battery.	P

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
Adding A1	If : - an ME system is intended to receive its power from an isolated power supply (IPS) or an uninterruptible power supply (UPS), and - the ME system can draw large transient currents when being switching on or off or when operating, the manufacturer shall restrict such transient currents to the allowed level according to the specification of the IPS or the UPS from which the ME system is intended to be supplied	Used of the ED.X module connected to the patient is allowed only if the laptop is powered by the internal battery.	NA
	If an IPS or UPS is not specified, the actual transient current level shall be disclosed in the technical description and any installation instructions		NA
16.4	**Enclosures**		
	Parts of non-ME equipment in the patient environment that can be contacted by the operator during routine maintenance, calibration, etc. after removal of covers, connectors, etc., without the use of a tool shall operate at a voltage not exceeding the voltage specified in 8.4.2 c) supplied from a source that is separated from the supply mains by two means of operator protection	The laptop is powered by internal battery or at 19.5 V_{dc} (adapter). The adapter provided two means of operator protection against AC mains.	P
16.5	**Separation devices**		
	When functional connection between ME equipment and other items of equipment of an ME system or other systems can cause the allowable values of leakage current to be exceeded, then safety measures incorporating a separation device shall be applied	The separation from AC mains is provided by the plug of detachable cord. The ED.X module is provided by roket switch located on it for the supply interruption.	P
	The separation device shall have the dielectric strength, creepage distances and air clearances required for one means of operator protection appropriate for the highest voltage occurring across the separation device during a fault condition	Marked plug. Market roket switch.	P
16.6	**Leakage currents**		
16.6.1	**Touch current**		
	In normal condition, the touch current from or between parts of the ME system within the patient environment shall not exceed 100 μA	See 8.7 from this TR.	P
	In the event of the interruption of any non-permanently installed protective earth conductor, the touch current from or between parts of an ME system within the patient environment shall not exceed 500 μA	Used of the ED.X module connected to the patient is allowed only if the laptop is powered by the internal battery.	NA
16.6.2	**Earth leakage current of multiple socket-outlet**		
	If the ME system or part of the ME system is supplied from a multiple socket-outlet, then the current in the protective earth conductor of the multiple socket-outlet shall not exceed 5 mA		NA
16.6.3	**Patient leakage current**		
	The patient leakage current and total patient leakage current of an ME system in normal condition shall not exceed the values specified for ME equipment, as given in Table 3 and Table 4	See 8.7 from this TR.	P

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
16.6.4	**Measurements**		
16.6.4.1	**General conditions for ME systems**		
Modification A1	The touch current, the patient leakage current, the total patient leakage current and the total earth leakage current are measured after the ME system still in thermal stability	The leakage currents were measured after the thermal stability of the system.	P
	The ME system is connected to a supply with a voltage equal to the highest rated mains voltage	The patient leakage current, the total patient leakage current and the touch current when the patient is connected to system were measured with the system powered from the laptop battery. The touch current when the patient is unconnected to system and earth leakage currents were measured with the system powered by AC mains	P
16.6.4.2	**Connection of the ME system to the measuring supply circuit**		
	a) the ME system is tested after being assembled according to its accompanying documents	The tests were conducted after the interconnection in configuration from user manual, of the delivered system.	P
	b) measuring arrangement	Connection to the protective earth of the supply mains.	P
16.7	**Protection against mechanical hazards**		
	If a mechanical hazard exists, the ME system shall comply with the applicable requirements of Clause 9	See 9 from this TR	P
16.8	**Interruption of the power supply to parts of an ME system**		
Replace A1	An ME system shall be so designed that an interruption and restoration of the power to the ME system as a whole, or any part of the ME system, shall not result in the loss of basic safety or essential performance	The system working: - unconnected to patient: powered from AC mains or the laptop battery - connected to patient: powered only from the laptop battery The interruption of AC mains not caused the interruption of the system functionality (remained power supply from the laptop battery) After reconnecting of AC mains the system worked correctly. The actuation of the roker switch (in OFF position) from ED.X module caused the interruption of the communication and of the signals generation to applied parts. The reactuation of the roker switch (in ON position) from ED.X module caused correct operation after communications have been established as software requirements. The USB-USB cable disconnection between the ED.X module and the laptop caused the interruption of the communication and of the signals generation to applied parts. The USB-USB cable reconnection between the ED.X module and the laptop caused correct operation after communications have been established as software requirements	P P P P
16.9	**ME system connections and wiring**		
16.9.1	**Connection terminals and connectors**		
Replace A1	Design and construction of electrical, hydraulic, pneumatic and gas connection terminals and connectors shall be such that incorrect connection of accessible connectors, removable without the use of a tool, shall be prevented unless it can be proven that no unacceptable risk can result. In particular:		P

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021	Results	Fulfilling the requirement
	- plugs for connection of patient leads or patient cables shall be so designed that they cannot be connected to other outlets of the same ME system that are likely to be located in the patient environment unless it can be proved that no unacceptable risk can result	The user manual specifies how make identification and connection of the applied parts. The manufacturer has established the management of risks in the document "Risk management report for Universal Electrophysiological Biofeedback Amplifier with Electrotherapy Function", code F-RD-002/2 of January 11, 2023	P
	- medical gas connections on the ME system for different gases to be operated in normal use shall not be interchangeable		NA
16.9.2	**Mains parts, components and layout**		
16.9.2.1 *Modification A1*	**Multiple socket-outlet**	Without multiple socket-outlet.	NA
16.9.2.2	**Protective earth connections in ME systems**		
Adding A1	For each part of an ME system that shares a mains connection, the impedance and current carrying capability of the total protective earth path of an ME system when tested as a unit shall comply with 8.6.4.	Without accessible parts connected to the protective earth circuit. The subassemblies enclosures from insulating material	NA
Adding A1 Modification A2	Where the pathway of a fault current caused by a live part to a protective earthed part is protected only by the supply mains circuit over-current release (e.g. circuit breaker or fuse), the protective earth resistance of that pathway shall not exceed 200 mΩ		
Adding A2	Where the pathway of a fault current caused by a live part to a protective earthed part is protected by additional intermediate circuit breakers or fuses with current ratings 13 A or lower, then compliance with 8.6.4 b) and 8.7.2, first dash, is achieved and the protective earth resistance to that part of the fault pathway may exceed 200 mΩ but shall be less than 400 mΩ.		
	Protective earth connections shall be made so that the removal of any single item of equipment in the ME system will not interrupt the protective earthing of any other part of the ME system, without at the same time disconnecting the electrical supply to that part.	Protective earth conductor is included in the detachable power cord for adapter.	P
	Additional protective earth conductors shall only be detachable by use of a tool		NA
16.9.2.3	**Protection of conductors**		
	Conductors that connect different items of equipment within an ME system shall be protected against mechanical damage	Standard cable (USB-USB).	P
17	**ELECTROMAGNETIC COMPATIBILITY OF ME EQUIPMENT AND ME SYSTEMS**		
Replace A2	The manufacturer shall address the risk(s) associated with electromagnetic disturbances	The user manual detailing electromagnetic phenomena that can influence the system and measures to be taken. The manufacturer has established the management of risks in the document "Risk management report for Universal Electrophysiological Biofeedback Amplifier with Electrotherapy Function", code F-RD-002/2 of January 11, 2023	P
	The tests according to IEC 60601-1-2 and IEC 60601-1-2:2014/AMD1:2020	According to B.1 of the Annex B, these tests are subject to another Test Report.	

Clause	Requirement according to SR EN 60601-2-10:2015 + A1:2017	Results	Fulfilling the requirement
201.4	**GENERAL REQUIREMENTS**		
	Clause 4 of the general standard applies, except as follows:	See 4, pages 3 to 5 from this TR	P
201.4.1	**Conditions for application to ME equipment or ME systems**		
201.4.1.101 *Adding*	**Additional conditions for application to ME equipment or ME systems**		
	In the case of combined ME equipment, the additional part shall comply with any relevant particular standard	The requirements were applied to the system with suplimentary EEG functions (according SR EN 60601-2-26:2015). See pages 72 to 78 of this TR	P
201.4.2 *Adding*	**Risk management process for ME equipment or ME systems**		
	Manufacturers shall include, within their risk analysis, the risk associated with the potential use of their stimulators and accessories to deliver current exceeding 10 mA or current densities for any electrode exceeding 2 mA/cm^2	The manufacturer has settled: - acceptable levels of risk; - risk management process; - acceptable residual risks	P
201.4.11 *Adding*	**Power input**		
	The equipment shall be operated in the output mode and using the load which creates the highest amplitude steady state current	ME system supply condition: U_{rated} = 230 V_{ac} /50Hz Measured : max. 39 W ED.X supply condition: U_{rated} = 5 V_{cc}, Measured : max. 495 mA Required : max. 500 mA (declared) ($I_{port\ USB}$ = 900 mA)	P
201.5	**GENERAL REQUIREMENTS FOR TESTING ME EQUIPMENT**		
	Clause 5 of the general standard applies.	See 5, pages 5 to 7 from this TR	P
201.6	**CLASSIFICATION OF ME EQUIPMENT AND ME SYSTEMS**		
	Clause 6 of the general standard applies, except as follows:	See 6, page 8 from this TR	P
201.6.2 *Modification*	**Protection against electric shock**		
	Shall do not provided with type B applied parts	It is provided with BF- type applied parts	P
201.6.6 *Modification*	**Mode of operation**		
	Only continuous operation	Continuous operation during the therapy cycle.	P
201.7	**ME EQUIPMENT IDENTIFICATION, MARKING AND DOCUMENTS**		
	Clause 7 of the general standard applies, except as follows:	See 7, pages 8 to 25 from this TR	P
201.7.2	**Marking on the outside of ME equipment or ME equipment parts**		
201.7.2.7 *Modification*	**Electrical input power from the supply mains**		
	The rated input power of a mains powered stimulator shall be the maximum power averaged over any period of 5 s under the specified operating conditions set out by the manufacturer	The maxim input power (declared) for ED.X module: 2,5 W (U_n= 5 V_{dc}; I=max. 500 mA (port USB)) The system (ED.X + laptop) can be used powered by AC mains via adapter (during processing of the data (not connected to the patient)) or from internal source (from laptop battery)	P
201.7.2.101 *Adding*	**Output**		
	ME equipment capable of delivering outputs in excess of 10 mA or 10 V averaged over any period of 1 s shall be marked near the electrode connections with symbol 	Without power output (U_{max} = 4 V, I = 1 mA) See user manual	NA
201.7.9	**Accompanying documents**		
201.7.9.2	**Instructions for use**		
201.7.9.2.101 *Adding*	**Additional information in instructions for use**		
	The instructions for use shall contain additionally:		

Clause	Requirement according to SR EN 60601-2-10:2015 + A1:2017	Results	Fulfilling the requirement
	a) information on the output waveform(s), including any d.c. component, pulse durations, pulse repetition frequencies, maximum amplitude of output voltage and/or current, and the effect of load impedance on these parameters	In user manual	P
	b) advice on the size and type of electrodes to be used and the method of application for each particular type of treatment for which the stimulator is intended	Electrodes delivery with equipment.	NA
	c) advice on any necessary precautions to be taken when the output contains a d.c. component		NA
	d) advice that a patient with an implanted electronic device (for example a cardiac pacemaker) should not be subjected to stimulation unless specialist medical opinion has first been obtained	In user manual	P
	e) a warning on the following potential hazards: - simultaneous connection of a patient to a high frequency surgical ME equipment may result in burns at the site of the stimulator electrodes and possible damage to the stimulator - operation in close proximity (e.g. 1 m) to a shortwave or microwave therapy ME equipment may produce instability in the stimulator output	In user manual	P
	- application of electrodes near the thorax may increase the risk of cardiac fibrillation	Applied parts for limbs and head.	NA
	f)for ME equipment capable of delivering output values in excess of 10 mA or 10 V: - information on maximum output values available at the electrodes recommended by the manufacturer for use with the stimulator		NA
	g) advice that any electrodes that have current densities exceeding 2 mA/cm^2 may require the special attention of the operator	Applied parts for limbs (active part of rubber thickness 2 mm, with dimensions 20 mm x 150 mm (s = 30 cm^2)) Applied parts for head (rubber, special form , L_{total} = 750 mm, L_{active} =160 mm, s_{active} = minim 48 cm^2 $s_{contacte}$ = 4,5 cm^2)	NA
	h) advice that stimulation should not be applied across or through the head, directly on the eyes, covering the mouth, on the front of the neck, (especially the carotid sinus), or from electrodes placed on the chest and the upper back or crossing over the heart	Applied parts for limbs and head	NA
201.7.9.3	**Technical description**		
201.7.9.3.1	**General**		
Adding	- the technical description shall specify the parameters mentioned in item a) of 201.7.9.2.101 along with the range of load impedances for which these parameters are valid	In user manual	P
201.8	**PROTECTION AGAINST ELECTRICAL HAZARDS FROM ME EQUIPMENT**		
	Clause 8 of the general standard applies, except as follows:	See 8, pages 25 to 46 from this TR	P
201.8.3	**Classification of applied parts**		
Modification	The applied parts of stimulators shall be type BF or type CF applied parts	Applied parts BF-type	P

Clause	Requirement according to SR EN 60601-2-10:2015 + A1:2017	Results	Fulfilling the requirement
201.9	**PROTECTION AGAINST MECHANICAL HAZARDS OF ME EQUIPMENT AND ME SYSTEMS**		
	Clause 9 of the general standard applies.	See 9, pages 47 to 49 from this TR	P
201.10	**PROTECTION AGAINST UNWANTED AND EXCESSIVE RADIATION HAZARDS**		
	Clause 10 of the general standard applies.	See 10, page 49 from this TR	NA
201.11	**PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER HAZARDS**		
	Clause 11 of the general standard applies.	See 11, pages 49 to 54 from this TR	P
201.12	**ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS**		
	Clause 12 of the general standard applies, except as follows:	See 12, pages 54 and 55 from this TR	P
201.12.1	**Accuracy of controls and instruments**		
201.12.1.101 *Adding*	**Output amplitude**		
	A means shall be provided to control the stimulator output from minimum to maximum continuously, or in discrete increments of not more than 1 mA or 1 V per increment. At its minimum setting, the output shall not exceed 2 % of that available at the maximum setting of the control	The software allows adjusting the output parameters: the waveforms and level. The waveforms by select the therapy type. The level continuous (on screen icon) The minimum adjustment is by cancellation (0% of the maximum output)	P
201.12.1.102 *Adding*	**Pulse parameters**		
	The values of pulse durations, pulse repetition frequencies and amplitudes, including any d.c. component, whether caused by an offset or by an unsymmetrical waveform, as described in the accompanying documents or indicated on the ME equipment (see 201.7.9.2), shall not deviate by more than ± 20 % when measured with a load resistance within the range specified in the accompanying documents (see 201.7.9.3)	The output waveforms for electrotherapy available at the outputs of electrostimulation were viewed without load and with load. The variation of the output levels was maximum 5 %.	P
201.12.2	**Usability**		
201.12.2.101 *Adding*	**Electrodes**		
	The stimulator shall comply with this standard when operated with either open-circuited or short-circuited electrodes Test: Operate the stimulator with all output controls set to the maximum position and each pair of output terminals left open-circuited for a period of 10 min and then short-circuited for a further period of 5 min. After this test the ME equipment shall comply with all the requirements of this standard	The test was performed with the electrodes în open-circuit or short-circuit All outputs for electrostimulation have been in open-circuit for 10 min after which they were kept in short-circuit for 5 min. After the test, the equipment was restarted and it worked correctly (selection of programs, selection of levels, selection of types of therapies, etc.). Working test was performed with internal power supply of the laptop.	P
201.12.4	**Protection against hazardous output**		
201.12.4.101 *Adding*	**Supply voltage fluctuations**		
	Supply voltage fluctuations of ± 10 % shall not affect the stimulator output amplitude, pulse duration or pulse repetition frequency by more than ± 10 %	The deviations of the supply voltage 207 V_{ac}÷253 V_{ac} not affect equipment operation (during processing of the data (not connected to the patient)) For the ED.X, the deviations of the supply voltage 4.5 V_{dc} ÷ 5.5 V_{dc} not affect functions ((selection of programs, selection of levels, selection of types of therapies, etc.) No occur variation of the output levels (internal circuits for stabilization of the voltage)	P

Clause	Requirement according to SR EN 60601-2-10:2015 + A1:2017	Results	Fulfilling the requirement
201.12.4.102	**Output interlock**		
Adding	A stimulator that is capable of delivering an output in excess of 10 mA or 10 V shall not be energizeable unless the output amplitude control(s) is (are) first set to its (their) minimum position This requirement shall also apply upon the restoration of the supply mains following a temporary interruption or following replacement of the internal electrical power source This requirement shall not apply when a stimulator is released from a pause mode, having been operating prior to being paused		NA
201.12.4.103	**Output indicator**		
Adding	In normal condition and single fault condition, ME equipment shall indicate when it can deliver an output of more than 10 mA or 10 V, or can deliver pulses having an energy exceeding 10 mJ per pulse, into a load resistance of 1 000 Ω. If the indication is by means of a signal lamp, its colour shall be yellow		NA
201.12.4.104	**Limitation of output parameters**		
Adding	a) ME equipment intended for therapeutic applications: With a load resistance of 500 Ω the output current shall not exceed the follow limits: -for d.c. pulse: 80 mA -for pulse frequency≤ 400 Hz : 50 mA -for 400 Hz <pulse frequency≤ 1500 Hz: 80 mA -for 1500 Hz <pulse frequency: 100 mA If the output has a.c. and d.c. components, then these components shall be measured separately and compared with the allowable limits For pulse durations of less than 0,1 s the pulse energy with a load resistance of 500 Ω shall not exceed 300 mJ per pulse. For longer pulse durations, the above-mentioned current limit for d.c. applies Additionally, the output voltage shall not exceed a peak value of 500 V, when measured under open-circuit condition Where the applied part(s) is (are) energized by more than one patient circuit simultaneously (for example for interferential therapy), the above limits shall apply to each of these patient circuits b) ME equipment intended for diagnostic applications: For ME equipment intended for dentistry and ophthalmology, the d.c. current with a load resistance of 2 000 Ω shall not exceed 10 mA	 1,1 mA / circuit U_{output} max. 4 V (4 (arms and legs) + 1 (head)) patient circuits 	 NA NA NA P NA NA P P NA
201.13	**HAZARDOUS SITUATIONS AND FAULT CONDITIONS FOR ME EQUIPMENT**		
	Clause 13 of the general standard applies.	See 13, pages 56 to 58 from this TR	P
201.14	**PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)**		
	Clause 14 of the general standard applies.	See 14, page 58 from this TR	P
201.15	**CONSTRUCTION OF ME EQUIPMENT**		
	Clause 15 of the general standard applies.	See 15, pages 59 to 61 from this TR	P
201.16	**ME SYSTEMS**		
	Clause 16 of the general standard applies.	See 16, pages 61 to 66 from this TR	P
201.17	**ELECTROMAGNETIC COMPATIBILITY OF ME EQUIPMENT AND ME SYSTEMS**		
	Clause 17 of the general standard applies	See 17, page 66 from this TR	P

Clause	Requirement according to SR EN 60601-2-10:2015 + A1:2017	Results	Fulfilling the requirement
202	**ELECTROMAGNETIC COMPATIBILITY - REQUIREMENTS AND TESTS**		
Adding	IEC60601-1-2:2007 applies except as follows:	See Test Report nº 167 / 2023.03.14 issued by OICPE-LICPE	P
202.6.1	**Emissions**		
202.6.1.1.2	**Tests**		
	a) patient cables		
Adding	Connect all relevant electrodes to the contents of a 1 litre capacity phantom filled with 0,9 % saline Position the phantom within 0,4 m of the ME equipment	The measurements were repeat with electrodes placed at 0.4 m of equipment and immersed in saline solution. The values measured do not differ from those specified in the Test Report nº 167 / 2023.03.14 issued by OICPE-LICPE	P
202.6.2	**Immunity**		
202.6.2.1.5	**Patient-coupled ME equipment and ME systems**		
Adding	Connect all relevant electrodes to the contents of a 1 litre capacity phantom filled with 0,9 % saline	The measurements were repeat with electrodes placed at 0.4 m of equipment and immersed in saline solution. The values measured do not differ from those specified in the Test Report nº 167 / 2023.03.14 issued by OICPE-LICPE	P

Clause	Requirement according to SR EN 60601-2-26:2015	Results	Fulfilling the requirement
201.4	**GENERAL REQUIREMENTS**		
	Clause 4 of the general standard applies, except as follows:	See 4, pages 3 to 5 from this TR	P
201.4.3	**Essential performance**		
201.4.3.101	**Additional essential performance requirements**		
Adding	Additional essential performance requirements are found in the follow subclauses: - Accuracy of signal reproduction: 201.12.1.101.1 - Input dynamic range and differential offset voltage: 201.12.1.101.2 - Input noise: 201.12.1.101.3 - Frequency response: 201.12.1.101.4 - Common mode rejection: 201.12.1.101.5	 See 201.12.1.101.1, page 76 from this TR. See 201.12.1.101.2, page 77 from this TR. See 201.12.1.101.3, page 77 from this TR. See 201.12.1.101.4, page 77 from this TR. See 201.12.1.101.5, page 77 from this TR.	P
201.5	**GENERAL REQUIREMENTS FOR TESTING ME EQUIPMENT**		
	Clause 5 of the general standard applies, except as follows:	See 5, pages 5 to 7 from this TR	P
201.5.4	**Other conditions**		
Adding	aa) Unless otherwise stated, tests shall be carried out with the accessories and the recording materials specified by the manufacturer For ME equipment with an internal electrical power source, if the test result is affected by the internal electrical power source voltage, then the test shall be performed using the least favourable internal electrical power source voltage specified by the manufacturer. If necessary for the purpose of conducting the test, an external battery or d.c. power supply may be used to provide the necessary test voltage	With the accessories provided by the manufacturer	P
201.5.8	**Other conditions**		
Modification	Tests called for in 201.8.5.5.1 of this particular standard and in 8.5.5 of the general standard shall be carried out prior to the leakage current and dielectric strength tests described in subclauses 8.7 and 8.8 of the general standard and prior to the tests specified in subclause 201.12.1.101 of this particular standard		NA
201.6	**CLASSIFICATION OF ME EQUIPMENT AND ME SYSTEMS**		
	Clause 6 of the general standard applies, except as follows:	See 6, page 8 from this TR	P
201.6.2	**Protection against electric shock**		
Replace	Applied parts shall be classified as type BF or type CF applied parts (see 7.2.10 and 8.3 b) of the general standard)	It is provided with type BF applied parts	P
201.6.6	**Mode of operation**		
Replace	ME equipment shall be classified for continuous operation	Continuous operation during the investigation.	P
201.7	**ME EQUIPMENT IDENTIFICATION, MARKING AND DOCUMENTS**		
	Clause 7 of the general standard applies, except as follows:	See 7, pages 8 to 25 from this TR	P
201.7.2	**Marking on the outside of ME equipment or ME equipment parts**		
201.7.2.1	**Minimum requirements for marking on ME equipment and on interchangeable parts**		
Adding	If the ME equipment is specified as being protected against the effects of defibrillation:		NA

Clause	Requirement according to SR EN 60601-2-26:2015	Results	Fulfilling the requirement
	Parts of ME equipment (for example, patient cables or sensors) specified as being protected against the effects of defibrillation shall be marked with symbol  (defibrilation-proof type BF applied part) or  (defibrilation-proof type CF applied part).		
201.7.9	**Accompanying documents**		
201.7.9.2	**Instructions for use**		
201.7.9.2.101	**Additional information in instructions for use**		
Adding	The instructions for use shall also contain:	The instructions for use does not offer medical advice or interpretations.	P
	a) The intended use/intended purpose including environment of use Likely misuse should be identified by risk analysis and disclosed if necessary (e.g. 'not for determination of brain death') The procedures necessary for safe operation	The main function of the equipment is therapy (electrostimulation).	P
	b) The procedures necessary for safe operation		P
	c) Instructions for connecting a potential equalization conductor, if applicable		P
	d) That conductive parts of electrodes and associated connectors for applied parts, including the neutral electrode, should not contact other conductive parts including earth		NA
	e) Advise for the operator regarding whether the ME equipment incorporates means to protect the patient against burns when used with high frequency surgical equipment. Advice shall be given regarding the location of electrodes and lead wires etc, to reduce the hazard of burns in the event of a defect in the neutral electrode connection of the high frequency surgical equipment		P
	f)The need for regular testing of the ME equipment and its accessories		P
	g) Precautions to take when using a defibrillator on a patient; a description of how the discharge of a defibrillator affects the ME equipment; a warning that defibrillator protection requires use of manufacturer specified accessories including lead wires and patient cables. The specification (or type-number) of such accessories shall be disclosed (see 201.8.5.5.1)		NA
	h) The choice and application of specified patient cables and lead wires; the choice and application of electrodes	The electrodes provided with equipment.	NA
	i)The subsequent operation of the ME equipment after interruption of supply mains exceeding 30 s (see 201.11.8)	The ED.X module is powered by the battery laptop.	NA
	j) Any hazard due to simultaneous use of other patient-connected ME equipment, for example, a cardiac pacemaker or other electrical stimulators		NA

Clause	Requirement according to SR EN 60601-2-26:2015	Results	Fulfilling the requirement
	k) Technical specifications for the ME equipment of sufficient detail to allow the operator to understand what is being measured and any limitations. Minimally this shall include: -frequency range and bandwidth -a description of all functions -a description of waveform displays (if applicable) l) Any known susceptibilities to electromagnetic phenomena		P
201.8	**PROTECTION AGAINST ELECTRICAL HAZARDS FROM ME EQUIPMENT**		
	Clause 8 of the general standard applies, except as follows:	See 8, pages 25 to 46 from this TR	P
201.8.1	**Fundamental rule of protection against electric shock**		
201.8.1.101	**Multipurpose channel(s)**		
Adding	If electroencephalographs allow channels to be used for signals other than EEG, then this facility shall be tested to applicable clauses of relevant standards	The applied parts of ED.X are used also for stimulation. See figure 1 from of this TR.	P
201.8.3	**Classification of applied parts**		
Replace	The applied parts of ME equipment shall be type BF or type CF applied parts	Applied parts BF-type	P
201.8.5	**Separation of parts**		
201.8.5.2	**Separation of patient connections**		
201.8.5.2.3	**Patient leads or patient cables**		
Adding	NOTE 101 For EMC (electromagnetic compatibility) and physical cable management, leads of electroencephalograph are usually kept short and tied together.		P
201.8.5.5	**Defibrillation-proof applied parts**		
201.8.5.5.1	**Defibrillation protection**		
Adding	If protection against the effects of defibrillation is provided for ME equipment the following tests shall be performed: For defibrillator testing the ME equipment is operated using the patient cables as specified by the manufacturer The following requirements and tests apply in addition to the requirements and tests as specified in 8.5.5.1 of the general standard	Not applicable. The equipment is not provided with protection against the effects of defibrillation.	NA
Modification	**Common mode test**		
Modification	**Differential mode test**		
201.8.5.5.2	**Energy reduction test**		
Adding	The test setup for energy reduction test is shown in Figure 201.103 Test to be conducted with manufacturer's recommended patient cable	Not applicable. The equipment is not provided with protection against the effects of defibrillation.	NA
201.8.7	**Leakage currents and patient auxiliary currents**		
201.8.7.1	**General requirements**		
	b) the specified values of the earth leakage current, the touch current, the patient leakage current and the patient auxiliary current apply in any combination of the following conditions:	See also 8.7.1, page 33 from this TR	P
Adding	- with any input selectors or montage selectors set so as to produce the worst case conditions and so that the test requirements of the general standard are fulfilled. The worst case shall be determined by inspection of the circuit diagram and/or the electroencephalograph and its associated accessories		P

Clause	Requirement according to SR EN 60601-2-26:2015	Results	Fulfilling the requirement
201.9	**PROTECTION AGAINST MECHANICAL HAZARDS OF ME EQUIPMENT AND ME SYSTEMS**		
	Clause 9 of the general standard applies.	See 9, pages 47 to 49 from this TR	P
201.10	**PROTECTION AGAINST UNWANTED AND EXCESSIVE RADIATION HAZARDS**		
	Clause 10 of the general standard applies.	See 10, page 49 from this TR	NA
201.11	**PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER HAZARDS**		
	Clause 11 of the general standard applies, except as follows:	See 11, pages 49 to 54 from this TR	P
201.11.6.3	**Spillage on ME equipment and ME systems**		
Replace	Portable/transportable ME equipment or parts of the ME equipment separable while remaining functioning shall be so constructed so that, in the event of spillage of liquids (accidental wetting), no hazardous situation results from the ingress of liquids.	The ED.X module, with the laptop, is intended to placed on a table near the patient.	P
	The ME equipment shall meet the dielectric strength requirements specified in 8.8.3 of the general standard and shall comply with the requirements of this particular standard	After the artificial rainfall conditioning (IP X1 according to SR EN 60529:1995 + A1:2003 + A2:2015 + AC:2017 + AC:2019) was conducted dielectric strength test.	P
	Place the portable/transportable ME equipment or parts of the ME equipment in the least favourable position of normal use.	The equipment was placed on a rotary table, at 0.5 m from the water tank, with the connectors having entered pairs	P
	Subject the ME equipment for 30 s to an artificial rainfall of 3 mm/min falling vertically from a height of 0,5 m above the top of the ME equipment An intercepting device may be used to determine the duration of the test	Was provided at a rate of fall of water from the tank about 3 mm/min; the exposure time was 30 sec.	P
	Immediately after 30 s exposure, remove any visible moisture on the enclosure	The ED.X module was wiped out the remaining water on the outer surface.	P
	Immediately after the above test, verify (by inspection) that any water that entered the ME equipment cannot adversely affect the basic safety of the ME equipment.	After the opening has been found no accumulation of water inside.	P
	Verify that the ME equipment meets the relevant dielectric strength test (8.8.3 of the general standard) and does not result in a hazardous situation	After the artificial rainfall conditioning:	
		a) was applied 3000 V_{rms}, 50 Hz for 1 min. between mains supply terminals shorted and a metal foil over the adapter insulated enclosure (two MOOP) No breakdowns and flashovers occurred.	P
		b) was applied 3000 V_{rms}, 50 Hz for 1 min. between mains supply terminals shorted and a metal foil over the laptop keyboard (two MOOP) No breakdowns and flashovers occurred.	P
		c) was applied 3000 V_{rms}, 50 Hz for 1 min. between mains supply terminals shorted and a metal foil over the ED.X module enclosure (two MOOP) No breakdowns and flashovers occurred	P
		d) was applied 3000 V_{rms}, 50 Hz for 1 min. between mains supply terminals shorted and a metal foil over the applied parts connected to the ED.X module (two MOOP) No breakdowns and flashovers occurred	P
		e) was applied 4000 V_{rms}, 50 Hz for 1 min. between mains supply terminals shorted and a metal foil over the applied parts connected to the ED.X module (two MOPP) (used mode non-recommended by the manufacturer) No breakdowns and flashovers occurred.	P

Clause	Requirement according to SR EN 60601-2-26:2015	Results	Fulfilling the requirement
		f) was applied 1000 V_{rms}, 50 Hz for 1 min. between the supply terminals shorted of the ED.X module and a metal foil over the applied parts connected to the EDUCTOR 1 module (two MOPP). No breakdowns and flashovers occurred	P
	After this test, verify that the ME equipment complies with the requirements of this particular standard	After dielectric strength test was ON equipment and was launched software for EEG function. The system worked properly, the laptop screen diagram is displayed in real time.	P
201.11.8	**Interruption of the power supply / supply mains to ME equipment**		
Adding	If the supply mains to the ME equipment is interrupted for less than 30 s, no change of operator settings shall occur, including the mode of operation, or all stored patient data shall remain available	The ED.X module is powered by the battery laptop.	NA
	Compliance is checked by observing the ME equipment operating mode, operator settings, and stored data and interrupting the supply mains for a period of between 25 s and 30 s by disconnecting the power supply cord	The power supply of the ED.X module provided by laptop battery ensures operating autonomy of the system for long periods (depending on the state of battery)	P
	If the supply mains is interrupted for more than 30 s, the subsequent operation shall be one of the following: - reversion to the manufacturer's default settings - reversion to previous responsible organization's default settings or - reversion to the last settings used		NA
	If the ME equipment contains an internal electrical power source and the supply mains is interrupted, the ME equipment shall continue normal operation by switching automatically to operating from its internal electrical power source, and the mode of operation, all operator settings and stored data shall not be changed	The power supply of the ED.X module provided by laptop battery ensures operating autonomy of the system for long periods (depending on the state of battery), without changing of the software, of settings, the course of program, the stored data.	P
	Power-saving measures may be taken provided the ME equipment continues to conform to this particular standard	The system works correctly during the power-saving status of the laptop (closing display)	P
	ME equipment shall visually indicate the operation from its internal electrical power source	When "external source" is connected to the laptop, the regime "main supply" is signalized by white LED	P
201.12	**ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS**		
	Se aplică cerinţele art. 12 din SR EN 60601-1, cu următoarele excepţii:	See 12, pages 54 and 55 from this TR	P
201.12.1	**Accuracy of controls and instruments**		
201.12.1.101 *Adding*	**Essential performance requirements**		
201.12.1.101.1 *Adding*	**Accuracy of signal reproduction**		
	Input signals in the range of ± 0,5 mV, varying at a rate to 12 mV/s, shall be reproduced on the output with an error of ≤ ± 20 % of the nominal value of the output or ± 10 μV, whichever is greater	It was applied a signal f = 2 Hz triangular to each patient connection, other connection is connected to the reference. It has been adjusted to ensure the signal generator to a variation of 10% (70 μV), from rated signal value. Was amplified output level of the generator, successively, 2 times (140 μV), 5 times (350 μV), and 10 times (700 μV). The signal was displayed with 3% maximum deviation.	P

Clause	Requirement according to SR EN 60601-2-26:2015	Results	Fulfilling the requirement
		It was applied to a triangular signal with f = 6 Hz each patient connection, other connection is connected to the reference. It was adjusted the output of the signal generator to 1 mV and was checked displayed on the laptop display. The signal was displayed with 5.6 % deviation	
201.121.101.2	**Input dynamic range and differential offset voltage**		
Adding	With a d.c. offset voltage in the range of ± 300 mV and differential input signal voltages of ± 0,5 mV that vary at rates up to 12 mV/s, when applied to any lead wire, the time-varying output signal amplitude shall not change by more than ±10 % over the specified range of d.c. offset	It was applied to a triangular signal with f = 6 Hz each patient connection, other connection is connected to the reference. It was adjusted the output of the signal generator to 1 mV and was checked displayed on the laptop display. It was applied successively the offset level +300 mV and - 300 mV. The signal was displayed with 3.5 % deviation.	P
201.121.101.3	**Input noise**		
Adding	The signal noise caused by the EEG amplifier and patient cable shall not exceed 6 $\mu V_{peak\text{-}to\text{-}peak}$ referred to the input (RTI)	All conductors was connected together. Input noise did not exceed the value of 4 $\mu V_{peak\text{-}to\text{-}peak}$	P
201.121.101.4	**Frequency response**		
Adding	ME equipment shall meet the requirement for a frequency response (bandwidth) of at least 0,5 Hz to 50 Hz when tested with sinusoidal input signals. The output at 0,5 Hz and 50 Hz shall be within 71 % to 110 % of the output obtained with a 5 Hz sine wave input signal	Was applied a signal with level 200 $\mu V_{peak\text{-}to\text{-}peak}$ and 5 Hz, 0.5 Hz and 50 Hz frequences and the signal was visualized on the chart The deviation of signal on diagram displayed on the laptop display is between + 7% and - 8%, compared to the 5Hz signal.	P
201.121.101.5	**Common mode rejection**		
Adding	A 1 $V_{r.m.s.}$ signal at mains frequency (50 Hz/60 Hz) with 200 pF source capacitance, connected between earth and all lead wires connected together shall not produce an output signal greater than 10 mm peak-to-peak at an adjusted gain of 0,1 mm/μV over a 60 s period. The patient cable specified by the manufacturer shall be used	A 1 $V_{r.m.s.}$ signal was applied to the entries follow the test sequence. The signal displayed was tuned to 50% (67.5 mm) of the diagram displayed on the laptop display.	P
	Repeat the test with a +300 mV_{dc} and -300 mV_{dc} offset voltage in series with the imbalance impedance, by opening S_{DC} and testing with the switch Sp in each of its two positions	It repeated the test sequence by applying an offset of + 300 mV. It repeated the test sequence by applying an offset of - 300 mV.	P
	The measured output amplitude shall not be greater than 10 mm peak-to-peak.	The signal variation displayed was up to 5% (6.7 mm)	P
201.13	**HAZARDOUS SITUATIONS AND FAULT CONDITIONS FOR ME EQUIPMENT**		
	Clause 13 of the general standard applies.	See 13, pages 56 to 58 from this TR	P
201.14	**PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)**		
	Clause 14 of the general standard applies.	See 14, page 58 from this TR	P
201.15	**CONSTRUCTION OF ME EQUIPMENT**		
	Clause 15 of the general standard applies.	See 15, pages 59 to 61 from this TR	P
201.16	**ME SYSTEMS**		
	Clause 16 of the general standard applies.	See 16, pages 61 to 66 from this TR	P
201.17	**ELECTROMAGNETIC COMPATIBILITY OF ME EQUIPMENT AND ME SYSTEMS**		
	Clause 17 of the general standard applies, except as follows:	See 17, page 66 from this TR	P
202	**ELECTROMAGNETIC COMPATIBILITY - REQUIREMENTS AND TESTS**		
Adding	IEC 60601-1-2:2007 applies except as follows:	See Test Report nº 167 / 2023.03.14 issued by OICPE-LICPE	P

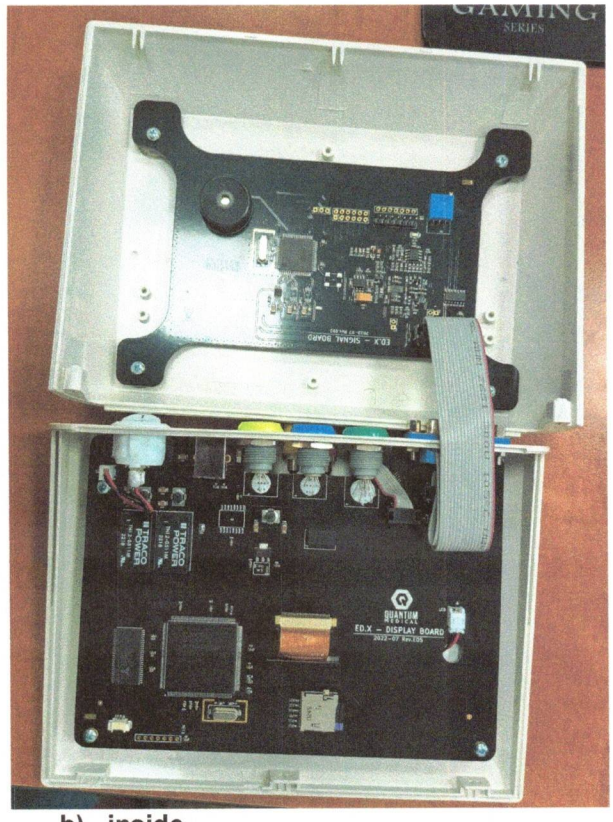
Clause	Requirement according to SR EN 60601-2-26:2015	Results	Fulfilling the requirement
202.5.2.2.2	**Requirements applicable to ME equipment and ME systems other than those specified for use only in a shielded location**		
Adding	Electroencenphalographs and their accessories shall not be considered as life-supporting ME equipment		P
202.6.1	**Emissions**		
202.6.1.1.2	**Tests**		
	a) patient cables		
Replace	ME equipment shall be tested with the patient cable/s as specified by the manufacturer with all SIP/SOP cables connected to the ME equipment (see Figure 202.101); the distances of SIP/SOP cables between the open end and floor (ground plane) shall be ≥ 40 cm. If the manufacturer specifies patient cables with different length only one representative sample of each length has to be tested.	The measurements were repeat with electrodes placed at 0.4 m from the ground plane. The values measured do not differ from those specified in the Test Report nº 167 / 2023.03.14 issued by OICPE-LICPE	P
	The RC-network (Cp, Rp) and the metal plate (7) of Figure 202.101 are not used during radiated emissions testing		P
202.6.2	**Immunity**		
202.6.2.2	**Electrostatic discharge (ESD)**		
202.6.2.2.1	**Requirements**		
Adding	ME equipment may show temporary degradation during discharges. Within 30 s the ME equipment shall resume normal operation in the previous operating mode, without loss of any operator settings or stored data, and shall continue to perform its intended function	The tests were repeat with application of the electrostatic discharge for 40 s total test time The status of the equipment do not differ from those specified in the Test Report nº 167 / 2023.03.14 issued by OICPE-LICPE	P
202.6.2.3	**Radiated RF electromagnetic fields**		
202.6.2.3.1	**Requirements**		
	a) General		
Adding	Immunity test level of 3 V/m applies	See Test Report nº 167 / 2023.03.14 issued by OICPE-LICPE	P
202.6.2.3.2	**Tests**		
Adding	The test setup for radiated RF electromagnetic fields is shown in Figure 202.102 aa) Any signal input/output part cable and power supply cord are arranged generally as in Figure 202.102. Maintain distances of ≥ 40 cm between SIP/SOP cables and the floor (ground plane).	The tests were repeat with electrodes placed at 0.4 m from the ground plane. The values measured do not differ from those specified in the Test Report nº 167 / 2023.03.14 issued by OICPE-LICPE	P
202.6.2.4	**Electrical fast transients and bursts**		
202.6.2.4.1 *Modification*	**Requirements**	ECG function is performed with the sistem powered from the laptop battery.	NA
202.6.2.4.2 *Modification*	**Tests**		
202.6.2.6	**Conducted disturbances, induced by RF fields**		
202.6.2.6.1 *Modification*	**Requirements**	ECG function is performed with the sistem powered from the laptop battery.	NA
202.6.2.6.2 *Modification*	**Tests**		

Fulfilling the requirement:

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

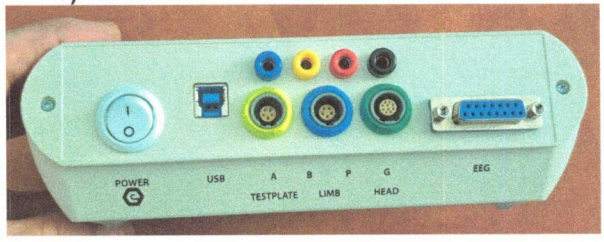
Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021 SR EN 60601-2-10:2015 + A1:2017 SR EN 60601-2-26:2015	Results	Fulfilling the requirement

a) label



b) inside

c) display



d) connectors şi switch

Figure 1 – ED.X modulul

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021 SR EN 60601-2-10:2015 + A1:2017 SR EN 60601-2-26:2015	Results	Fulfilling the requirement

a) USB-USB cable b) head applied part c) limb applied parts

Figure 2 – Interconnection cables and applied parts for ED.X module

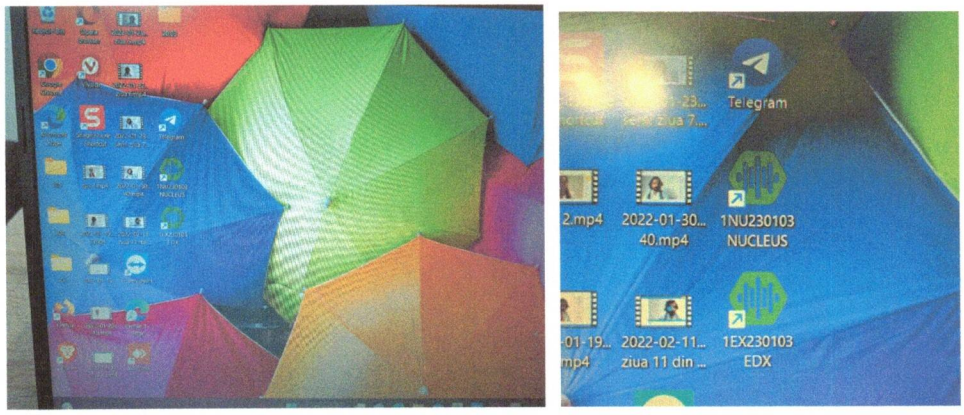


Figure 3 – The laptop display with softwares for biofeedback systems

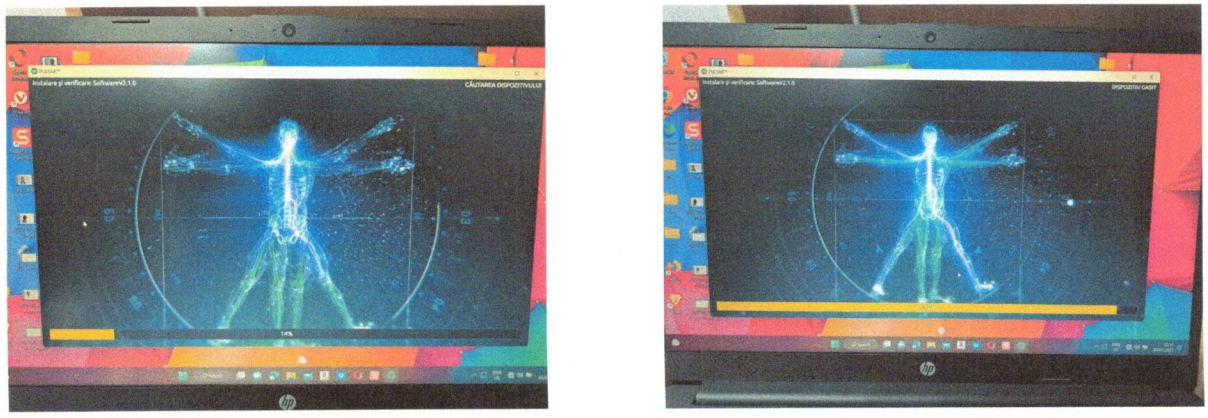


Figure 4 – Seek and discovery of device (ED.X module)

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021 SR EN 60601-2-10:2015 + A1:2017 SR EN 60601-2-26:2015	Results	Fulfilling the requirement

Figure 5 –Some informations on ED.X module display

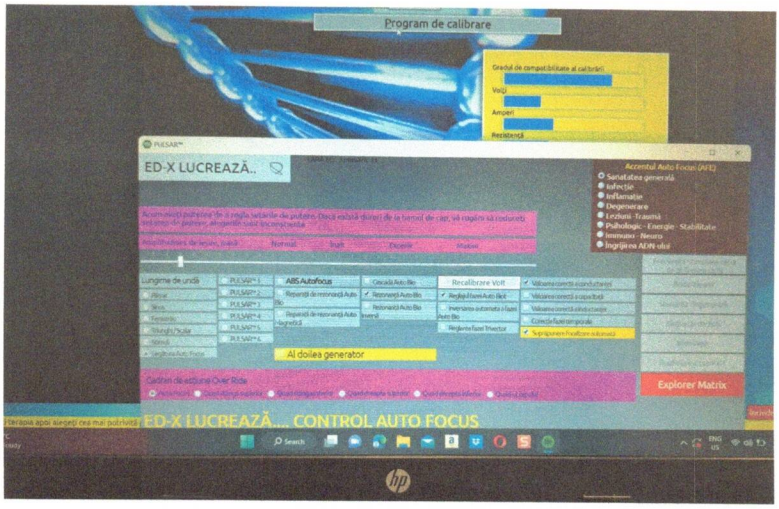


Figure 6 –ED.X module working

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021 SR EN 60601-2-10:2015 + A1:2017 SR EN 60601-2-26:2015	Results	Fulfilling the requirement

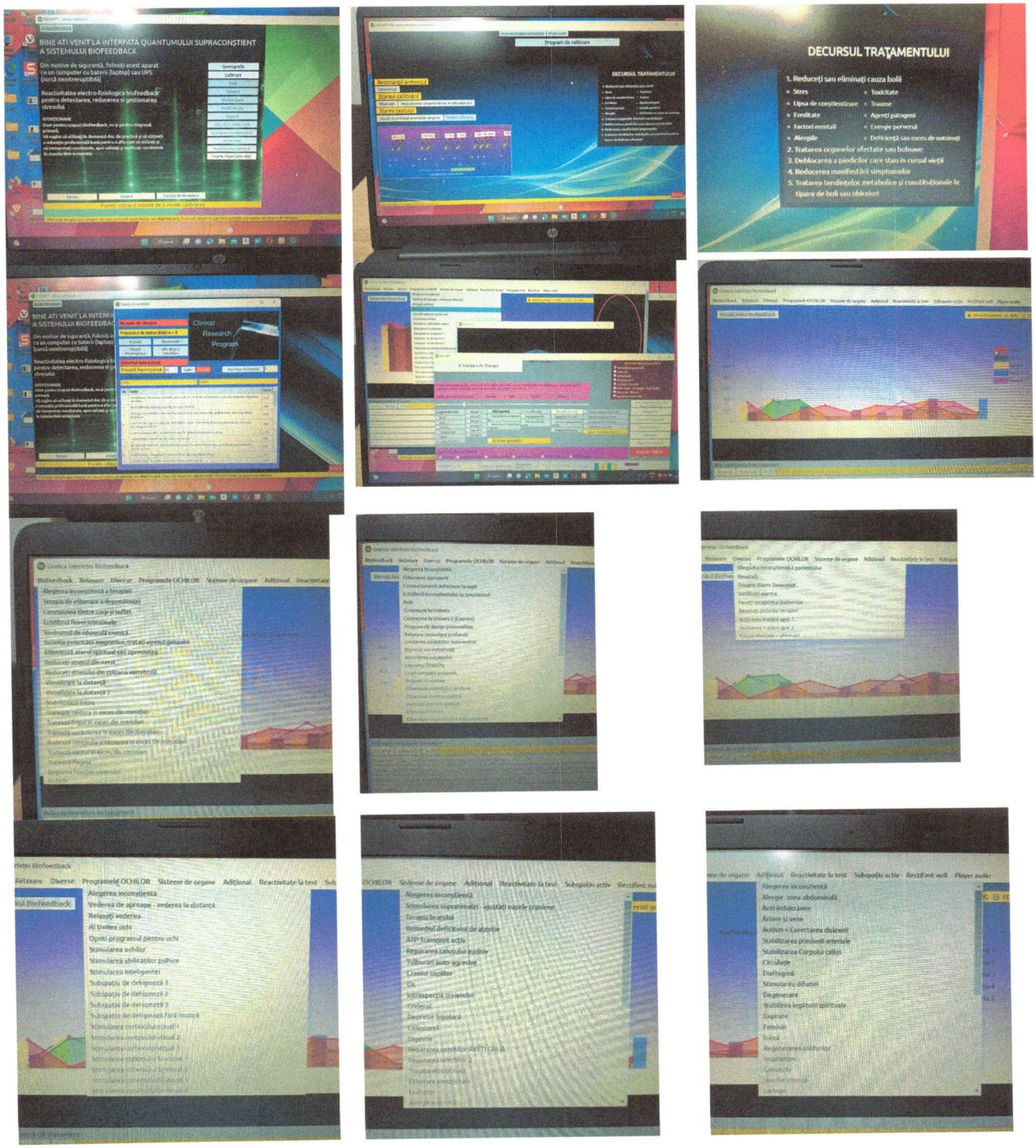


Figure 7 –Some informations on the laptop display

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021 SR EN 60601-2-10:2015 + A1:2017 SR EN 60601-2-26:2015	Results	Fulfilling the requirement

Table 1 – The sequence of testing according Annex B from SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015

No.	Test or inspection	Clause
B.1	General The tests can be performed independently: - "Radiation hazards " (clause 10) - "Biocompatibility " (clause 11.7) - "Usability " (clause 12.2) - "Alarm systems " (clause 12.3) - "Programmable ME Systems " (clause 14) - "Electromagnetic compatibility " (clause 17)	See also 5.8
B.2	Risk management process for ME equipment or ME systems and essential performance	4.2 + 4.3
B.3	General requirements	4.1 + 4.5...4.10 + 5.1...5.7
B.4	Classification of ME EQUIPMENT and ME SYSTEMS	6
B.5	Determination of applied parts and accessible parts	5.9
B.6	ME equipment identification, marking and documents	7.2....7.8.2
B.7	Energy consumption (power input)	4.11
B.8	Limitation of voltage, current or energy	8.4
B.9	Separation of parts	8.5.1 ... 8.5.4
B.10	Creepage distances and air clearances	8.9
B.11	HAZARDS associated with moving parts	9.2 fără 9.2.2.4.1
B.12	HAZARD associated with surfaces, corners and edges	9.3
B.13	Serviceability	15.2
B.14	Accuracy of controls and instruments and protection against hazardous outputs	12.1 + 12.4
B.15	Peric Instability hAZARDS	9.4
B.16	Noise, vibration and acoustic energy	9.6.2
B.17	Interruption of the power supply / supply mains to ME EQUIPMENT	11.8
B.18	Protective earthing, functional earthing and potential equalization of ME equipment	8.6
B.19	Excessive temperatures in ME EQUIPMENT	11.1
B.20 *Replace A1*	Leakage currents and patient auxiliary currents and dielectric strength at steady-state operating temperature	8.4.2 + 8.7 + 8.8.3
B.21	Humidity preconditioning treatment	5.7
B.22 *Replace A1*	Leakage currents AND patient auxiliary currents and dielectric strength after humidity preconditioning at ambient temperature in the laboratory	8.4.2 + 8.7 + 8.8.3
B.23	Defibrillation protection	8.5.5
B.24	Expelled parts hazard	15.3 + 9.2.2.4.1
B.25	Pressure vessels and parts subject to pneumatic and hydraulic pressure	9.7
B.26	Hazards associated with support systems	9.8
B.27	Mechanical strength	15.3 + 9.2.2.4.1
B.28	Hazardous situations and fault conditions	13
B.29	Mains supply transformers of ME equipment and transformers providing separation in accordance with 8.5	15.5
B.30	ME equipment components and general assembly	15.4 + 8.10
B.31	Mains parts, components and layout	8.11
B.32	Insulation other than wire insulation	8.8.4
B.33	Fire prevention and constructional requirements for fire enclosures of ME equipment	11.2 + 11.3
B.34	Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME equipment	11.6
B.35	Category AP and Category APG ME equipment	11.4
B.36	Verification of markings	7.1 + 7.2....7.8.2

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021 SR EN 60601-2-10:2015 + A1:2017 SR EN 60601-2-26:2015	Results	Fulfilling the requirement

Table 2 - Patient leakage currents and patient auxiliary currents

	type B applied part		type BF applied part		type CF applied part	
	Limit (μA) max.	Measured (μA)	Limit (μA) max.	Measured (μA)	Limit (μA) max.	Measured (μA)
Patient auxiliary current, in normal condition and d.c.	10	-	10	*1,9 **3,7 ***5,8	10	-
Patient auxiliary current, in normal condition and a.c.	100	-	100	-	10	-
Patient auxiliary current, in single fault condition and d.c.	50	-	50	* 10,5 **14	50	-
Patient auxiliary current, in single fault condition and a.c.	500	-	500	-	50	-
Patient leakage current from patient connection to earth, in normal condition and d.c.	10	-	10	*3,9 **6,1 ***7,3	10	-
Patient leakage current from patient connection to earth, in normal condition and a.c.	100	-	100	-	10	-
Patient leakage current from patient connection to earth, in single fault condition and d.c.	50	-	50	* 14,5 **21,8	50	-
Patient leakage current from patient connection to earth, in single fault condition and a.c.	500	-	500	-	50	-
Patient leakage current caused by an external voltage a SIP/SOP, in normal condition and d.c.	10	-	10	-	10	-
Patient leakage current caused by an external voltage a SIP/SOP, in normal condition and a.c.	100	-	100	-	10	-
Patient leakage current caused by an external voltage a SIP/SOP, in single fault condition and d.c.	50	-	50	-	50	-
Patient leakage current caused by an external voltage a SIP/SOP, in single fault condition and a.c.	500	-	500	-	50	-
Total patient leakage current with the same types of applied part connected together, in normal condition and d.c.	50	-	50	*9,1 **12,4	50	-
Total patient leakage current with the same types of applied part connected together, in normal condition and a.c.	500	-	500	-	50	-
Total patient leakage current with the same types of applied part connected together, in single fault condition and d.c.	100	-	100	* 20,1 **33	100	-
Total patient leakage current with the same types of applied part connected together, in single fault condition and a.c.	1000	-	1000	-	100	-
Total patient leakage current caused by an external voltage a SIP/SOP, in normal condition and d.c.	50	-	50	-	50	-
Total patient leakage current caused by an external voltage a SIP/SOP, in normal condition and a.c.	500	-	500	-	50	-
Total patient leakage current caused by an external voltage a SIP/SOP, in single fault condition and d.c.	100	-	100	-	100	-
Total patient leakage current caused by an external voltage a SIP/SOP, in single fault condition and a.c.	1000	-	1000	-	100	-

*before humidity treatment
** after humidity treatment
*** in the special case from 8.7.4.9, the maximum value.

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021 SR EN 60601-2-10:2015 + A1:2017 SR EN 60601-2-26:2015	Results	Fulfilling the requirement

Table 3 - Patient leakage currents under the special test conditions

	type B applied part		type BF applied part		type CF applied part	
	Limit (μA) max.	Measured (μA)	Limit (μA) max.	Measured (μA)	Limit (μA) max.	Measured (μA)
Patient leakage current caused by an external voltage on the patient connection of an F- type applied part to	NA	-	5000	-	50	-
Patient leakage current caused by an external voltage on a metal accessible part not protectively earthed to	500	-	500	-	NT	-
Total patient leakage current caused by an external voltage on the patient connection of an F- type applied part to	NA	-	5000	-	100	-
Total patient leakage current caused by an external voltage on a metal accessible part not protectively earthed to	1000	-	1000	-	NT	-

NA = not applicable ;
NT = not tested

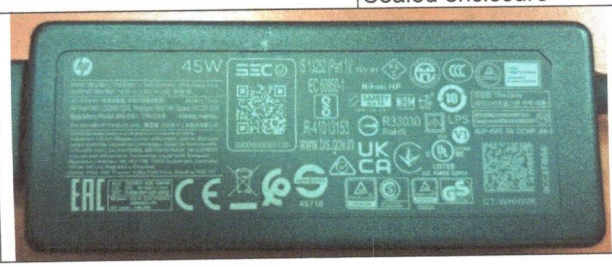
Table 4 – Touch currents

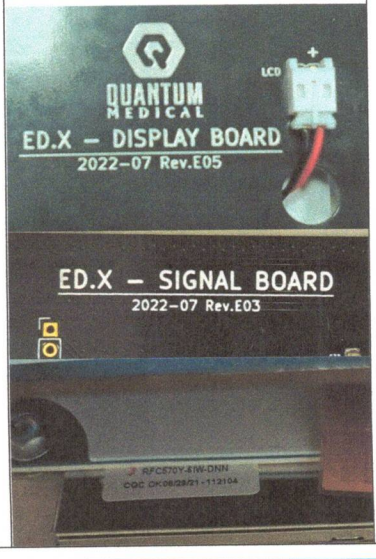
	Between ⇒ ⇓	Adapter enclosure		Laptop keyboard		Laptop display		ED.X enclosure		ED.X display	
		Limit (μA) max.	Measured (μA)	Limit (μA) max.	Measured (μA)	Limit (μA) max.	Measured (μA)	Limit (μA) max.	Measured (μA)	Limit (μA) max.	Measured (μA)
In normal condition and a.c. supply (for system)	AC mains	100	*74 **91	100	*55 **68	100	*57 **70	100	*39 **50	100	*41 **50
In normal condition and d.c. supply (only for the ED.X module)	USB connector	100	-	100	-	100	-	100	*8,2 **9,5	100	*8,3 **9,4
In single fault condition and a.c. supply (for system)	AC mains	500	*382 **415	500	*115 **177	500	*119 **182	500	*100 **128	500	*101 **131
In single fault condition and d.c. supply (only for the ED.X module)	USB connector	500	-	500	-	500	-	500	*37 **45	500	*39 **47

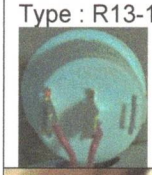
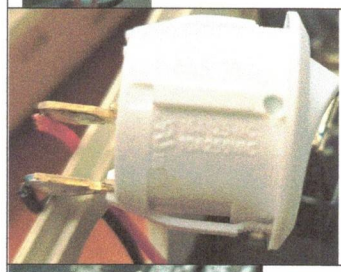
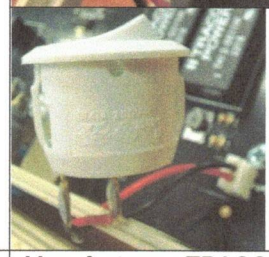
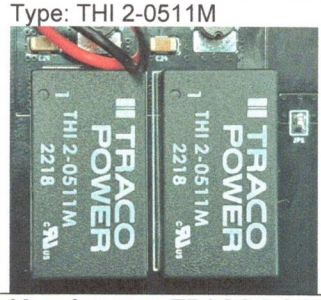
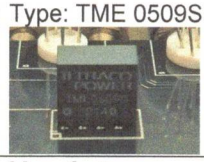
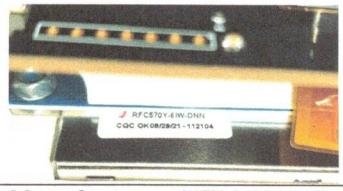
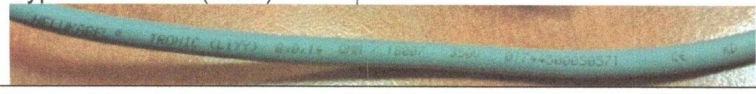
*before humidity treatment
** after humidity treatment

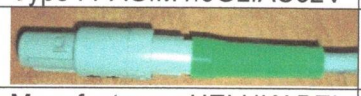
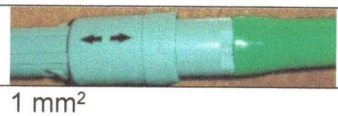
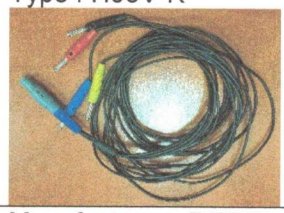
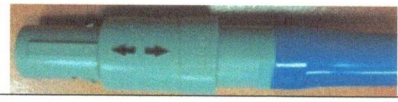
Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021 SR EN 60601-2-10:2015 + A1:2017 SR EN 60601-2-26:2015	Results	Fulfilling the requirement

Table 5 - safety components

No.	Component	Manufacturer /model /type	Datasheet	Observations
1	Detachable power cord			
	- plug	Manufacturer : LINETEK Type : LP-34 	16 A 250 V	KEMA KEUR, FI, N, D, S, DVE, CEBEC, NF, ÖVE, EAC
	- cable	Manufacturer : LINETEK Series : CABO FLEXiVEL Type : H03VV-F 	3 G 0,75 mm² 300 /300 V LIGHT DUTY	◄VDE► CEBEC KEMA-KEUR IEMMEQU FI, N, D, S öVE, S, ◄SABS► NF-USE-1336
	- socket-connector	Manufacturer : LINETEK Type : LS15 	2,5 A 250 V	DVE KEMA KEUR, FI, N, D, S, DVE, CEBEC, NF, ÖVE, EAC, S, SRBS
2	Adapter (power supply)	Manufacturer : HP Model : TPN-DA16 	Input U=100–240 V~;50–60 Hz I = 1,4 A Output U = 19,5 V_{dc} ; I = 2,31 A P =45 W For use with HP product only. For use with Information Technology Equipment. Energy performance : VI Recyclable Protection against short circuit, overvoltages, overtemperatures Sealed enclosure	UK CA, TÜVRheinland, GS, CERTIFICADO, Verified Energy Performance, NOM NYCE, UL LISTED, KC, EAC, SAFETY MARK

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021 SR EN 60601-2-10:2015 + A1:2017 SR EN 60601-2-26:2015	Results	Fulfilling the requirement
3	Laptop	Manufacturer : HP Model : 15-dw3043nq ID : 3C6P9EA	External input :19,5 Vdc; 2,31 A Processor : Intel® Core™ i3-1115G4 (4,1 GHz, Intel® Turbo Boost, 6 MB L3 cache, 2 core, graphic integrated processor (Intel® UHD Graphics)) 8 GB DDR4-2666 MHz RAM 256 GB PCIe® NVMe™ M.2 SSD 3-cell, 41 Wh Li-ion Battery (15.6") diagonal, FHD (1920 x 1080), anti-glare display Realtek RTL8821CE-M 802.11a/b/g/n/ac (1x1) Wi-Fi® and Bluetooth® 4.2 combo Integrated 10/100/1000 GbE LAN HP True Vision 720p HD camera with integrated dual array digital microphones multi-format SD media card reader 1 SuperSpeed USB Type-C® 5Gbps signaling rate; 2 SuperSpeed USB Type-A 5Gbps signaling rate; 1 HDMI 1.4b; 1 RJ-45; 1 AC smart pin; 1 headphone/microphone combo Recyclable ( )	EAC UK CA
			
4	Medical equipment	Manufacturer : **QUANTUM MEDICAL S.R.L.** Model : **NUCLEUS**	U_{supply} = 5 V_{dc} I_{supply} = maximum 0,5 A 3 main subassemblies: - Display board - Signal board - Display Connectivity: - with BF applied parts for biofeedback therapy (on lower limbs, upper limbs and head) connected to dedicated connectors (LIMB and HEAD) - optional, with applied parts the evaluating patient's condition (EEG type) - USB 3.0 Type B plug (power supply and communication)	Tested with system
			

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021 SR EN 60601-2-10:2015 + A1:2017 SR EN 60601-2-26:2015	Results	Fulfilling the requirement
	- roker switch	Manufacturer : SCI Type : R13-112 	
			16 A / 125 V_{ac} 10 A / 250 V_{ac}
			10 (4) A / 250 V~ μ 25T85
	- dc-dc converters	Manufacturer : TRACO POWER Type: THI 2-0511M 	U_{input} = 5 V_{dc} U_{output} = 5 V_{dc} P = 2 W
	- dc-dc converter	Manufacturer : TRACO POWER Type: TME 0509S 	U_{input} = 5 V_{dc} U_{output} = 9 V_{dc} P = 1 W
	- display	Manufacturer: RAYSTAR OPTRONICS Type: RFC570Y-6IW-DNN 	U = 3,0….. 3,6 V_{dc} (display) 9,0…..10,5 V_{dc} (backlight) I_{rated} = 140 mA (display) 140 mA (backlight) TFT LCD, white, transmissive Diagonal : 5,7 “ Resolution : 320 × 240 (RGB) Aspect Ratio : 4:3 Backlight : LED, white
5	Cable for applied part used on head	Manufacturer: HELUKABEL Type : TRONIC (LiYY) 	8 x 0,14 mm², shielded 350 V

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021 SR EN 60601-2-10:2015 + A1:2017 SR EN 60601-2-26:2015	Results	Fulfilling the requirement
6	Connector for applied part used on head	Manufacturer : REDEL Type : PAG.M1.0GL.AC52V 	10 contacts 	
7	Cable for applied parts used on LIMB	Manufacturer : HELUKABEL Type : H05V-K 	1 mm² U0/U : 300/500 V	IEMMEQU ◄HAR►
8	Connector for applied parts used on LIMB	Manufacturer : REDEL Type : PAG.M0.5GL.AC65A	5 contacts 	

Clause	Requirement according to SR EN 60601-1:2007 + A1:2014 + A1/AC:2014 + A12:2015 + AC:2015 + A2:2021 SR EN 60601-2-10:2015 + A1:2017 SR EN 60601-2-26:2015	Results	Fulfilling the requirement

MEASUREMENT UNCERTAINTY

Test name (clause)	Measured / calculated quantity	Measurement apparatus / type / series or inventory	Calibration certificate/ issuer	Extended uncertainty[U]	Coverage factor [k]
0	1	2	3	4	5
4.11; 5.5; 8.5.3; 8.7.1; 201.4.11* 201.12.4.101*	a.c. voltage	Digital multimeter METRAHIT tip 28S serial 049264	01.01 – 0536/16.12.2020 B.B.S.C. (LE024)	0,06 V	2
4.11; 5.5; 8.5.3; 8.7.1; 201.4.11*	Power	Digital multimeter (Power Meters) METRAHIT type 29 S serial SF 4229	3283/07.12.2020/ Arc Brasov (LE031)	0,1 W	2
4.11; 5.5; 8.5.3; 8.7.1; 201.4.11*	Frequency	Digital multimeter (Power Meters) METRAHIT type 29 S serial SF 4229	3283/07.12.2020/ Arc Brasov (LE031)	0,01 Hz	2
4.11; 8.7.1 201.4.11*	d.c. voltage	Digital multimeter METRAHIT tip 28S serial 049264	01.01 – 0536/16.12.2020 B.B.S.C. (LE024)	0,1 mV	2
4.11; 8.7.1 201.4.11*	d.c. current	Digital multimeter METRAHIT tip 28S serial 049264	01.01 – 0536/16.12.2020 B.B.S.C. (LE024)	0,7 mA	2
5.7	temperature	Climatic chamber KPK 1700 Seria 094/90042607	24201-11.22/25.11.2022 METROMAT(LE 008)	0,5 °C	2
	humidity			3,1 %	2
5.9.2.2	force	Dynamometer Correx, Serial 57605/56	04815-03.21/29.03.2021 METROMAT(LE 008)	0,115 N	2
5.9.2.2; 7.1.3; 11.8; 15.3.2 201.12.2.101* 201.11.6.3**	time	Digital timer DELTA E 200 Seria M200473	06187-05.20/27.05.2020 METROMAT(LE 008)	0,04 s	2
8.4.3 201.12.1.101* 201.12.1.102* 201.12.2.101* 201.12.4.101*	time	Osciloscop digital tip WaveSurfer 424 LCRY0301J15110	01.01 – 0400/15.02.2020 B.B.S.C. (LE024)	3 ms	2
201.12.1.101.1** 201.12.1.101.2** 201.12.1.101.3** 201.12.1.101.4** 201.12.1.101.5**	voltage			0,5 V	2
8.7.3	leakage currents	Digital multimeter METRAHIT tip 28S serial 049264	01.01 – 0536/16.12.2020 B.B.S.C. (LE024)	** 0,03 mA	2
8.7.4	leakage currents	Digital multimeter METRAHIT tip 28S serial 049264	01.01 – 0536/16.12.2020 B.B.S.C. (LE024)	** 0,5 µA	2
8.8.3 201.11.6.3**	a.c. voltage	Dielectric strength equipment WIP6 serial 42250	24358-11.22/29.11.2022 METROMAT (LE008)	0,09 kV	2
	time	Digital timer DELTA E 200 Serial M200473	06187-05.20/27.05.2020 METROMAT(LE 008)	0,04 s	2
8.9.1.1 201.7.9.2.101*	dimensions	Electronic caliper MIB Serial GX04080398	361/10.09.2020/ IPROEB Bistrita (LE 018)	0,018 mm	2
9.4.2.2, 201.7.9.2.101* 202.6.1.1.2*, 202.6.2.1.5* 201.11.6.3**, 202.6.1.1.2** 202.6.2.3.2**	inclined plane	Measuring Tape UNIOR type 710P Seria : MTM197987	01.01 - 826/12.10.2020 / INM (CIPM MRA)	** 0,2 °	2
11.1	temperature	Digital thermometer KIMO typeTM 200 serial 05100170 + thermocouples serie T1/8386/50	163/16.03.2021/ IPROEB Bistriţa (LE018)	0,12 °C	2
11.6.5	Accessibility (dimensions)	Electronic caliper MIB Serial GX04080398	361/10.09.2020/ IPROEB Bistrita (LE 018)	0,018 mm	2
	force	Dynamometer Correx, Serial 57605/56	04815-03.21/29.03.2021 METROMAT(LE 008)	0,115 N	2
15.3.2	force	compression / tensile dynamometer serial 1346	F-03/215/2021 GELUTECH (LE 012)	0,8 N	2
15.3.6	dry heat	Heat chamber MEMMERT type UNE 500 Serial C505.1076	24199-11.22/24.11.2022 METROMAT (LE008)	1,1 °C	2
For tests on 202.6.1*, 202.6.2*, 202.6.1** şi 202.6.2** see Test Report nº 35 / 2021.01.14 issued by OICPE-LICPE					

*** Note: Uncertainty composed according to measurement channel..
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%