



PERRY JOHNSON LABORATORY ACCREDITATION, INC.

Certificate of Accreditation

Perry Johnson Laboratory Accreditation, Inc. has assessed the Laboratory of:

ELETTRA S.r.l.

Via F. Matteucci, 10, 50041 Calenzano (FI), Italy

Via Meucci, 93, 50041 Calenzano (FI), Italy

(Hereinafter called the Organization) and hereby declares that Organization is accredited in accordance with the recognized International Standard:

ISO/IEC 17025:2017 & Meets the Requirements of the FDA Accreditation Scheme for Conformity Assessment (ASCA) Program

This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (as outlined by the joint ISO-ILAC-IAF Communiqué dated April 2017):

Acoustic, Electrical, Mechanical, and Thermal Testing *(As detailed in the supplement)*

Accreditation claims for such testing and/or calibration services shall only be made from addresses referenced within this certificate. This Accreditation is granted subject to the system rules governing the Accreditation referred to above, and the Organization hereby covenants with the Accreditation body's duty to observe and comply with the said rules.

For PJLA:

Tracy Szerszen
President

Initial Accreditation Date:

April 14, 2020

Issue Date:

March 23, 2022

Expiration Date:

June 30, 2024

Revision Date:

March 02, 2023

Accreditation No.:

106573

Certificate No.:

L22-294-R1

Perry Johnson Laboratory
Accreditation, Inc. (PJLA)
755 W. Big Beaver, Suite 1325
Troy, Michigan 48084

The validity of this certificate is maintained through ongoing assessments based on a continuous accreditation cycle. The validity of this certificate should be confirmed through the PJLA website: www.pjilabs.com



Certificate of Accreditation: Supplement

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 Via Meucci, 93, 50041 Calenzano (FI), Italy
 Dott. Ing. Lorenzo Spinelli Phone: +39 055-8827323

Accreditation is granted to the facility to perform the following testing:

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Electrical Thermal Mechanical Acoustic ^F	<p>Medical electrical equipment – General requirements for basic safety and essential performance</p> <p>Particular requirements for basic safety and essential performance of medical beds</p>	<p>General requirements (par. 4); General requirements for testing ME equipment (par. 5); Classification of ME equipment and ME systems (par. 6); ME equipment identification, marking and documents (par.7); Protection against electrical hazards from ME equipment (par.8) ; Protection against mechanical hazards of me equipment and me systems (par. 9); Radiation (par. 10) Excessive temperatures (par. 11); Accuracy of controls and instruments and protection against hazardous outputs (par. 12) Hazardous situations and fault conditions (par. 13); Programmable electrical medical system (par. 14) Construction of me equipment (par. 15); ME systems (par. 16) Electromagnetic compatibility (par. 17)</p>	<p>IEC 60601–1+A1+A2</p> <p>EN 60601–1+A11+A1+A2+AC+A12</p> <p>IEC 80601–2–60; EN 80601–2–60</p> <p>IEC 60601–2–52; EN 60601–2–52+A1</p>	<p>Visual examination</p> <p>Power/current absorption up to 63A 35kW</p> <p>Grounding and bonding Up to 12 V, current up to 60 A; 0.01 Ω to 0.5 Ω</p> <p>Leakage current 2μA to 5 000 mA Up to 95% of relative humidity</p> <p>Dielectric strength test: 500 V to 30 kV/50 Hz–50 Hz</p> <p>Clearance, creepage 0.01 mm to 1 m</p> <p>Speed 0.1m/s to 1 m/s</p> <p>Angle: 5° to 10°</p> <p>Force up to 250 N</p> <p>Acoustic noise up to 140 dBA</p> <p>Climatic chamber: –70 °C to 150 °C Data Recorder: –50 °C to 400 °C</p> <p>Fault condition up to 63A</p> <p>Pull force up to 100 N; Torque 0.35 Nm Up to 1 J Drop up to 1 m</p>



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Electrical ^F	Medical electrical equipment – Particular requirements for the basic safety and essential performance of nerve and muscle stimulators	General requirements (par. 201.4); General requirements for testing ME equipment (par. 201.5); Classification of ME equipment and ME systems (par. 201.6); ME equipment identification, marking and documents (par. 201.7); 201.12.4); Accuracy of controls and instruments and protection against hazardous outputs (par. 201.12) Accuracy of controls and instruments and protection against hazardous outputs (par. 201.13) HAZARDOUS SITUATIONS and fault conditions ; (par 201.14) PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS); (par. 201.15) Construction of ME EQUIPMENT; (par.) 201.16 ME SYSTEMS; (par)201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS; (par. 202) Electromagnetic compatibility – Requirements and tests	IEC 60601–2–10+A1 EN 60601–2–10 +A1	Voltage up to 1 000 V Currents up to 20 mA Frequency up to 10 MHz



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Electrical ^F	Medical electrical equipment Part 2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories	201.4 General requirements 201.5 General requirements for testing of ME EQUIPMENT 201.6 Classification 201.7 ME EQUIPMENT identification, marking and documents 201.8 Protection against electrical HAZARDS from ME EQUIPMENT 201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS 201.10 Protection against unwanted and excessive radiation HAZARDS 201.11 Protection against excessive temperatures and other HAZARDS 201.12 Accuracy of controls and instruments and protection against hazardous outputs 201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT 201.15 Construction of ME EQUIPMENT 201.16 ME SYSTEMS	IEC 60601-2-2 EN 60601-2-2 EN 60825-1 IEC 60825-1+AC+A11	Measurements with 500V from Insulation resistance 1 MΩ up to 199 MΩ Defibrillator discharge test up to 2 kV High frequency leakage current up to 300mA with frequency up to 10 MHz High frequency dielectric test with frequency 400 kHz and voltage up to 7000 V peak Flexing test with angle ± 45° High frequency output power up to 5000 W frequency up to 10 MHz Continuity test with current up to 5A



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Electrical Acoustic ^F	Medical electrical equipment – General requirements for safety – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	4 General requirements 5 ME EQUIPMENT identification marking and documents 6 ALARM SYSTEMS 6.1 ALARM CONDITION 6.2 Disclosures for INTELLIGENT ALARM SYSTEM 6.3 Generation of ALARM SIGNALS 6.4 Disclosure of delays 6.5 ALARM PRESETS 6.6 ALARM LIMIT 6.7 ALARM SYSTEM security 6.8 ALARM SIGNAL inactivation states 6.9 ALARM RESET 6.10 NON-LATCHING and LATCHING ALARM SIGNALS 6.11 DISTRIBUTED ALARM SYSTEM 6.12 ALARM CONDITION logging	IEC 60601-1-8+A1+A2 EN 60601-1-8+A1+A11+A2	Acoustic noise up to 140 dBA Time interval from 10 ms to 10 s



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Electrical ^F	<p>Medical electrical equipment – Medical electrical equipment Part 2: Particular requirements for basic safety and essential performance of electrocardiographs</p> <p>Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment</p> <p>Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems</p>	<p>201.4 General requirements 201.5 General requirements for testing of ME EQUIPMENT . 201.6 Classification of ME EQUIPMENT and ME SYSTEMS 201.7 ME EQUIPMENT identification, marking and documents 201.8 Protection against electrical HAZARDS from ME EQUIPMENT 201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS 201.10 Protection against unwanted and excessive radiation HAZARDS 201.11 Protection against excessive temperatures and other HAZARDS 201.12 Accuracy of controls and instruments and protection against hazardous outputs 201.13 HAZARDOUS SITUATIONS and fault conditions 201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) 201.15 Construction of ME EQUIPMENT</p>	<p>IEC 60601–2–25 EN 60601–2–25 IEC 60601–2–27 EN 60601–2–27 IEC 60601–2–47+A1; EN 60601–2–47+A1</p>	<p>Defibrillator discharge test up to 5 kV</p> <p>Performance verification by means of accuracy tests with voltage range AC from 0 mV to 5 mV and DC from 0 V to 5 V</p>



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Electrical ^F	<p>Medical electrical equipment – Medical electrical equipment Part 2: Particular requirements for basic safety and essential performance of electrocardiographs</p> <p>Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment</p> <p>Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems</p>	<p>201.4 General requirements 201.5 General requirements for testing of ME EQUIPMENT . 201.6 Classification of ME EQUIPMENT and ME SYSTEMS 201.7 ME EQUIPMENT identification, marking and documents 201.8 Protection against electrical HAZARDS from ME EQUIPMENT 201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS 201.10 Protection against unwanted and excessive radiation HAZARDS 201.11 Protection against excessive temperatures and other HAZARDS 201.12 Accuracy of controls and instruments and protection against hazardous outputs 201.13 HAZARDOUS SITUATIONS and fault conditions 201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) 201.15 Construction of ME EQUIPMENT</p>	<p>IEC 60601–2–25 EN 60601–2–25 IEC 60601–2–27, EN 60601–2–27 IEC 60601–2–47 EN 60601–2–47</p>	<p>Defibrillator discharge test up to 5 kV</p> <p>Performance verification by means of accuracy tests with voltage range AC from 0 mV to 5 mV and DC from 0 V to 5V</p>



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Electrical Climatic and Mechanical ^F	Medical electrical equipment – General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	4 general requirements 4.1 additional requirements for supply mains 4.2 environmental conditions 5 general requirements for testing 6 classification 7 me equipment identification, marking and documents 8 protection against excessive temperatures and other hazards 8.5 additional requirements for an internal electrical power source 9 accuracy of controls and instruments and protection against hazardous outputs 10 construction of me equipment 10.1 additional requirements for mechanical strength 10.1.1 general requirements for mechanical strength 10.1.2 requirements for mechanical strength for non-transit-operable me equipment 10.1.3 requirements for mechanical strength for transit-operable me equipment 10.2 additional requirements for actuating parts of controls of me equipment 11 protection against strangulation or asphyxiation 12 additional requirements for electromagnetic emissions of me equipment and me systems 13 additional requirements for alarm systems of me equipment and me systems	IEC 60601-1-11+A1 EN 60601-1-11+A1	Max acceleration 30 g Max sinusoidal force 6670 N peak Max random force 5340 N rms Max Shock 50,8 mm.peak to peak Max Speed 1.78 m/s peak Static load 160 kg Climatic chamber: -50 °C to 70 °C Relative humidity from 10% to 95% IP grade IPX1 and IPX2 Power/current absorption up to 63A 35kW



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Electrical Thermal, Mechanical Acoustic ^F	<p>Safety requirements for electrical equipment for measurement, control and laboratory use Part 1: General requirements</p> <p>Part 2-032: Particular requirements for hand-held and hand-manipulated current sensor for electrical test and measurement</p> <p>Part2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials</p> <p>Part2-051: Particular requirements for laboratory equipment for mixing and stirring</p> <p>Part2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment</p> <p>Part2-033: Particular requirements for hand-held multimeters and other hand-held meters, for domestic and professional use, capable of measuring mains voltage</p> <p>Part 2-030: Particular requirements for testing and measuring circuits</p> <p>Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes</p> <p>Part 2-020: Particular requirements for laboratory centrifuges</p>	<p>4.4 Testing in SINGLE FAULT CONDITION</p> <p>5 Marking and documentation</p> <p>6 Protection against electric shock</p> <p>7 Protection against mechanical HAZARDS .</p> <p>8. Resistance to mechanical stresses</p> <p>9 Protection against the spread of fire</p> <p>10 Equipment temperature limits and resistance to heat</p> <p>11 Protection against HAZARDS from fluids</p> <p>12 Protection against radiation, including laser sources, and against sonic and</p> <p>13 Protection against liberated gases and substances, explosion and implosion</p> <p>14 Components and subassemblies</p> <p>15 Protection by interlocks</p> <p>16 HAZARDS resulting from</p>	<p>IEC 61010-1:2010/+1</p> <p>EN 61010-1:2010+A1</p> <p>IEC61010-2-032</p> <p>EN 61010-2-032 +A11</p> <p>IEC 61010-2-040;</p> <p>EN 61010-2-040</p> <p>IEC 61010-2-051;</p> <p>IEC 61010-2-051</p> <p>EN 61010-2-051</p> <p>IEC 61010-2-101;</p> <p>IEC 61010-2-101</p> <p>EN 61010-2-101;</p> <p>EN 61010-2-101;</p> <p>IEC 61010-2-101</p> <p>IEC 61010-2-033;</p> <p>EN 61010-2-033+A11</p>	<p>Visual examination</p> <p>Power/current absorption up to 63A 35kW</p> <p>Grounding and bonding Up to 12 V, current up to 60A; 0.01 Ω to 0.5 Ω</p> <p>Leakage current 2μA to 5000 mA</p> <p>Up to 95% of relative humidity</p> <p>Dielectric strength test with voltage range from 500V to 30 kV and frequency 50 Hz and 60 Hz</p> <p>Clearance, creepage 0.01 mm to 1 m</p> <p>Speed 0,1 to 1m/s</p> <p>Angle: 5° to 10°</p> <p>Force up to 250N</p> <p>Acoustic noise up to 140 dBA</p> <p>Climatic chamber: -70 °C to 150 °C</p> <p>Data Recorder: -50 °C to 400 °C</p> <p>Fault condition up to 63A</p> <p>Pull force up to 100 N; Torque 0.35 Nm Up to 1 J Drop up to 1m</p> <p>Pressure test up to 100 bar</p>



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Electrical Thermal, Mechanical Acoustic ^F	Part2-010: Particular requirements for laboratory equipment for the heating of materials	4.4 Testing in SINGLE FAULT CONDITION 5 Marking and documentation 6 Protection against electric shock 7 Protection against mechanical HAZARDS . 8. Resistance to mechanical stresses 9 Protection against the spread of fire 10 Equipment temperature limits and resistance to heat 11 Protection against HAZARDS from fluids 12 Protection against radiation, including laser sources, and against sonic and 13 Protection against liberated gases and substances, explosion and implosion 14 Components and subassemblies 15 Protection by interlocks 16 HAZARDS resulting from	IEC 61010-2-030; IEC 61010-2-030/Ec1 EN 61010-2-030 IEC 61010-2-030 EN 61010-2-030/A11 IEC 61010-2-81 EN 61010-2-81; IEC 61010-2-081 EN IEC 61010-2-081 IEC 61010-2-020; EN 61010-2-020 IEC 61010-2-020; EN 61010-2-020 IEC 61010-2-010 EN IEC 61010-2-010;	Visual examination Power/current absorption up to 63 A 35 kW Grounding and bonding Up to 12 V, current up to 60A; 0.01 Ω to 0.5 Ω Leakage current 2 μA to 5000 mA Up to 95% of relative humidity Dielectric strength test with voltage range from and frequency 50 Hz and 60 Hz Clearance, creepage 0.01 mm to 1 m Speed 0.1 m/s to 1 m/s Angle: 5° to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: -70 °C to 150 °C Data Recorder: -50 °C to 400 °C Fault condition up to 63 A Pull force up to 100 N; Torque 0.35 Nm Up to 1 J Drop up to 1m Pressure test up to 100 bar



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Electrical Thermal, Mechanical Acoustic ^F	<p>Safety requirements for electrical equipment for measurement, control and laboratory use</p> <p>Part 1: General requirements</p> <p>Part 2-032: Particular requirements for hand-held and hand-manipulated current sensor for electrical test and measurement</p> <p>Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials</p> <p>Part 2-051: Particular requirements for laboratory equipment for mixing and stirring</p> <p>Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment</p> <p>Part 2-033: Particular requirements for hand-held multimeters and other hand-held meters, for domestic and professional use, capable of measuring mains voltage</p> <p>Part 2-030: Particular requirements for testing and measuring circuits</p> <p>Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes</p> <p>Part 2-020: Particular requirements for laboratory centrifuges</p>	<p>4.4 Testing in SINGLE FAULT CONDITION</p> <p>5 Marking and documentation</p> <p>6 Protection against electric shock</p> <p>7 Protection against mechanical HAZARDS .</p> <p>8. Resistance to mechanical stresses</p> <p>9 Protection against the spread of fire</p> <p>10 Equipment temperature limits and resistance to heat</p> <p>11 Protection against HAZARDS from fluids</p> <p>12 Protection against radiation, including laser sources, and against sonic and</p> <p>13 Protection against liberated gases and substances, explosion and implosion</p> <p>14 Components and subassemblies</p> <p>15 Protection by interlocks</p> <p>16 HAZARDS resulting from</p>	<p>IEC 61010-1+A1</p> <p>EN 61010-1+A1</p> <p>IEC 61010-2-032</p> <p>EN 61010-2-032+A11</p> <p>IEC 61010-2-040; EN 61010-2-040</p> <p>IEC 61010-2-051; EN 61010-2-051</p> <p>IEC 61010-2-101; EN 61010-2-101;</p> <p>IEC 61010-2-033; EN 61010-2-033</p>	<p>Visual examination</p> <p>Power/current absorption up to 63A 35kW</p> <p>Grounding and bonding Up to 12 V, current up to 60A; 0.01 Ω to 0.5 Ω</p> <p>Leakage current form 2 μA to 5000 mA Up to 95% of relative humidity</p> <p>Dielectric strength test with voltage range from and frequency 50 Hz and 60 Hz</p> <p>Clearance, creepage 0.01 mm to 1 m Speed 0.1 m/s to 1m/s</p> <p>Angle: 5° to 10°</p> <p>Force up to 250 N</p> <p>Acoustic noise up to 140 dBA</p> <p>Climatic chamber: -70 °C to 150 °C Data Recorder: -50 °C to 400 °C</p> <p>Fault condition up to 63 A</p> <p>Pull force up to 100 N; Torque 0.35 Nm Up to 1 J Drop up to 1 m</p> <p>Pressure test up to 100 bar</p>



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Electrical, Thermal, Mechanical Acoustic ^F	Audio/Video, information and communication technology equipment Part 1: safety requirements	4. General requirements 5 Electrically-caused injury 6 Electrically-caused fire 7 Injury caused by hazardous substances 8 Mechanically-caused injury 9 Thermal burn injury 10 Radiation	IEC 62368-1 EN 62368-1 EN 62368-1+A11;	Visual examination Power/current absorption up to 63A 35kW Grounding and bonding Up to 12 V, current up to 60A; 0.01 Ω to 0.5 Ω Leakage current 2μA to 5000mA Up to 95% of relative humidity Dielectric strength test with voltage range from 500V to 30 kV and frequency 50 Hz and 60 Hz Clearance, creepage 0.01 mm to 1 m Speed 0.1 m/s to 1m/s Angle: 5 °to 10° Force up to 250 N Acoustic noise up to 140 dBA Climatic chamber: -70 °C to 150 °C Data Recorder: -50 °C to 400 °C Fault condition up to 63 A Pull force up to 100 N; Torque 0.35 Nm Up to 1 J Drop up to 1 m



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Verification tests of the degree of protection of enclosures ^F	Equipment enclosures and electrical components	Grado IP/IP Grade 1X, 2X, 3X, 4X, 5X, 6X, X1, X2, X3, X4;X5; X6; X7	IEC 60529+A1+A2 EN 60529+A1+A2	Water flow from 1mm/min to 100l/min Probes diameter: 50 mm to 1 mm Depression of enclosures 20mbar
Mechanical testing of vibrations and shocks ^F	Electrical and electronic equipment and components	Prove di vibrazione sinusoidali Sinusoidal vibration tests Prove di vibrazioni random Random vibration tests Prove di urto Impact tests	IEC 60068-1 EN 60068-1 IEC 60068-2-27 EN 60068-2-27 IEC 60068-2-64/A1 EN 60068-2-64 IEC 60068-2-6 EN 60068-2-6 IEC 60068-2-47 EN 60068-2-47 EN 50155 IEC 61373 EN 61373 EN 50125-3 IS 402: ASTM 4169	Max acceleration 30g Max sinusoidal force 6670 N peak Max random force 5340 N rms Max Shock 50,8 mm.peak-peak Max Speed 1.78 m/s peak Static load 160 Kg



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Electromagnetic Compatibility ^F	Electrical lighting and similar equipment	Immunity tests to radiofrequency electromagnetic field; magnetic fields at mains frequency; injected currents; bursts, surge, dips, esd	IEC 61547+A1; IEC 61547, EN 61547+A1, EN 61547	Electromagnetic fields 3 V/m in the frequency range from 80 MHz to 2700 MHz Magnetic field at 50/60 Hz with level 3 A/m RF currents from 150 kHz to 80 MHz with level 3V
	Household appliances, electric tools and similar apparatus	Immunity tests to Radiated em fields, conducted rf currents, burst, surge, ESD and dips Conducted emission tests	CISPR 14-2+A1+A2;; CISPR 14-2 CISPR 14-2; EN 55014-2+A1: IS1/A2; EN 55014-2 EN 55014-2	Electromagnetic fields 3 V/m in the frequency range from 80 MHz to 1000 MHz RF currents from 150 kHz to 230 MHz with level up to 3V Burst and fast transient up to 4 KV Surge up to 4 KV ESD up to 30 KV Conducted emissions in the frequency range 150 kHz to 30 MHz Immunity to dips and voltage variations from 10 ms to 5 s



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Electromagnetic Compatibility ^F	Electrical equipment for measurement, control and laboratory use	Immunity to electromagnetic Radiated fields, injected rf currents, magnetic fields at mains frequency, burst, surge, ESD and dips Conducted emission tests	IEC 61326-1, EN 61326-1	Electromagnetic fields 10 V/m in the frequency range from 80 MHz to 2700 MHz RF currents from 150 kHz to 80 MHz with level up to 10 V Magnetic field at 50/60 Hz with level up to 30A/m Burst and fast transient up to 4 KV Surge up to 4 KV ESD up to 30 KV Conducted emissions in the frequency range 150 kHz to 30 MHz Immunity to dips and voltage variations from 10ms to 5s Radiated emission tests from 30 MHz to 6 GHz



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Electromagnetic Compatibility ^F	Medical electrical equipment	Identification, marking and documents (par. 5); Measurements of harmonic and flicker emissions and immunity tests to electromagnetic Radiated fields, injected rf currents, magnetic fields at mains frequency, burst, surge, ESD and dips Conducted and radiated emission tests (par. 6, 7, 8, 9)	IEC 60601-1-2+A1 EN 60601-1-2+A1	Electromagnetic fields up to 28V/m in the frequency range from 80 MHz to 6000 MHz RF currents from 150 kHz to 80 MHz with level up to 10 V Magnetic field at frequency 50 Hz and 60 Hz with level up to 30 A/m Burst and fast transient up to 4 KV Surge up to 4 KV ESD up to 30 KV Conducted emissions in the frequency range 150 kHz to 30 MHz Immunity to dips and voltage variations from 10ms to 5s Radiated emission tests from 30 MHz to 6 GHz
Electromagnetic Compatibility Tests ^{FO}	Electrosensitive protective equipment	immunity tests to electromagnetic Radiated fields, injected rf currents, magnetic fields at mains frequency, burst, surge, ESD and dips	IEC 61496-1+A1, IEC 61495-1 EN 61496-1+ A1, EN 61496-1	RF currents from 150 kHz to 80 MHz with level up to 20V Magnetic field at frequency 50 Hz and 60 Hz with level up to 100A/m Burst and fast transient up to 4 KV Surge up to 4 KV Esd up to 30 KV Conducted emissions in the frequency range 150 kHz to 30 MHz Immunity to dips and voltage variations from 10 ms to 5 s



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Electromagnetic Compatibility Tests ^{FO}	Railway applications – Electromagnetic compatibility Part 4: Emission and immunity of the signalling and telecommunications apparatus	Immunity to electromagnetic fields (2.1, 2.2) Immunity to magnetic fields at line frequency (2.3); Immunity to radiofrequency common mode currents (3.1; 4.1; 5.1; 6.1) Immunity to burst, surge, ESD and dips Conducted emission test	EN 50121-4+A1,	Electromagnetic fields up to 20 V/m in the frequency range from 80 MHz to 6000MHz RF currents from 150 kHz to 80 MHz with level up to 10 V Magnetic field at frequencies 0 Hz, 15.7 Hz and 50 Hz with level up to 300 A/m Burst and fast transient up to 4 KV Surge up to 4 KV Esd up to 30 KV Conducted emissions in the frequency range 150 kHz to 30 MHz Immunity to dips and voltage variations from 10 ms to 5 s Radiated emission tests from 30 MHz to 6 GHz



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Electromagnetic Compatibility Tests ^F	Appliances for railway applications – Fixed power supply installations and apparatus	Immunity tests to electromagnetic fields Immunity to magnetic fields at line frequency; Immunity to radiofrequency common mode currents Immunity to burst, surge, ESD and dips Conducted emission test	EN 50121-5+A1	Electromagnetic fields up to 20 V/m in the frequency range from 80 MHz to 6000MHz RF currents from 150 kHz to 80 MHz with level up to 10 V Magnetic field at frequencies 0, 15,7Hz and 50 Hz with level up to 300A/m Burst and fast transient up to 4 KV Surge up to 4 KV ESD up to 30 KV Conducted emissions in the frequency range 150 kHz to30 MHz Immunity to dips and voltage variations from 10 ms to 5 s Radiated emission tests from 30 MHz to 6 GHz



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Electromagnetic Compatibility Tests ^F	Railway applications – Electromagnetic compatibility Part 3-2: Rolling stock – Apparatus	Immunity tests to electromagnetic fields Immunity to magnetic fields at line frequency; Immunity to radiofrequency common mode currents Immunity to burst, surge, ESD and dips Conducted emission test	EN 50121-3-2+ A1	Electromagnetic fields up to 20 V/m in the frequency range from 80 MHz to 6 000MHz RF currents from 150 kHz to 80 MHz with level up to 10 V Burst and fast transient up to 4 KV Surge up to 4 KV ESD up to 30 KV Conducted emissions in the frequency range 150 kHz to 30 MHz Immunity to dips and voltage variations from 10 ms to 5 s Radiated emission tests from 30 MHz to 6 GH
Electromagnetic Compatibility Tests ^{FO}	Electric and electronic equipment for industrial environments	Immunity to electromagnetic fields Immunity to magnetic fields at line frequency; Immunity to radiofrequency common mode currents Immunity to burst, surge, ESD and dips Conducted emission test	IEC 61000-6-2 EN 61000-6-2	Electromagnetic fields up to 10 V/m in the frequency range from 80 MHz to 6 000 MHz RF currents from 150 kHz to 80 MHz with level up to 10 V Magnetic field at frequencies 50 Hz and 60 Hz with level up to 10 A/m Burst and fast transient up to 4 KV Surge up to 4 KV ESD up to 8 KV Conducted emissions in the frequency range 150 kHz to 30 MHz Immunity to dips and voltage variations from 10 ms to 5s



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Electromagnetic Compatibility Tests ^F	Electric and electronic equipment for residential, commercial and light-industrial environments	Immunity to electromagnetic fields Immunity to magnetic fields at line frequency; Immunity to radiofrequency common mode currents Immunity to burst, surge, ESD and dips Conducted emission test	IEC 61000-6-1, EN 61000-6-1	Electromagnetic fields up to 3 V/m in the frequency range from 80 MHz to 6000 MHz RF currents in the frequency range from 150 kHz to 80 MHz with level up to 3 V Magnetic field at 50/60 Hz with level up to 3 A/m Burst and fast transient up to 4 KV Surge up to 4 KV ESD up to 8 KV Conducted emissions in the frequency range 150 kHz to 30 MHz Immunity to dips and voltage variations from 10 ms to 5 s Radiated emission tests from 30 MHz to 6GHz
	Apparecchiature multimediali/Multimedia equipment	Immunity tests to continuous rf disturbances; Power frequency magnetic fields; broadband impulsive conducted disturbances; Immunity to burst, surge, ESD and dips	CISPR35; EN 55035+A11 ETSI 301 489-1	Electromagnetic fields up to 3 V/m in the frequency range from 80 MHz to 6 000 MHz RF currents in the frequency range from 150 kHz to 80 MHz with level up to 3 V Magnetic field with level up to 3 A/m at frequencies 50 Hz and 60 Hz Burst and fast transient up to 4 KV Surge up to 4 KV ESD up to 8 KV Immunity to dips and voltage variations from 10 ms to 5 s Radiated emission tests from 30 MHz to 6 GHz



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Electromagnetic Compatibility Tests ^{FO}	Adjustable speed electrical power drive system	Immunity tests to continuous rf disturbances; Power frequency magnetic fields ; broadband impulsive conducted disturbances Immunity to burst, surge, ESD and dips Conducted emission test	IEC 61800-3+A1; EN 61800-3 +A1	Electromagnetic fields up to 10 V/m in the frequency range from 80 MHz to 1000 MHz RF currents from 150 kHz to 80 MHz with level up to 10 V Magnetic field with level up to 30A/m at frequencies 50 Hz and 60 Hz Burst and fast transient up to 4 KV Surge up to 4 KV ESD up to 8 KV Immunity to dips and voltage variations from 10ms to 5s Conducted emissions in the frequency range 150 kHz to 30 MHz Radiated emission tests from 30 MHz to 6 GHz



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Electromagnetic Compatibility Tests ^F	Programmable controllers	Immunity tests to electromagnetic fields, rf injected currents, magnetic fields Immunity to burst, surge, ESD and dips Conducted emission test	IEC 61131-2; EN 61131-2	Electromagnetic fields up to 10 V/m in the frequency range from 80 MHz to 2700 MHz RF currents from 150 kHz to 80 MHz with level up to 10 V Burst and fast transient up to 4 KV Surge up to 4 KV ESD up to 8 KV Immunity to dips and voltage variations from 10 ms to 5 s Conducted emissions in the frequency range 150 kHz to 30 MHz Radiated emission tests from 30 MHz to 6 GHz
	Road traffic signal systems	Immunity tests to electromagnetic fields, rf injected currents, magnetic fields Immunity to burst, surge, ESD and dips	EN 50293, EN 50293	Electromagnetic fields up to 10 V/m in the frequency range from 80 MHz to 2700 MHz RF currents from 150 kHz to 80 MHz with level up to 10 V Magnetic field with level up to 30A/m at frequencies 50 Hz and 60 Hz Burst and fast transient up to 4 KV Surge up to 4 KV ESD up to 8KV Immunity to dips and voltage variations from 10ms to 5s Radiated emission tests from 30 MHz to 6 GHz



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Electromagnetic Compatibility Tests ^F	Alarm systems, components of fire, intruder and social alarm systems	Immunity tests to electromagnetic fields, rf injected currents Immunity to burst, surge, ESD and dips	EN 50130-4+A1+A2, EN 50130-4+A1+A2	Electromagnetic fields up to 10 V/m in the frequency range from 80 MHz to 2700 MHz RF currents from 150 kHz to 80 MHz with level up to 10 V Burst and fast transient up to 4 KV Surge up to 4 KV ESD up to 8KV Immunity to dips and voltage variations from 10ms to 5s Radiated emission tests from 30 MHz to 6 GHz
	Uninterruptible power systems (UPS) Part 2: Electromagnetic compatibility (EMC) requirements	Immunity tests to electromagnetic fields, rf injected currents, magnetic fields	IEC 62040-2; EN 62040-2	Electromagnetic fields up to 10 V/m in the frequency range from 80 MHz to 2700 MHz RF currents from 150 kHz to 80 MHz with level up to 10 V Magnetic field with level up to 30A/m at frequencies 50 Hz and 60 Hz Burst and fast transient up to 4 KV Surge up to 4 KV ESD up to 8KV Immunity to dips and voltage variations from 10ms to 5s Conducted emission tests in the frequency range 150-30MHz Radiated emission tests from 30 MHz to 6 GHz



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Electromagnetic Compatibility Tests ^F	Electromedical equipment, industrial equipment, information technology, lighting equipment, household appliances	Immunity to the electromagnetic field Radiated with radiofrence	EN 61000-4-3+A1+A2 IEC 61000-4-3+A1+A2	Electromagnetic fields 80MHz to 6GHz 20Vm max
		Immunity to rf current	EN 61000-4-6 IEC 61000-4-6	Rf currents from 150 kHz-80 MHz Voltage level up to 30 V
		Immunity to ESD	EN 61000-4-2 IEC 61000-4-2	Electrostatic discharge test in air and contact from ±1 kV to ±15 kV
		Immunity to Bursts/fast transient	IEC 61000-4-4+A1+A2 EN 61000-4-4:+A1+A2	Immunity to burst/fast transients up to 4 KV, 100 KHz
		Immunity to Surge	IEC 61000-4-5:+A1, EN 61000-4 5:+A1	Immunity to surge up to 4 KV
		Immunity to dips and voltage variations	IEC 61000-4-11:A1 IEC 61000-4-11+A1 EN 61000-4-11:+A1	Immunity to dips and voltage variation
		Harmonic current emissions	EN 61000-3-2:+A1+A2 IEC 61000-3-2+A1+A2	Max current 16 A



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Electromagnetic Compatibility Tests ^{FO}	Electromedical equipment, industrial equipment, information technology, lighting equipment, household appliances	Flicker measurement (parameters pst, plt, dt, dc, dmax)	EN 61000-3-3+ A1 IEC 61000-3-3+A1+A2	Max current 16 A
	Electromedical equipment, industrial equipment, information technology, lighting equipment, household appliances	Immunity to magnetic fields	EN 61000-4-8 IEC 61000-4-8	100A/m
Measurement of conducted electromagnetic disturbance ^{FO} and measurement of radiated electromagnetic disturbance ^F	Luminaries and associated products	Conducted emission tests	CISPR 15+/A1; CISPR 15	Voltage disturbances in the frequency range 9 kHz to 30 MHz Radiated emission tests from 30 MHz to 6 GHz
	Household appliances, electric tools and similar apparatus	Radiate emission tests	EN 55015+A1 EN 55015+A11 CISPR 14-1; CISPR 14-1 EN55014-1 CISPR 32; EN 55032:2015+ A1 ETSI 301 489-1 CISPR 11+A1 EN 55011+A1	
	Electronic appliances			
	Industrial, scientific and medical appliances			
Electric and electronic equipment for residential, commercial and light-industrial environments		Conducted emission tests	IEC 61000-6-3+A1 IEC 61000-6-3 IEC 61000-6-8 IEC 61000-6-3+A1 EN 61000-6-3 EN 61000-6-8	Conducted emissions in the frequency range 150 kHz to 30 MHz
		Harmonics		Harmonics on power line
		Flicker		Flicker on power line
		Emission tests		Radiated emission tests from 30 MHz to 6 GHz



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Measurement of conducted electromagnetic disturbance ^{FO} and measurement of radiated electromagnetic disturbance ^F	Electric and electronic equipment for industrial environments	Conducted emission tests Harmonics Flicker Radiated emission tests	IEC 61000-6-4A1, IEC 61000-6-4 EN 61000-6-4/A1 EN 61000-6-4	Conducted emissions in the frequency range 150 kHz to 30 MHz Harmonics on power line Flicker on power line Radiated emission tests from 30 MHz to 6 GHz
Electrical, Mechanical and Laser Radiation Measurement ^F	Medical electrical equipment Part 2: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment	201.4 General requirements 201.5 General requirements for tests 201.6 Classification 201.7 Identification, nameplate data and documentation 201.8 Protection against electrical HAZARDS 201.9 Protection against MECHANICAL HAZARDS 201.10 Protection against undesirable and excessive radiation HAZARDS 201.11 Protection against excessive temperatures and other DANGERS 201.12 Accuracy of controls and instruments and protection against hazardous emissions dangerous emissions 201.13 DANGER SITUATIONS and failure conditions 201.14 PROGRAMMABLE ELECTROMEDICAL SYSTEMS (PEMS) 201.15 Construction 201.16 EM SYSTEMS 201.17 Electromagnetic compatibility	IEC/60601-2-22 IEC 60601-2-22/A1 EN 60601-2-22 EN 60601-2-22:/A1	Force up to 200 N Laser power measurements up to 30 W



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Effective use of Radio Spectrum ^F	Radio equipment : Short Range Devices Wideband transmission Systems	Radio tests : Conducted power: Spectrum analyzer method Power meter method Radiated power: Anechoic chamber + Spectrum analyzer method	ETSI 300 328 ETSI 300 220 ETSI 300 440	Frequency range: 9 kHz to 30 GHz
Electrical Safety Tests ^{FO}	Control panels and machine electrical equipments	Dielectric strength test Insulation Residual voltage Temperature Grounding and bonding	IEC 61439-1 EN 61439-1 IEC 61439-2; EN 61439-2 IEC 60204-1 IEC 60204-1/A1 EN 60204-1 EN 60204-1/A1	Dielectric strength up to 30 KV Grounding and bonding up to 60A Insulation resistance up to 1000 V Residual voltage on supply and internal capacitive circuits Temperature test up to 300 °C
	UPS; Power electronic converter DC power supply	Dielectric strength test Insulation Residual voltage Temperature Grounding and bonding Leakage test	IEC 62040-1 EN 62040-1 : /AC EN 62477-1 +A11+A1+A12 IEC 61204-7 EN 61204-7	Dielectric strength up to 6 kV Grounding and bonding up to 60 A Insulation resistance up to 1000 V Residual voltage on supply and internal capacitive circuits Temperature test up to 300 °C Leakage current from 0.1 mA to 1000 mA



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Electrical; Optical ^F	Medical electrical equipment of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use Luminaries	201.4 General requirements 201.5 General requirements for testing 201.6 Classification of me equipment and ME SYSTEMS 201.7 identification, marking and documents 201.8 Protection against electrical HAZARDS from ME EQUIPMENT 201.9 Protection against mechanical HAZARDS of me equipment and ME SYSTEMS 201.10 Protection against unwanted and excessive radiation HAZARDS 201.11 Protection against excessive temperatures and other HAZARDS 201.12 Accuracy of controls and instruments and protection against hazardous outputs 201.13 HAZARDOUS SITUATIONS and fault conditions 201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) 201.15 Construction of ME EQUIPMENT . 201.16 ME SYSTEMS 201.17 Electromagnetic compatibility of me equipment and ME SYSTEMS	EN 60601-2-57: IEC 60601-2-57: EN 62471 IEC 62471	Radiance and irradiance tests form 200 to 1000 nm resolution 1 nm Luminance 0.2 cd/m ² to 100 000 cd/m ² Illuminance 1 lx to 1 500 000 lx Pedal activation force: 2 Nm to 200 Nm Uniformity radiation with resolution 2 mm Pulse length measurement form 1ms to 1s Irradiance measurements under fault conditions up to 300 W



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Electrical ^F	Medical electrical equipment - microwave therapy equipment	201.4 General requirements 201.5 General requirements for testing 201.6 Classification of me equipment and ME SYSTEMS 201.7 identification, marking and documents 201.8 Protection against electrical HAZARDS from ME EQUIPMENT 201.9 Protection against mechanical HAZARDS of me equipment and ME SYSTEMS 201.10 Protection against unwanted and excessive radiation HAZARDS 201.11 Protection against excessive temperatures and other HAZARDS 201.12 Accuracy of controls and instruments and protection against hazardous outputs 201.13 HAZARDOUS SITUATIONS and fault conditions 201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) 201.15 Construction of ME EQUIPMENT . 201.16 ME SYSTEMS 201.17 Electromagnetic compatibility of me equipment and ME SYSTEMS	EN 60601-2-6: 2015/A1/A2 IEC 60601-2-6: 2012/A1/A2	RF power up to 300 W Radiated field from 0.8 V/m to 800 V/m and Radiated power density from 0.3 mW/m ² up to 300 000 W/m ² Acoustic noise up to 140 dBA Time interval from 10 ms to 30 min



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Electrical Thermal ^F	Screening thermographs for human febrile temperature screening	201.4 General requirements 201.5 General requirements for testing of ME EQUIPMENT 201.6 Classification of ME EQUIPMENT and ME SYSTEMS 201.7 ME EQUIPMENT identification, marking and documents 201.8 Protection against electrical HAZARDS from ME EQUIPMENT 201.9 Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS 201.10 Protection against unwanted and excessive radiation HAZARDS 201.11 Protection against excessive temperatures and other HAZARDS 201.12 Accuracy of controls and instruments and protection against hazardous outputs 201.13 HAZARDOUS SITUATIONS and fault conditions 201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) 201.15 Construction of ME EQUIPMENT 201.16 ME SYSTEMS 201.17 Electromagnetic	EN 80601-2-59 IEC 80601-2-59:	Temperature accuracy, drift, uniformity and stability from 20 °C to 45 °C with accuracy 0.2 °C



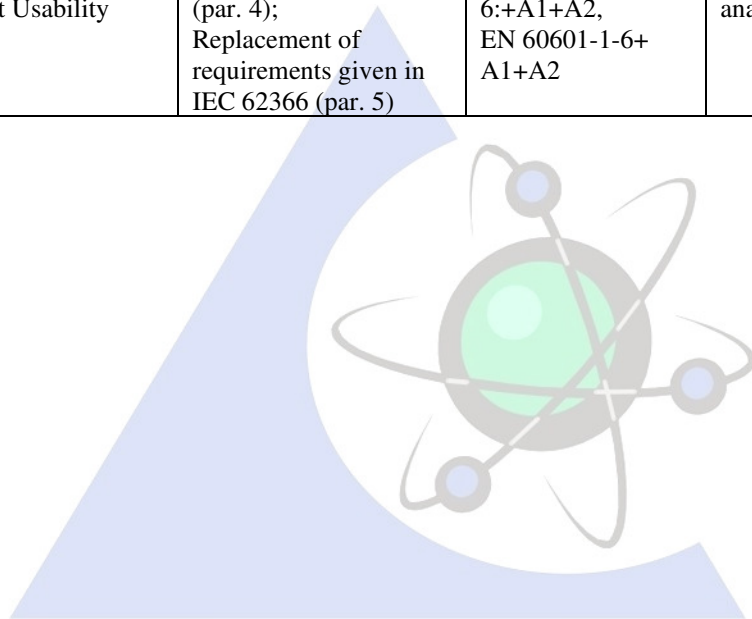
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Electrical; Thermal ^F	Screening thermographs for human febrile temperature screening	compatibility of ME EQUIPMENT and ME SYSTEMS 201.101 Laboratory accuracy of a screening thermograph 201.102 Screening thermograph alarm conditions	EN 80601-2-59; IEC 80601-2-59	Temperature accuracy, drift, uniformity and stability from 20 °C to 45 °C with accuracy 0.2 °C
Documental Analysis ^F	Medical electrical equipment Usability	General requirements (par. 4); Replacement of requirements given in IEC 62366 (par. 5)	IEC 60601-1-6:+A1+A2, EN 60601-1-6+ A1+A2	Usability validation document analysis





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FIELD OF TEST	ITEMS, MATERIALS OR PRODUCTS TESTED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD OR TECHNIQUE USED	RANGE (WHERE APPROPRIATE) AND DETECTION LIMIT
Electrical Mechanical ^F	Particular requirements for basic safety and essential performance of :critical care ventilators ventilatory support equipment for ventilatory impairment ventilatory support equipment for ventilatory insufficiency Home healthcare environment ventilators for ventilator-dependent patients Particular requirements for basic safety and essential performance of an anaesthetic workstation	201. 4 General requirements 201. 5 General requirements for testing of ME equipment 201. 6 Classification of ME equipment and ME systems 201. 7 ME equipment identification, marking and documents 201. 8 Protection against electrical hazards from ME equipment 201. 9 Protection against mechanical hazards of ME equipment and ME systems 201. 10 Protection against unwanted and excessive radiation hazards 201. 11 Protection against excessive temperatures and other hazards 201. 12 Accuracy of controls and instruments and protection against hazardous outputs 201. 13 Hazardous situations and fault conditions for ME equipment 201. 14 Programmable electrical medical systems (PEMS) 201. 15 Construction of ME equipment 201. 16 ME systems 201. 17 Electromagnetic	EN 80601-2-12: ISO 80601-2-12 EN 80601-2-79 ISO 80601-2-79 EN 80601-2-80 ISO 80601-2-80 EN 80601-2-72 ISO 80601-2-72 EN 80601-2-13 EN 80601-2-13+A2 ISO 80601-2-13 ISO 80601-2-13+A2 EN 80601-2-84 ISO 80601-2-84	Max acceleration 30 g Max sinusoidal force 6 670 N peak Max random force 5 340 N rms Mx Shock 50,8 mm.peak to peak Max Speed 1.8 m/s peak Static load 160 Kg IP grade IPX1 and IPX2 ventilation pressure 0 kPa to 10 kPa ± 1 % or 0.02 kPa FlowSense high flow sensor ± 300 L/min ± 2 % or 0.1 L/min FlowSense low flow sensor ± 12 L/min ± 2 % or 0.01 L/min differential pressure ± 2 kPa ± 0.5 % or ± 0.002 kPa differential pressure ± 20 kPa ± 0.5 % or ± 0.02 kPa differential pressure ± 100 kPa ± 0.5 % or ± 0.1 kPa Breath Rate (frequency) 1 BrPM to 100 BrPM ± 0.1 BrPM 101 BrPM to 200 BrPM ± 0.2 BrPM high pressure 0 MPa to 1 MPa (0 - 10 bar) ± 1.5 % or ± 1 kPa O2-concentration: 0 % to 100 % ± 1 Vol % Multi-Gas Sensor: CO2 0 – Vol % to 10 Vol % ± 0.2 Vol% + 2% of reading



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Electrical Mechanical ^F	Particular requirements for basic safety and essential performance of :critical care ventilators ventilatory support equipment for ventilatory impairment ventilatory support equipment for ventilatory insufficiency Home healthcare environment ventilators for ventilator-dependent patients Particular requirements for basic safety and essential performance of an anaesthetic workstation	compatibility of ME equipment and ME systems 201. 101 Gas connections 201. 102 Requirements for the VBS and accessories 201. 103 Spontaneous breathing during loss of power supply 201. 104 Indication of duration of operation 201. 105 Functional connection 201. 106 Display loops 201. 107 Timed ventilatory pause 202 Electromagnetic disturbances — Requirements and tests 206 Usability 208 General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	EN 80601-2-12 ISO 80601-2-12 EN 80601-2-79 ISO 80601-2-79 EN 80601-2-80 ISO 80601-2-80 EN 80601-2-72 ISO 80601-2-72 EN 80601-2-13 EN 80601-2-13+A2 ISO 80601-2-13 ISO 80601-2-13+A2 EN 80601-2-84 ISO 80601-2-84	Max acceleration 30 g Max sinusoidal force 6 670 N peak Max random force 5 340 N rms Max Shock 50,8 mm.peak to peak Max Speed 1.8 m/s peak Static load 160 Kg IP grade IPX1 and IPX2 Ventilation pressure 0 kPa to 10 kPa ± 1 % or 0.02 kPa FlowSense high flow sensor ± 300 L/min ± 2 % or 0.1 L/min FlowSense Low flow sensor ± 12 L/min ± 2 % or 0.01 L/min Differential ± 20 mbar ± 2 kPa ± 0.5 % or ± 0.002 kPa Differential pressure ± 200 mbar ± 20 kPa ± 0.5 % or ± 0.02 kPa Differential pressure ± 1 bar ± 100 kPa ± 0.5 % or ± 0.1 kPa Breath Rate (frequency) 1 BrPM to 100 BrPM ± 0.1 BrPM 101 BrPM to 200 BrPM ± 0.2 BrPM High pressure 0 Mpa to 1 Mpa (0 bar to 10 bar) ± 1.5 % or ± 1 kPa O2-concentration: 0 % to 100 % ± 1 Vol % Multi-Gas Sensor: CO2 0 Vol % to 10 Vol % ± 0.2 Vol% + 2% of reading



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Electrical Mechanical ^F	Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment	201.4 General requirements 201.5 General requirements for tests on EM equipment 201.6 Classification of EM EQUIPMENT and EM SYSTEM 201.7 Identification, nameplate data and documentation of EM equipment 201.8 Protection against electrical hazards due to EM EQUIPMENT 201.9 Protection against MECHANICAL HAZARDS of EM EQUIPMENT and EM SYSTEMS 201.10 Protection against DANGERS from unintended and excessive radiation 201.11 Protection against excessive temperatures and other HAZARDS 201.12 Protection against DANGEROUS emissions 201.13 DANGER SITUATIONS and fault conditions 201.14 PROGRAMMABLE ELECTROMEDICAL SYSTEMS (SEMP) 201.15 CONSTRUCTION OF EM EQUIPMENT 201.16 EM SYSTEM 201.17 Electromagnetic compatibility of EM EQUIPMENT and the	EN 60601-2-16 IEC 60601-2-16	Temperature measurements in the range 37 °C ± 5 °C Medium liquid flux measurements with gravity method (from 0.1 ml/min to 500 ml/min) Liquid pressure from 10 mmHg to 400 mmHg Treatment time from 1s to 30 min IP grade test for IPX1



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Electrical Mechanical ^F	Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment	EM SYSTEM 202 Electromagnetic compatibility - Requirements and tests 208 General requirements, tests and guidelines for alarm systems used in electromedical equipment and systems 210 Process requirements for the development of PHYSIOLOGICAL CLOSED RING CONTROLS CLOSED RING PHYSICAL CONTROLLERS 211 Prescriptions for ELECTROMEDICAL EQUIPMENT and ELECTROMEDICAL SYSTEMS ELECTROMEDICAL EQUIPMENT AND SYSTEMS FOR HOME USE	EN 60601-2-16 IEC 60601-2-16	Temperature measurements in the range 37 °C ±5 °C Medium liquid flux measurements with gravity method (from 0.1 ml/min to 500 ml/min) Liquid pressure from 10 mmHg to 400 mmHg Treatment time from 1 s to 30 min IP grade test for IPX1



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Electrical Mechanical ^F	Particular requirements for basic safety and essential performance of ultrasonic physiotherapy equipment	201.4 General requirements 201.5 General requirements for testing of ME EQUIPMENT 201.6 Classification of ME EQUIPMENT and ME SYSTEMS 201.7 ME EQUIPMENT identification, marking and documents 201.8 Protection against electrical HAZARDS from ME EQUIPMENT 201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS 5 201.10 Protection against unwanted and excessive radiation HAZARDS 201.11 Protection against excessive temperatures and other HAZARDS 201.12 Accuracy of controls and instruments and protection against hazardous outputs 9 201.13 HAZARDOUS SITUATIONS and fault conditions 201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) 1 201.15 Construction of	EN 60601-2-5 IEC 60601-2-5	Ultrasound power 0 W to 30 W frequency 0.5 MHz up to 10 MHz Ultrasound intensity up to 5 W/cm ² in the range 0.5 MHz up to 10 MHz Radiating surface from 0.7 cm ² to 80 cm ² Homogeneity of the radiation field from 1 to 10 Stability of ultrasound radiating emission in time and with voltage supply variation Pull force up to 100 N; Torque 0.35 Nm Up to 1 J Drop up to 1 m



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Electrical Mechanical ^F	Particular requirements for basic safety and essential performance of ultrasonic physiotherapy equipment	ME EQUIPMENT 201.16 ME SYSTEMS 201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS 202 Electromagnetic compatibility – Requirements and tests	EN 60601-2-5 IEC 60601-2-5	Ultrasound power 0-30W frequency 0.5 MHz to 10 MHz Ultrasound intensity up to 5W/cm ² in the range 0.5 MHz to 10 MHz Radiating surface from 0.7 cm ² to 80 cm ² Homogeneity of the radiation field from 1 to 10 Stability of ultrasound radiating emission in time and with voltage supply variation Pull force up to 100 N; Torque 0.35 Nm Up to 1 J Drop up to 1 m
Climatic ^F	Electrical, electronic, electromechanical appliances	Cold Test Dry Heat Test Damp heat Test Temperature variation test Low temperature storage test	IEC 60068-2-1; EN 60068-2-1; IEC 60068-2-2;; EN 60068-2-2 IEC 60068-2-30; EN 60068-2-30 IEC 60068-2-14; EN 60068-2-14 FS IS 402 EN 50155	Temperature range: -70°C to 180°C Relative humidity range 5 % to 95 %



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Electrical ^F	Electrical, electronic, electromechanical appliances	AC dielectric strength test DC insulation test Impulse High voltage test	FS IS 402 EN 50155: EN 50155 IEC 61851-1, EN 61851-1: IEC 61851-1; EN 61851-1 IEC 60060-1; EN 60060-1	AC dielectric strength test up to 30 kV DC dielectric strength test up to 6.5 kV HV impulse test up to 20kV
	Electrical, electronic, electromechanical appliances	Power supply test: Voltage variation test Frequency variation test; Overvoltage test Dips and short interruption test Third harmonic test	FS IS 402 EN 50155	AC voltage up to 300 V DC Voltage up to 425 V Frequency up to 5000 Hz Dips form 10 ms to 5 s
Mechanical ^F	Electrical, electronic, electromechanical appliances	Free fall test	EN 60068-2-31 IEC 60068-2-31	Drop height: 300 mm to 1500 mm Max load 85 kg



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Electrical ^F	Household and similar electrical appliances	Classification	IEC 60335-1	Visual Evaluation
		Marking and instructions	+A1	
		Construction Internal Cables	+A2+A12+A13:	Visual Evaluation and torque up to 2.5 Nm
		Components	IEC60335-1	
		Terminals for external Cables	EN 60335-1+A11+A1+A2+A15	Force up to 20 N
		Protection against access to live parts	IEC 60335-2-32;	Power/current absorption up to 63A 35kW
		Starting of Motor Appliances		EN 60335-2-32
		Protection against overload of transformers and associated circuits	IEC 60335-2-65+A1;	Overload up to 35kW
		Power and current absorbed		EN 60335+A1
		Heating	IEC 60335-2-102+A1+ A2,	Power/current absorption up to 63A 35kW
		Abnormal operation		EN 60335-2-102+A1,
		Leakage current and dielectric strength at operating temperature	EN 60335-2-102;	Climatic chamber: -10 °C to 60 °C Data Recorder: -10 °C to 300 °C
		Leakage current and Dielectric strength	EN60335-2-102	Data Recorder: -50 °C to 400 °C Power/current up to 63A 35kW
		Resistance to humidity	IEC 60335-2-102	Up to 1 mA/kW; Up to 5 000 Vac
		Stability and Mechanical Hazards		Dielectric strength test with voltage range from 500V to 30 kV and frequency 50 Hz and 60 Hz Leakage current 2μ to 5 000mA
		Mechanical Resistance	IEC 60335-2-102	Up to 95 % RH
		Connection to the mains and external flexible cables		Up to 20°
		Grounding Provisions	IEC 60335-2-102	Up to 1 J
		Screws and Connections		Flexing test up to 10 N; 20 000 flexing; 360° Pull force up to 100 N; Torque 0.35 Nm
		Surface distances, in the air and distances through a solid insulation	IEC 60335-2-102	Up to 12 V; 0.01 Ω to 0.5 Ω
Resistance to Heat and Fire	Up to 2.5 Nm			
Toxicity Radiation and Similar Hazards	IEC 60335-2-102	0.01 mm to 1 m		
Protection against rust		Glow wire Up to 960 °C Flammability test according to IEC 60695-11-10 EMF: Up to 100 % 100 °C ± 5 °C; 10 min		



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Electrical ^F	Household and similar electrical appliances	Classification	IEC 60335-2-54+A1+A2, EN 60335-2-54+A11+A1	Visual Evaluation
		Marking and instructions		
		Construction Internal Cables		
		Components		
		Terminals for external Cables	IEC 60335-2-24; IEC 60335-2-24+ A1+A2, EN 60335-2-24+A1+A2+A11	Visual Evaluation and torque up to 2.5 Nm
		Protection against access to live parts		Force up to 20 N
		Starting of Motor Appliances		Power/current absorption up to 63A 35kW
		Protection against overload of transformers and associated circuits	IEC 60335-2-30+A1+A2 EN 60335-2-30+A11+A1+A2+A12	Overload up to 35kW
		Power and current absorbed		Power/current absorption up to 63A 35kW
		Heating	IEC 60335-2-89+ A1+A2 IEC 60335-2-89+ A1 + A2, EN 60335-2-89:+A1+A2+A11	Climatic chamber: -10 °C to 60 °C Data Recorder: -10 °C to 300 °C
		Abnormal operation		Data Recorder: -50 °C to 400 °C Power/current up to 63A 35kW
		Leakage current and dielectric strength at operating temperature	IEC 60335-2-89+ A1 + A2, EN 60335-2-89:+A1+A2+A11	Up to 1 mA/kW; Up to 5 000 Vac
		Leakage current and Dielectric strength		Dielectric strength test with voltage range from 500V to 30 kV and frequency 50 Hz and 60 Hz Leakage current 2μ±5 000mA
		Resistance to humidity		Up to 95 % RH
		Stability and Mechanical Hazards		Up to 20°
		Mechanical Resistance		Up to 1 J
		Connection to the mains and external flexible cables		Flexing test up to 10 N; 20 000 flexing; 360° Pull force up to 100 N; Torque 0.35 Nm
		Grounding Provisions		Up to 12 V; 0.01 Ω to 0.5 Ω
		Screws and Connections		Up to 2.5 Nm
		Surface distances, in the air and distances through a solid insulation		0.01 mm to 1 m
Resistance to Heat and Fire		Glow wire Up to 960 °C Flammability test according to IEC 60695-11-10		
Toxicity Radiation and Similar Hazards		EMF: Up to 100 %		
Protection against rust		100 °C ± 5 °C; 10 min		



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Electrical ^F	Household and similar electrical appliances	Classification	IEC 60335-2-101+A1+A2; EN 60335-2-101/ A1/ A2	Visual Evaluation
		Marking and instructions		
		Construction Internal Cables		
		Components	IEC 60335-2-6+A1;	Visual Evaluation and torque up to 2.5 Nm
		Terminals for external Cables		
		Protection against access to live parts	EN 60335-2-6+A1+A11	Force up to 20 N
		Starting of Motor Appliances	IEC 60335-2-36+A1+A2;	Power/current absorption up to 63A 35kW
		Protection against overload of transformers and associated circuits	IEC 60335-2-36+2002+A1+A2+A11	Overload up to 35kW
		Power and current absorbed	IEC 60335-2-36	Power/current absorption up to 63A 35kW
		Heating	EN 60335-2-36	Climatic chamber: -10 °C to 60 °C Data Recorder: -10 °C to 300 °C
		Abnormal operation	IEC 60335-2-75	Data Recorder: -50 °C to 400 °C
		Leakage current and dielectric strength at operating temperature	IEC 60335-2-75+A1+A2;	Power/current up to 63A 35kW
		Leakage current and Dielectric strength	EN 60335-2-75	Up to 1 mA/kW; Up to 5 000 Vac
		Resistance to humidity	EN 60335-2-75+A1+A11+A2+A12	Dielectric strength test with voltage range from 500V to 30 kV and frequency 50 Hz and 60 Hz Leakage current 2μ÷5 000mA
		Stability and Mechanical Hazards	IEC 60335-2-43;	Up to 95 % RH
		Mechanical Resistance	EN 60335-2-43+A11	Up to 20°
		Connection to the mains and external flexible cables		Up to 1 J
		Grounding Provisions		Flexing test up to 10 N; 20 000 flexing; 360° Pull force up to 100 N; Torque 0.35 Nm
		Screws and Connections		Up to 12 V; 0.01 Ω to 0.5 Ω
		Surface distances, in the air and distances through a solid insulation		Up to 2.5 Nm
Resistance to Heat and Fire		0.01 mm to 1 m		
Toxicity Radiation and Similar Hazards		Glow wire Up to 960 °C Flammability test according to IEC 60695-11-10		
Protection against rust		EMF: Up to 100 %		



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Electrical ^F	Household and similar electrical appliances	Classification	IEC 60335-2-21+A1;	Visual Evaluation
		Marking and instructions	IEC 60335-2-21	
		Construction Internal Cables	EN 60335-2-21+A1	Visual Evaluation and torque up to 2.5 Nm
		Components	EN 60335-2-21	
		Terminals for external Cables	IEC 60335-2-35+A1+A2+	Force up to 20 N
		Protection against access to live parts	EN 60335-2-35+A1+A2	Power/current absorption up to 63A 35kW
		Starting of Motor Appliances	IEC 60335-2-98+A1+A2+A1,	Overload up to 35kW
		Protection against overload of transformers and associated circuits	EN 60335-2-98+A1+A2+A11	Power/current absorption up to 63A 35kW
		Power and current absorbed	IEC 60335-2-80+A1+A2,	Climatic chamber: -10 °C to 60 °C Data Recorder: -10 °C to 300 °C
		Heating	EN 60335-2-80+A1+A2	Data Recorder: -50 °C to 400 °C Power/current up to 63A 35kW
		Abnormal operation	IEC 60335-2-80+A1+A2,	Up to 1 mA/kW; Up to 5 000 Vac
		Leakage current and dielectric strength at operating temperature	IEC 60335-2-80+A1+A2	Dielectric strength test with voltage range from 500V to 30 kV and frequency 50 Hz and 60 Hz Leakage current 2μ÷5 000mA
		Leakage current and Dielectric strength	IEC 60335-2-50+A1+A2,	Up to 95 % RH
		Resistance to humidity	EN 60335-2-50+A1	Up to 20°
		Stability and Mechanical Hazards		Up to 1 J
		Mechanical Resistance		Flexing test up to 10 N; 20 000 flexing; 360° Pull force up to 100 N; Torque 0.35 Nm
		Connection to the mains and external flexible cables		Up to 12 V; 0.01 Ω to 0.5 Ω
		Grounding Provisions		Up to 12 V; 0.01 Ω to 0.5 Ω
		Screws and Connections		Up to 2.5 Nm
		Surface distances, in the air and distances through a solid insulation		0.01 mm to 1 m
Resistance to Heat and Fire		Glow wire Up to 960 °C Flammability test according to IEC 60695-11-10		
Toxicity Radiation and Similar Hazards		EMF: Up to 100 %		
Protection against rust				



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Electrical ^F	Household and similar electrical appliances	Classification	IEC 60335-2-14+ A1+A2, EN 60335-2-14+A1+ A11+ A12	Visual Evaluation
		Marking and instructions		
		Construction Internal Cables		
		Components		
		Terminals for external Cables	IEC 60335-2-15+A1+A2 EN 60335-2-15+A1+A2+A11	Visual Evaluation and torque up to 2.5 Nm
		Protection against access to live parts		Force up to 20 N
		Starting of Motor Appliances		Power/current absorption up to 63A 35kW
		Protection against overload of transformers and associated circuits	IEC 60335-2-15 EN 60335-2-15	Overload up to 35kW
		Power and current absorbed		Power/current absorption up to 63A 35kW
		Heating	IEC 60335-2-59+ A1+A2, EN 60335-2-59+ A1+A2+A11	Climatic chamber: -10 °C to 60 °C Data Recorder: -10 °C to 300 °C
		Abnormal operation		Data Recorder: -50 °C to 400 °C Power/current up to 63A 35kW
		Leakage current and dielectric strength at operating temperature	IEC 60335-2-59 EN 60335-2-59	Up to 1 mA/kW; Up to 5 000 Vac
		Leakage current and Dielectric strength		Dielectric strength test with voltage range from 500V to 30 kV and frequency 50 Hz and 60 Hz Leakage current 2μ÷5 000mA
		Resistance to humidity	IEC 60335-2-2+A1, IEC 60335-2-2; EN 60335-2-2+A1+A2+ A11, EN 60335-2-2+A11+ A1	Up to 95 % RH
		Stability and Mechanical Hazards		Up to 20°
		Mechanical Resistance		Up to 1 J
		Connection to the mains and external flexible cables		Flexing test up to 10 N; 20 000 flexing; 360° Pull force up to 100 N; Torque 0.35 Nm
		Grounding Provisions		Up to 12 V; 0.01 Ω to 0.5 Ω
		Screws and Connections		Up to 12 V; 0.01 Ω to 0.5 Ω
		Surface distances, in the air and distances through a solid insulation		Up to 2.5 Nm
Resistance to Heat and Fire		0.01 mm to 1 m		
Toxicity Radiation and Similar Hazards		Glow wire Up to 960 °C Flammability test according to IEC 60695-11-10		
Protection against rust		EMF: Up to 100 %		



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Electrical ^F	Household and similar electrical appliances	Classification	IEC 60335-2-39	Visual Evaluation
		Marking and instructions	A1+ A2+; IEC 60335-2-39+A1,	
		Construction Internal Cables	EN 60335-2-39+	Visual Evaluation and torque up to 2.5 Nm
		Components	A1+ A2+	
		Terminals for external Cables	IEC 60335-2-39	Force up to 20 N
		Protection against access to live parts	EN 60335-2-39	
		Starting of Motor Appliances	IEC 60335-2-17+A1+A2+	Power/current absorption up to 63A 35kW
		Protection against overload of transformers and associated circuits	EN 60335-2-17+A1+A2	
		Power and current absorbed	IEC 60335-2-17	Overload up to 35kW
		Heating	EN 60335-2-17	
		Abnormal operation	IEC 60335-2-3+A1,	Power/current absorption up to 63A 35kW
		Leakage current and dielectric strength at operating temperature	EN 60335-2-3+A1+ A2+A11;	
		Leakage current and Dielectric strength	IEC 60335-2-3	Climatic chamber: -10 °C to 60 °C Data Recorder: -10 °C to 300 °C
		Resistance to humidity	EN 60335-2-3	
		Stability and Mechanical Hazards	IEC 60335-2-23+A1;	Data Recorder: -50 °C to 400 °C Power/current up to 63A 35kW
		Mechanical Resistance	EN 60335-2-23:	
		Connection to the mains and external flexible cables	A1+	Up to 1 mA/kW; Up to 5 000 Vac
		Grounding Provisions	A11+A2+A12	
		Screws and Connections		Dielectric strength test with voltage range from 500V to 30 kV and frequency 50 Hz and 60 Hz Leakage current 2μ÷5 000mA
		Surface distances, in the air and distances through a solid insulation		
Resistance to Heat and Fire		Up to 95 % RH		
Toxicity Radiation and Similar Hazards				
Protection against rust		Up to 20°		
		Up to 1 J		
		Flexing test up to 10 N; 20 000 flexing; 360° Pull force up to 100 N; Torque 0.35 Nm		
		Up to 12 V; 0.01 Ω to 0.5 Ω		
		Up to 12 V; 0.01 Ω to 0.5 Ω		
		Up to 2.5 Nm		
		0.01 mm to 1 m		
		Glow wire Up to 960 °C Flammability test according to IEC 60695-11-10		
		EMF: Up to 100 %		



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Accreditation is granted to the facility to perform the following testing:

FIELD OF TEST	ITEMS, MATERIALS OR PRODUCTS TESTED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION STANDARD METHOD OR TECHNIQUE USED	RANGE (WHERE APPROPRIATE) AND DETECTION LIMIT
Electrical ^F	Household and similar electrical appliances	Classification	IEC 60335-2-9+A1+A2	Visual Evaluation
		Marking and instructions	IEC 60335-2-9	
		Construction Internal Cables	EN 60335-2-9+A1+A2+A12+A13	Visual Evaluation and torque up to 2.5 Nm
		Components		
		Terminals for external Cables		Force up to 20 N
		Protection against access to live parts	IEC 60335-2-48+ A1	Power/current absorption up to 63A 35kW
		Starting of Motor Appliances	IEC 60335-2-48; EN 60335-2-48+A1+A11+A2	Overload up to 35kW
		Protection against overload of transformers and associated circuits		
		Power and current absorbed	IEC 60335-2-5+A1	Power/current absorption up to 63A 35kW
		Heating	EN 60335-2-5+A11+A1	Climatic chamber: -10 °C to 60 °C Data Recorder: -10 °C to 300 °C
		Abnormal operation		Data Recorder: -50 °C to 400 °C Power/current up to 63A 35kW
		Leakage current and dielectric strength at operating temperature	IEC 60335-2-105+A1+A2;	Up to 1 mA/kW; Up to 5 000 Vac
		Leakage current and Dielectric strength	IEC 60335-2-105+A1; EN 60335-2-105+A1+A11+A2	Dielectric strength test with voltage range from 500V to 30 kV and frequency 50 Hz and 60 Hz Leakage current 2μ±5 000mA
		Resistance to humidity		Up to 95 % RH
		Stability and Mechanical Hazards		Up to 20°
		Mechanical Resistance		Up to 1 J
		Connection to the mains and external flexible cables		Flexing test up to 10 N; 20 000 flexing; 360° Pull force up to 100 N; Torque 0.35 Nm
		Grounding Provisions		Up to 12 V; 0.01 Ω to 0.5 Ω
		Screws and Connections		Up to 12 V; 0.01 Ω to 0.5 Ω
		Surface distances, in the air and distances through a solid insulation		Up to 2.5 Nm
Resistance to Heat and Fire		0.01 mm to 1 m		
Toxicity Radiation and Similar Hazards		Glow wire Up to 960 °C Flammability test according to IEC 60695-11-10		
Protection against rust		EMF: Up to 100 %		



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Electrical ^F	Household and similar electrical appliances	Classification	IEC 60335-2-41 EN 60335-2-41+A1+A2	Visual Evaluation
		Marking and instructions		
		Construction Internal Cables	IEC 60335-2-8+A1+A2; EN 60335-2-8+A1+A2+A11+A12	Visual Evaluation and torque up to 2.5 Nm
		Components		Force up to 20 N
		Terminals for external Cables		Power/current absorption up to 63A 35kW
		Protection against access to live parts	IEC 60335-2-60 EN 60335-2-60+A11+A12	Overload up to 35kW
		Starting of Motor Appliances		Power/current absorption up to 63A 35kW
		Protection against overload of transformers and associated circuits	IEC 60335-2-60 EN 60335-2-60+A11+A12	Overload up to 35kW
		Power and current absorbed		Power/current absorption up to 63A 35kW
		Heating		Climatic chamber: -10 °C to 60 °C Data Recorder: -10 °C to 300 °C
		Abnormal operation		Data Recorder: -50 °C to 400 °C Power/current up to 63A 35kW
		Leakage current and dielectric strength at operating temperature		Up to 1 mA/kW; Up to 5 000 Vac
		Leakage current and Dielectric strength		Dielectric strength test with voltage range from 500V to 30 kV and frequency 50 Hz and 60 Hz Leakage current 2μ±5 000mA
		Resistance to humidity		Up to 95 % RH
		Stability and Mechanical Hazards		Up to 20°
		Mechanical Resistance		Up to 1 J
		Connection to the mains and external flexible cables		Flexing test up to 10 N; 20 000 flexing; 360° Pull force up to 100 N; Torque 0.35 Nm
		Grounding Provisions	Up to 12 V; 0.01 Ω to 0.5 Ω	
		Screws and Connections	Up to 12 V; 0.01 Ω to 0.5 Ω	
		Surface distances, in the air and distances through a solid insulation	Up to 2.5 Nm	
Resistance to Heat and Fire	0.01 mm to 1 m			
Toxicity Radiation and Similar Hazards	Glow wire Up to 960 °C Flammability test according to IEC 60695-11-10			
Protection against rust	EMF: Up to 100 %			



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Electrical ^F	Luminaires – General requirements and tests	Appliance components / Components of luminaires	IEC 60598-1; EN 60598-1+A11	No tools
		Equipment classification / Classification of luminaires /Marking	IEC 60598-2-22+A1,	Visual Evaluation
		Construction	EN 60598-2-22+A1	0.2 Nm to 20 Nm 0.2 J to 1 J 1 N to 1 200 N
		External and internal wiring	IEC 60598-2-22 EN 60598-2-22	30 N to 120 N 0.08 Nm to 0.35 Nm
		Provision for earthing		0.01 Ω to 0.5 Ω
		Protection against electric shock	IEC 60598-2-4, EN 60598-2-4;	Test gauges D.L. = 100 Nm
		Capacitors discharge		Up to 250 Vac
		Protection against the penetration of dust, solid bodies and humidity / Resistance to dust, solid object and moisture	IEC 60598-2-18+A1, EN 60598-2-18+A1	1 Nm to 3 Nm 0.07 l/m to 100 l/m
		Insulation resistance and dielectric strength, contact current and current in the protective conductor / Insulation resistance and electric resistance, current and protective conductor current	IEC 60598-2-1; EN 60598-2-1 IEC 60598-2-7+A1+A2, IEC 60598-2-7; EN 60598-2-7+A2+A 13 IEC 60598-2-3+	0.5 M Ω to 50 M Ω 1 V to 5 000 V 0 mA to 10 mA
		Surface and air insulation distances / Creepage distances and clearances	A1, EN 60598-2-3 +A1	0.1 mm to 150 mm
		Endurance and heating tests	IEC 60598-2-20 EN 60598-2-20	Climatic chamber: -10 °C to 60 °C Data Recorder: -10 °C to 300 °C
		Resistance to heat, fire and surface currents / Resistance to heat, fire and tracking	IEC 60598-2-2, EN 60598-2-2	25 °C to 280 °C 550 °C to 960 °C
		Screw terminals Terminals and electrical connections without screws / Screwless terminals and electrical connections		1 Nm to 100 Nm



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Electrical Climatic and Mechanical ^F	Medical electrical equipment – General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment	4 general requirements 4.1 additional requirements for supply mains 4.2 environmental conditions 5 Classification of me equipment and me systems 6 ME equipment identification, marking and documents 7 Protection against electrical hazards from me equipment 8 protection against excessive temperatures and other hazards 9 accuracy of controls and instruments and protection against hazardous outputs 10 construction of me equipment 10.1 additional requirements for mechanical strength 10.1.1 general requirements for mechanical strength 10.1.2 requirements for mechanical strength for fixed or permanently installed me equipment intended for use in a road ambulance 10.1.3 requirements for mechanical strength for transportable 10.1.4 requirements for mechanical strength for me equipment intended for airborne use me equipment 10.2 requirements for mounting of ME 11 additional requirements for electromagnetic emissions of me equipment and me systems	IEC 60601–1–12+A1 EN 60601–1–12+A1:2020	Max acceleration 30 g Max sinusoidal force 6670 N peak Max random force 5340 N rms Max Shock 50,8 mm peak to peak Max Speed 1.78 m/s peak Static load 160 kg Climatic chamber: –50 °C to 70 °C Data Relative humidity from 10% to 95% IP grade IPX1 and IPX2 Power/current absorption up to 63A 35kW



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Portable lung ventilator	Portable lung ventilator	201. 4 General requirements 201. 5 General requirements for testing of ME equipment 201. 6 Classification of ME equipment and ME systems 201. 7 ME equipment identification, marking and documents 201. 8 Protection against electrical hazards from ME equipment 201. 9 Protection against mechanical hazards of ME equipment and ME systems 201. 10 Protection against unwanted and excessive radiation hazards 201. 11 Protection against excessive temperatures and other hazards 201. 12 Accuracy of controls and instruments and protection against hazardous outputs 201. 13 Hazardous situations and fault conditions for ME equipment 201. 14 Programmable electrical medical systems (PEMS) 201. 15 Construction of ME equipment 201. 16 ME systems 201. 17 Electromagnetic compatibility of ME equipment and ME systems 201. 101 Gas connections 201. 102 Requirements for the VBS and accessories 201. 103 Spontaneous breathing during loss of power supply 201. 104 Indication of duration of operation 201. 105 Functional connection 201. 106 Display loops 201. 107 Timed ventilatory pause 202 Electromagnetic disturbances — Requirements and tests 206 Usability 208 General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	ISO 80601-2-84:	Max acceleration 30 g Max sinusoidal force 6 670 N peak Max random force 5 340 N rms Mx Shock 50,8 mm.peak to peak Max Speed 1.8 m/s peak Static load 160 Kg IP grade IP34 ventilation pressure 0 kPa to 10 kPa \pm 1 % or 0.02 kPa FlowSense high flow sensor \pm 300 L/min \pm 2 % or 0.1 L/min FlowSense low flow sensor \pm 12 L/min \pm 2 % or 0.01 L/min differential pressure \pm 2 kPa \pm 0.5 % or \pm 0.002 kPa differential pressure \pm 20 kPa \pm 0.5 % or \pm 0.02 kPa differential pressure \pm 100 kPa \pm 0.5 % or \pm 0.1 kPa Breath Rate (frequency) 1 BrPM to 100 BrPM \pm 0.1 BrPM 101 BrPM to 200 BrPM \pm 0.2 BrPM high pressure 0 MPa to 1 MPa (0 - 10 bar) \pm 1.5 % or \pm 1 kPa O ₂ -concentration: 0 % to 100 % \pm 1 Vol % Multi-Gas Sensor: CO ₂ 0 – Vol % to 10 Vol % \pm 0.2 Vol % + 2% of reading



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Electromagnetic fields	Radio equipment : Short Range Devices Wideband transmission Systems Cellular terminals (GNSS) receivers Fixed Radio Systems Wireless power transmission systems	EMC/EMF Protection	EN 62311 EN 62479 EN 50385	10Hz to 26GHz
Electromagnetic compatibility	Electrical and electronic devices for vehicle application / electrical and electronic applications for vehicular	EMC / EMC tests: Immunity to Electrical disturbances: Conducted and coupled method	ISO 7637-1 ISO 7637-2 ISO 7637-3 Reg. UNECE R10 EN 50498	Pulse 1 Pulse 2a/2b Pulse 3a/3b Pulse 4
		EMC / EMC tests: Immunity to RF conducted disturbance: Harness excitation methods	ISO 11452-1 ISO 11452-4 Reg. UNECE R10	Up to 300 mA 1 MHz to 400 MHz
		EMC / EMC tests: Immunity to RF radiated disturbance: ALSE (Absorber lined shielded enclosure) Test methods	ISO 11452-1 ISO 11452-2 Reg. UNECE R10	20 MHz to 6 GHz Amplitude Modulation/ Pulse Modulation D.L. = 30 V/m
		EMC tests: Conducted emissions: Voltage measurements Test method	CISPR 25; Reg. UNECE R10 EN 50498	9 kHz to 200 MHz
		EMC tests: Radiated emissions: ALSE (Absorberlined shielded enclosure) Test method	CISPR 25; Reg. UNECE R10 EN 50498	150 kHz to 18 GHz



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Electromagnetic Compatibility Tests ^{FO}	Electromedical equipment, industrial equipment, information technology, lighting equipment, household appliances, railway electronic equipment	Immunity to pulsed magnetic fields	EN 61000-4-9 IEC 61000-4-9	1 000A/m
		Conducted immunity tests in the frequency range 0 Hz a 150 kHz	EN 61000-4-16 IEC 61000-4-16	Continuous disturbances up to 150V Transitory disturbances up to 700V
		Fire hazard testing Test flames. 50 W horizontal and vertical flame test methods	IEC 60695-11-10 EN 60695-11-10	Horizontal and vertical combustion
Flamability Tests ^F	information technology, lighting equipment, household appliances,	Glow wire test	IEC 60695-2-10 EN 60695-2-11	Temperature from 550°C to 960°C
		Needle flame test	IEC 60695-11-5 EN 60695-11-5	8mm height flame for time from 5s to 120s

FDA ASCA Basic Safety and Essential Performance Scope of Accreditation

METHOD USED
IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION
IEC 60601-1-6 Edition 3.1 2013-10
IEC 60601-2-5: Edition 3.0 2009-07
IEC 60601-2-6: Edition 2.1 2016-04
IEC 60601-2-16 Edition 5.0 2018-4
IEC 60601-2-57 Edition 1.0 2011-01
IEC 60601-2-22 Edition 4.0 2019-11
ISO 80601-2-12 Second edition 2020-02
ISO 80601-2-13 First edition 2011-08-11
ISO 80601-2-59 Edition 2.0 2017-09
ISO 80601-2-72 First edition 2015-04-11
ISO 80601-2-79 First Edition 2018-07
ISO 80601-2-80 First edition 2018-07
ISO 80601-2-84 Second edition 2022

1. The presence of a superscript F means that the laboratory performs testing of the indicated parameter at its fixed location. Example: Outside Micrometer ^F would mean that the laboratory performs this testing at its fixed location.
2. The presence of a superscript FO means that the laboratory performs testing of the indicated parameter both at its fixed location and onsite at customer locations. Example: Outside Micrometer ^{FO} would mean that the laboratory performs this testing at its fixed location and onsite at customer locations.