

	<p>INSTITUT PRO TESTOVÁNÍ A CERTIFIKACI, a.s.</p> <p>zkušební laboratoř elektrických výrobků Sokolovská 573 686 01 Uherské Hradiště</p>	 
<p>(Institute for Testing and Certification Inc.)</p>		
<p>Trial Laboratory of Electrical Appliances Sokolovská 573 686 01 Uherské Hradiště</p>		

TEST LABORATORY No. 1004.3

Document no: 3328/07

Accredited by the Czech Institute for Accreditation

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TEST DOCUMENT

of the electro-impedance computer mamograph MEIK®



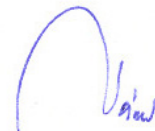
Accredited test laboratory

no. 1004.3

Institute of Testing and Certification



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*All the comparisons of the measured and required values are above the requirements of the accreditation norm ČSN EN ISO/IEC 17025.

1 GENERAL INFORMATION

1.1 Contracting authority

Institute of Testing and Certification Inc.

Centre no. 360

Tř. T. Bati 299

764 21 Zlín

Identification no. 47910381

Tax code CZ47910381

Commission no. 803600225

Date: 18 June 2007

1.2 Dealer

POLYX TRADE INTERNACIONAL Ltd.

Sreznevského 17

831 03 Bratislava

Slovakia

1.3 Time frame and tests procedure

The tested sample was delivered to the Institute of testing and certification Inc., division 4 Electrical goods, on 19 June 2007 and it was registered to be tested under the number IK 144/07.

Date of initiation of test: 13 August 2007

Date of termination of test: 24 August 2007

The parameters of normal climatic conditions were being checked during the individual tests and no diversions were measured.

Normal climatic conditions:

Temperature of surrounding environment (+15 to +35) °C

Atmospheric pressure (86 to 106) kPa

Relative humidity (25 to 75) %

1.4 Denomination and characterization of tested samples

The electro-impedance computer mamograph MEIK®, production no. 302 was delivered to be tested, equipped with programming software MEIK version 5.0.

1.5 List of used norms (ČSN = Czech State Norm)

ČSN EN 60601-1:1994, +(A1, A11, A12):95, A13:97, A2:97, +A13:1996, Cor.1:1997, (A1,A11,A12/Cor.1):1997, (A1,A11,A12/Cor.2):1997+A2:1997 (Czech version EN 60601-1:1990 changes included)

1.6 List of used tools and appliances

Multimeter DMM2000

Production no. 708697

Dynamometer	Registration no. QD0814
a set of K batteries	Registration no. QD 5074
Switch between measured points ZZ004-B	Production no. 001
Power supply RMG 500	Production no. 42273
Testing device for leaking voltage	Registration no. QD 5081
Kango breaker 0.5 J	Registration no. QO 0039
Climatic test chamber VCV 4034	Production no. 58566095740010
Bullets for ball indentation method	Registration no. QD 0755
Stopwatch 898	Production no. QD5087
Measuring containers	Registration no. QD 0875
Caliper	Registration no. QD 0890

Tools and appliances undergo regular metrological checks and were periodically checked and acknowledged correct.

2 RESULTS OF INDIVIDUAL TESTS

Abbreviations used:	*H – test evaluation	P – passed
	N/A – not applicable	F – failed
	+ - above the requirements of accreditation	

2.1 Electrical safety

Chapter	Requirements of the chapter of ČSN EN 60601-1	Notes	*H
	PART 1 – IN GENERAL		P
4	TESTING CONDITIONS IN GENERAL		P
+4.1	Type-testing.		P
+4.2	Tests must not be repeated if not stated otherwise.		P
+4.3	Tests are conducted on one sample only.		P
+4.4	Resistance of parts which may cause safety hazard.		N/A
+4.5	Surrounding temperature, humidity, atmospheric pressure – see 10.2.1		P
	Reference conditions		N/A
+4.6	Next conditions:		P
	A/ the least favourable conditions compared with the manual,		P
	B/ the least favourable setting set by operating staff,		P
	C/ limit values of pressure and cooling fluid flow,		N/A
	D/ simultaneous simulation of just one defect,		P
	E/ drinking water used as cooling fluid.		N/A
+4.7	Power supply:		
	A/ In case test results are influenced by deviations from norm, they are taken into account.		N/A
	Running of the voltage must respond to 10.2.2a).		N/A
	Deviations of test voltage -		N/A
	max. 2% - alternating < 1,000 V and direct < 1,500 V,		N/A
	max. 3% - alternating > 1,000 V and direct > 1,500 V.		N/A
	B/ Deviation of the frequency of alternating current -		N/A
± 1 Hz for frequencies 0 – 100 Hz,		N/A	
± 1% for frequencies over 100 Hz.		N/A	

Chapter	Requirements of the chapter of ČSN EN 60601-1	Notes	*H
	C/ Appliance intended for more than one current, or for alternating and direct currents.		N/A
	D/ Influence of polarity in appliance powered by direct current.		N/A
	E/ The least favourable current for supply.		N/A
	F/ Equipment or spare parts stated by producer.		P
	G/ Appliance with given supply.	PC USB	P
	H/ Used measuring tools.		N/A
+4.8	Initial acclimatization.		P
+4.9	Repairs and adjustments:		N/A
	-presentation of another sample		N/A
	-implementation of repairs and adjustments		N/A
+4.10	Reaction to humidity (before tests according to 19.4 and 20.4)	93%, 26°C;	P
	-ordinary appliance	48 hours	P
	-appliance protected against dripping or splashing water		N/A
+4.11	Ordering of tests according to supplement C (tests C.23 – C.29 in given order).		P
5	CLASSIFICATION		P
+5.1	According to the type of protection against a current-related injury:		N/A
	A/ Appliance powered by an external source (classes I, II)	II	P
	B/ Appliance with an internal source of electrical power.		N/A
+5.2	According to the degree of protection against a current-related injury (supplement of type B, BF, CF).	BF	P
+5.3	According to the degree of protection against damaging water leakage – IEC 529.	IPX0	N/A
+5.4	According to the methods of sterilization and disinfection.		N/A
+5.5	According to the degree of protection against flammable mixtures (categories AP, APG).	not suitable for places with flammable anesthetics	N/A
+5.6	According to the type of cycle (continuous, short-term, interrupted, short-term workload, interrupted workload)	continuous cycle	P
6	IDENTIFICATION, LABELLING AND DOCUMENTATION		P
	Labels must be permanently attached and readable.		P
+6.1	Labels on the surface of appliance:		P
	A/ Mains operated appliance		N/A
	B/ Appliance with internal power supply		N/A
	C/ Appliance powered from a given energy supply		P
	D/ Minimal requirements for labelling – 6.1e), 6.1f), 6.1g), 6.1l), 6.1q)	e) f) g) l)	P
	E/ origin denomination – name or trade mark	PKF 'SIM TECHNOLOGY'	P
	F/ denomination of model and type	MEIK	P
	G/ source connection – power supply voltage or range, type of source	5V DC, PC USB	P
	H/ source frequency (Hz)		N/A
	J/ power use (chapter 8 – A, VA, W)	2 VA	P
	K/ mains output – denomination of additional mains socket		N/A
	L/ classification	BF	P
	M/ type of cycle		N/A
	N/ fuse – accessible from the outside of appliance		N/A

Chapter	Requirements of the chapter of ČSN EN 60601-1	Notes	*H
	P/ output – output voltage, power, energy output, frequency		N/A
	Q/ physical effects (signs and warnings)		N/A
	R/ appliance in category AP/APG (chapter 38)		N/A
	S/ high-voltage distribution frame – accessible from the outside of appliance		N/A
	T/ cooling conditions		N/A
	U/ mechanical stability (chapter 24)		P
	V/ protective wrapping – shipping and stocking		N/A
	Y/ earthing clips		N/A
	- connection of conducting wire to level potentials		N/A
	- functional earthing clip		N/A
	Z/ removable protective measures		N/A
	Test of abrasion durability – 15 s denatured alcohol, 15 s isopropyl alcohol		P
	Labelling must be readable after all the test were done and must not alter.		P
+6.2	A/ Readability of signs inside the appliance.		N/A
	B/ Labelling of the load of heating elements and heating bulbs.		N/A
	C/ Labelling of high-voltage parts.		N/A
	D/ Type of battery		N/A
	and the method of its insertion (art. 56.7b).		N/A
	E/ Labelling of fuse in areas inaccessible by operating staff.		N/A
	F/ Labelling of protective earthing clip -icon-		N/A
	G/ Functional earthing clip -icon-		N/A
	G/ Labelling of clips which connect the central power cable in permanently connected appliances – N.		N/A
	J/ Labels required according to 6.2f), h), k), l).		N/A
	K/ Labelling of correct power cord connection.		N/A
	L/ Internal temperature warning > 75°C.		N/A
	N/ Labelling of condensers and circuits according to 15 c).		N/A
+6.3	A/ ON/OFF labelling at mains switches.		N/A
	B/ Labelling of control positions on the appliance.		N/A
	C/ Labelling of control elements resetting which may cause hazard to the patient's safety.		N/A
	F/ Control functions used by operating staff must be identified.		N/A
	G/ Indication of parameters in figures.		N/A
+6.4	A/ Signs used must comply with the requirements of supplement D, (6.1q).		P
	B/ Control elements and operation signs – IEC 878.		N/A
+6.5	A/ Green and yellow colour-coding of the protective earthing wire on its whole length.		N/A
	B/ Green and yellow colour-coding of cords connecting accessible metal parts with the earthing clip.		N/A
	C/ Green and yellow colour-coding used only for 18b), 6.5b), 18e), 181.		N/A
	D/ Light blue colour-coding of the central wire in mains supply cable.		N/A
	E/ The colours used for cord colour-coding must comply with the norms IEC 277 or IEC 245.		N/A
	F/ Labelling of wires parallel to the green and yellow colour-coded wire.		N/A

Chapter	Requirements of the chapter of ČSN EN 60601-1	Notes	*H
+6.6	A/ Labelling of the content of pressure tanks.		N/A
	B/ Labelling of the connection point.		N/A
+6.7	A/ Coloured light indications.	green, yellow	P
	B/ Colours of non-backlit buttons.		N/A
+6.8	Documentation		P
+6.8.1	Documentation must contain a manual, technical description, address of producer, dealer or technical support.		P
	Classification stated in chapter 5.		P
	Labelling according to 6.1.		P
	Explanation of warning signs on the appliance.		N/A
+6.8.2	Operating instructions		P
	A/ General information		P
	B/ Liability of producer – not applicable/not used.		N/A
	C/ Input or output signal used only to connect a specific appliance (19.2b), 19.2c)).		N/A
	D/ Cleaning, disinfection and sterilization of parts which are in contact with the patient.	2.2.5 Documentation	P
	E/ Mains-powered appliance with additional power source.		N/A
	F/ Extraction of primary battery cells.		N/A
	G/ Accumulator batteries.		N/A
	H/ Appliance with special power source or battery charger.	2.1 Documentation	P
J/ Environment protection.		N/A	
+6.8.3	Technical description		P
	A/ In general		P
	B/ Exchange of fuse and other parts.		N/A
	C/ Connection diagram, lists of spare parts, etc.		N/A
	D/ Environment conditions for shipping and stocking.		N/A
7	POWER SUPPLY		P
+7.1	Current or power must not be higher than stated:		P
	A/ appliances mainly powered by internal motor		N/A
	+25% in stated power < 100W or 100VA,		N/A
	+15% in stated power > 100W or 100VA,		N/A
	B/ other appliances-		P
	+15% in stated power < 100W or 100VA,		P
	+10% in stated power > 100W or 100VA.		N/A
Measured values stable.	see supplement #1	P	
	PART 2 – ENVIRONMENT CONDITIONS		P
8	BASIC SAFETY CATEGORIES – supplement A.1.1		P
9	DETACHABLE SAFETY DEVICES – compensated 6.1 z)		N/A
10	ENVIRONMENT CONDITIONS		P
+10.1	Ability to sustain conditions guaranteed by producer.		P
+10.2	Operation		P
+10.2.1	A/ range of operational temperature +10°C to +40°C,		P
	B/ relative humidity in operation 30% to 75%,		P
	C/ atmospheric pressure in operation 700hPa to 1060hPa.		P
	D/ input water temperature 25°C in water-cooled appliances.		N/A
+10.2.2	A/ Appliance must be suitable for feeding:		P
	-voltage		P
	≤ 250V for a manual appliance		P
	≤ 250V for direct or one-phase feeding within ≤ 4kVA of power input		N/A
	≤ 500 V for multi-phase feeding within ≤ 4kVA of power		N/A

	input		
Chapter	Requirements of the chapter of ČSN EN 60601-1	Notes	*H
	≤ 500 V for other appliances		N/A
	-low enough internal impedance		N/A
	-power oscillation ≤ ± 10% of stated		P
	-tension in between any conducting wires of system ≤ + 10% of stated		N/A
	-tension of sine wave		N/A
	-frequency ≤ 1 kHz		N/A
	-deviation from frequency		N/A
	-safety measures		N/A
	B/ Exchangeable power source		N/A
11	Not used.		N/A
12	Not used – transferred to 3.6.		N/A
	PART 3 – PROTECTION AGAINST POWER-RELATED INJURY		P
13	IN GENERAL		P
	Appliance design.		P
14	REQUIREMENTS ACCORDING TO CLASSIFICATION		P
+14.1	Appliance of class I:		N/A
	A/ Accessible power-conducting parts.		N/A
	B/ Usage of separate protective conducting wire.		N/A
+14.2	A/ Appliance of class II is only:		P
	1) Appliance of class II with insulation cover.		N/A
	2) Appliance of class II with metallic cover.		N/A
	3) Appliance which is a combination of 1) and 2).		P
	B/ Equipment to change protective devices.		N/A
+14.3	Not used.		N/A
+14.4	Appliance of class I and II		P
	A/ Additional protection to the basic insulation.		P
	B/ Appliances powered from external source.	polarity can't be changed	N/A
+14.5	Appliance with internal power source		N/A
	A/ Not used.		N/A
	B/ Appliance with internal power source and also with the ability to be connected to the mains distribution unit.		N/A
+14.6	Applicable parts of types B, BF, CF.		N/A
	A/ Not used.		N/A
	B/ Not used.		N/A
	C/ Applicable part for direct connection to the heart – type CF.		N/A
	D/ Not used.		N/A
15	POWER OR ENERGY LIMITATIONS/REGULATIONS	no hazard	N/A
	A/ Not used.		N/A
	B/ After 1 second after disconnection the tension must not exceed 60V between:		N/A
	-plug pins and cover (condenser ≥ 3,000 pF connected between the conducting wire and earth),		N/A
	-pins (condensers > 0.1 μF connected between conducting wires)		N/A
	Test of ten disconnections.		N/A
	C/ Live parts of condensers or parts of circuits attached to them.		N/A
16	COVERS AND PROTECTIVE LIDS		P
	A/ Protection against touching live parts and parts which may become live – sensing heads test.		N/A
	B/ Opening in the upper part of cover – sensing head test.		N/A

	C/ Conducting parts of control mechanisms.		N/A
Chapter	Requirements of the chapter of ČSN EN 60601-1	Notes	*H
	D/ Parts inside the cover under voltage > 25V (alternating) or 60V (direct)		N/A
	E/ Covers must be replaced only with a tool or automatic detachable device must be used.		P
	F/ Openings to set the controls.		N/A
17	DEPARTMENTS		P
	A/ Department for attachable parts, leaking voltage test (see 19.4).		P
	B/ Not used.		N/A
	C/ Conductive connection to accessible metallic parts.		P
	D/ Manual bendable appliances of class I.		N/A
	Insulation test.		N/A
	E/, F/ Not used.		N/A
	G/ Accessible parts which are not attachable – leaking voltage test (see 19.4).		P
	H/ Organization used to separate the attachable part resistant to defibrillation.		N/A
18	PROTECTIVE EARTHING, FUNCTIONAL EARTHING AND LEVELLING OF POTENTIALS		N/A
	A/ Connection of accessible parts to protective earthing clip in appliance of class I.		N/A
	B/ Connection of protective earthing clip.		N/A
	C/, D/ Not used.		N/A
	E/ Connection of leading wire facility to level potentials.		N/A
	F/ The impedance between the protective earthing clip and earthed metallic part must be < 0.2Ω.		N/A
	The impedance between the protective contact in the power plug and the earthed metallic part must be < 0.2Ω.		N/A
	G/ Impedance of other protective earthing connections.		N/A
	H/, J/ Not used.		N/A
	K/ Functional earthing clips.		N/A
	L/ Functional earthing in appliance of class II.		N/A
	Labelling of functional earthing clip.		N/A
19	PERMANENTLY LEAKING VOLTAGE AND AUXILIARY CURRENTS THROUGH PATIENT		P
19.1	A/ Quality of electrical insulation.		P
	B/ In all given working and environmental conditions leaking voltage must not exceed values as in 19.3.		P
	C/ Appliance intended to be connected to the SELV power source.		P
	D/ Measuring of leaking voltage through the cover in appliance of class I.		P
	E/ Leaking voltage through patient (supplement K) in appliances of types B, BF, CF.		P
	F/ Auxiliary current through patient.		P
	g		P
	G/ Appliances with multi-patient connection.		P
19.2	States of one defect.	see supplement #1	P
	A/ Leaking voltage when conducting wires disconnected.		N/A
	B/ Leaking voltage through patient at 110% of the value of maximum supply potential.		P
	C/ Leaking voltage through the signal input cover at 110% of the value of maximum supply potential.		P
19.3	A/ Acceptable values of permanently leaking voltage and		P

	auxiliary currents through patient – table 4.		
Chapter	Requirements of the chapter of ČSN EN 60601-1	Notes	*H
	B/ The effective value of none of the leaking voltages must exceed 10mA.		P
	C/, D/, E/ Not used.		N/A
19.4	Tests	see supplement #1	P
	A/ In general: - after one hour, after preparation; -at operating temperature.		P
	B/ Measuring the power circuit.		P
	C/ Connection to the power circuit.		P
	D/ Organization when measuring.		P
	E/ Measuring product MD		P
	F/ Measuring the leaking voltage into the ground.		N/A
	G/ Measuring the leaking voltage through the cover.		P
	H/ Measuring the leaking voltage through patient.		P
	J/ Measuring the auxiliary current through patient.		P
20	DIELECTRIC STRENGTH		P
20.1	General requirements for all types of appliances.		P
20.2	Requirements for an appliance with an attachable part.		P
20.3	Values of test voltage.		P
20.4	A/ Test of voltage for 1 minute (start of 10 seconds, decline of 10 seconds).	see supplement #1	P
	B/ The course and frequency of test voltage.	50Hz	P
	C/, D/, E/ Not used.		N/A
	F/ Overleap or disruptive breakdown must not occur.	no risk	P
	G/ Voltage in reinforced insulation.		P
	H/ Application of metal foil – 19.4g/5).		P
	J/ Device for restricting voltage will be detached.		N/A
	K/ Short-circuiting of signal inputs and outputs.		P
	L/ Engines with condensers.		N/A
	PART 4 – PROTECTION AGAINST MECHANICAL HAZARD		P
21	MECHANICAL STRENGTH		P
	Covers must be adequately tough.		P
	A/ Test of toughness of cover through force of 45N		P
	B/ Test of toughness of cover through a hit of 0.5J.		P
	C/ Test through quadruple of weight in mobile appliances.		N/A
+21.1	Not used.		N/A
+21.2	Not used.		N/A
+21.3	Parts of appliance used as support for patient.		N/A
+21.4	Not used.		N/A
21.5	Test of free fall on appliances or parts held in hands.		N/A
21.6	Test of fall in portable and mobile appliances.		P
22	MOVEABLE PARTS		N/A
+22.1	Not used.		N/A
+22.2	Moveable parts which may cause hazards:		N/A
	A/ Transportable appliance		N/A
	B/ Permanently installed appliance		N/A
+22.3	Securing of cords, chains and ropes.		N/A
+22.4	Moveable parts which may jeopardize the patient.		N/A
+22.5	Not used.		N/A
+22.6	Parts which mechanically wear out.		N/A
+22.7	Emergency disconnection in case of electrically induced mechanical movement.		N/A
23	SURFACES, CORNERS, ANGLES		P
24	STABILITY WHEN RUNNING NORMALLY		P
+24.1	Appliance must not topple off when running normally or it		P

	must comply with the requirements of 24.3.		
Chapter	Requirements of the chapter of ČSN EN 60601-1	Notes	*H
	Test through inclination.		P
+24.2	Not used.		N/A
+24.3	Requirements in case of overturn.		N/A
+24.4	Not used.		N/A
+24.5	Not used.		N/A
+24.6	Handles and other manipulation elements.		N/A
	A/ Appliances or its parts that are manipulated with and that weigh > 25 kilograms.		N/A
	B/ Portable devices that weigh > 25 kilograms.		N/A
25	LOOSE PARTS		N/A
+25.1	Use of protective means.		N/A
+25.2	Screens with dimension more than 16 centimetres.		N/A
26	VIBRATIONS AND NOISE – No general requirement		N/A
27	PNEUMATIC AND HYDRAULIC ACTIVITY – No general requirement		N/A
28	SUSPENDED PARTS		N/A
+28.1	Requirements are to be applied on parts of appliance on which parts are hung		N/A
+28.2	Not used.		N/A
+28.3	Suspension system with safety device.		N/A
+28.4	Metallic suspension systems without safety device		N/A
	1) The total load must not exceed the safe operational load.		N/A
	2) Safety factor in parts where support features are not likely to be influenced by corrosion, wear-off or alike ≥ 4 .		N/A
	3) Safety factor in parts where support features are likely to be influenced by corrosion, wear-off or alike ≥ 8 .		N/A
	4) Multiplication by coefficient 1.5 in case a metal with specific ductility lower than 5% is used.		N/A
	5) Safety factor for the time of durability of ropes in suspension system.		N/A
	PART 5 – PROTECTION AGAINST UNDESIRABLE OR EXCESSIVE RADIATION	no danger	N/A
29	X-RAYS – No general requirement		N/A
30	ALPHA, BETA, GAMMA, NEUTRON AND OTHER PARTICLE RADIATION – No general requirement		N/A
31	MICROWAVE RADIATION – No general requirement		N/A
32	LIGHT RAYS (INCLUDING LASERS) – No general requirement		N/A
33	INFRARED RADIATION – No general requirement		N/A
34	ULTRAVIOLET RADIATION – No general requirement		N/A
35	ACOUSTIC ENERGY (INCLUDING ULTRASOUND) – No general requirement		N/A
36	ELECTROMAGNETIC COMPATIBILITY		P
	PART 6 – PROTECTION AGAINST THE DANGER OF FLAMMABLE ANAESTHETICS MIXTURES	not intended/suited for environment with flammable anaesthetics	N/A
	PART 7 – PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS		P
42	EXCESSIVE TEMPERATURES	see supplement #1	P
42.1	Parts of appliance with safety function must not reach		P

	temperatures exceeding the values in table 10a.		
Chapter	Requirements of the chapter of ČSN EN 60601-1	Notes	*H
42.2	Parts of appliance must not reach temperatures exceeding the values in table 10b.		P
42.3	Surface temperature of parts which are not intended to transfer warmth over to the patient.		P
	Temperature measuring as in 42.1 – 42.3		P
	1) Placement and cooling		N/A
	2) Feeding		P
	3) Utility factor		P
	4) Temperature measuring		P
	5) Testing criteria		P
42.4	Not used.		N/A
42.5	Enclosure of accessible hot surfaces.		N/A
43	FIRE PROTECTION		P
+43.1	BENDING STRENGTH AND STIFFNESS		P
	Appliance must be strong and stiff enough (tests as in chapter 21).		P
+43.2	Atmosphere enriched in oxygen – No general request.		N/A
44	OVERFLOW, SPILLING, LEAKAGE AND INGRESS OF LIQUIDS. CLEANING, STERILIZATION, DISINFECTION.		P
+44.1	Satisfactory degree of protection against the danger caused by overflow, spilling, leakage or ingress of liquids, cleaning, sterilization or disinfection.		P
+44.2	Overflowing liquid must not damp the electrical safety insulation.		N/A
	Test of overflow.		N/A
+44.3	Spilt liquid must not penetrate the electrical safety insulation.		N/A
	Test of spill.		N/A
+44.4	Leaking liquid must not penetrate the electrical safety insulation.		N/A
	Test of leakage.		N/A
+44.5	Appliance must be water resistant.		P
44.6	Protection against undesired penetration of water.		N/A
	Test of covering as in IEC 529.	IPX0	N/A
	Test of dielectric strength.		N/A
+44.7	Cleaning, sterilization and disinfection of part which will be in contact with the patient.		P
	Test of sterilization or disinfection.		P
+44.8	Compatibility with materials used in appliance – no general request.		N/A
45	PRESSURE CONTAINERS AND PARTS EXPOSED TO PRESSURE		N/A
45.1	Not used.		N/A
45.2	National regulations apply to the container.		N/A
	National regulations do not apply to the container.		N/A
	Additional tests.		N/A
45.3	The highest pressure must not exceed the highest permitted pressure for the part.		N/A
45.4	Not used.		N/A
45.6	Not used.		N/A
45.7	Appliance must be equipped with a pressure valve wherever pressure may occur.		N/A
45.8	Not used.		N/A
45.9	Not used.		N/A
45.10	Not used.		N/A

46	HUMAN ERROR – Not used.		N/A
Chapter	Requirements of the chapter of ČSN EN 60601-1	Notes	*H
47	ELECTROSTATIC DISCHARGE – Not used.		N/A
48	BIOCOMPATIBILITY		N/A
49	SUPPLY INTERRUPTION		P
+49.1	Thermal fuse and compact circuit breakers with automatic reset		N/A
+49.2	Interruption and re-initiation of supply.		P
+49.3	Mechanical release of patient in case of mains distribution failure.		N/A
	PART 8 – ACCURACY OF OPERATING DATA AND PROTECTION AGAINST UNAUTHORIZED ENTRY		N/A
50	ACCURACY OF OPERATING DATA		N/A
51	PROTECTION AGAINST UNAUTHORIZED ENTRY		N/A
+51.1	Deliberate trespass of limit values – no general request.		N/A
+51.2	Indication of parameters with regard to safety – no general request.		N/A
+51.3	Reliability of components – not used.		N/A
+51.4	Accidental setting of higher output values.		N/A
	PART 9 – ABNORMAL OPERATION AND FAILURE CONDITIONS. TESTS OF ENVIRONMENT INFLUENCE.		P
52	ABNORMAL OPERATION AND FAILURE CONDITIONS		P
+52.1	One defect must not cause a safety hazard.		P
+52.2	Not used.		N/A
+52.3	Not used.		N/A
+52.4	Types of jeopardy:		P
+52.4.1	Occurrence of flames, melted metal, toxic or flammable gas, deformation of cover or dangerous temperatures.		N/A
	Tests are not required provided the loss in power of circuits and parts is ≤ 15 W.	2.5 W	P
+52.4.2	Limit values of leaking voltage as in 19.3, table 4.		P
	Exceeding limit values of voltage in basic insulation on parts as stated in 16a) 5).		P
+52.4.3	Initiation, interruption or blockage of movements.		N/A
+52.5	Air and creepage distances shorter than required must be shorted out		N/A
+52.5.1	Overload of mains transformers – article 57.9		N/A
+52.5.2	Thermostat failures		N/A
+52.5.3	Short out any integral parts of the double insulation.		N/A
+52.5.4	Interruption of protective earthing conducting wire – 19.4		N/A
+52.5.5	Malfunction of cooling		N/A
+52.5.6	Blockage of movable parts.		N/A
+52.5.7	Interruption and shorting of motor condensers.		N/A
+52.5.8	Additional tests of appliance powers by motor.		N/A
	Winding temperature		N/A
+52.5.9	Defects of spare parts		N/A
+52.5.10	a/ Overload of an appliance with heating elements.		N/A
	b/ Overload of an appliance with a motor.		N/A
	c/ General conditions for heating elements tests.		N/A
	d/ Conditions for heating elements tests.		N/A
	e/ Additional conditions for heating elements tests.		N/A
	f/ Conditions for engine tests.		N/A
	g/ Conditions for appliance intended for short-term or interrupted operation.		N/A
	h/ Appliance with 3-phase motors.		N/A
	24-hour submersion of sample into conductive liquid.		N/A

	Test of electric strength		N/A
Chapter	Requirements of the chapter of ČSN EN 60601-1	Notes	*H
53	TEST OF ENVIRONMENT EFFECTS		P
	In accordance with article 4.10 and chapter 10.		P
	PART 10 – STRUCTURE REQUIREMENTS.		P
54	IN GENERAL		P
+54.1-3	Not used.		N/A
55	COVERS AND LIDS		N/A
+55.1-4	Not used.		N/A
56	PARTS AND COMPLETE ASSEMBLY		P
+56.1	In general		P
	A/ Not used.		N/A
	B/ Spare parts labelling		P
	C/ Not used.		N/A
	D/ Attachment of parts.		P
	E/ Not used.		N/A
	F/ Attachment of conducting wires.		N/A
+56.2	Not used.		N/A
+56.3	Connection – in general.		P
	A/ Construction of connecting parts.		P
	B/ Connection between different parts of appliance.		P
+56.4	Connection of condensers.		N/A
+56.5	Protection devices		N/A
+56.6	Thermal protection and protection against overload		N/A
	A/ Usage:		N/A
	-thermal fuse repairable by soldering,		N/A
	-thermal protection		N/A
	-independent non-self-resetting thermal fuse for the thermostat use		N/A
	Tests of thermal protections.		N/A
	Appliance equipped with a liquid container with the possibility of heating.		N/A
	B/ Permitted temperature range.		N/A
+56.7	Batteries		N/A
	A/ Box.		N/A
	B/ Connection.		N/A
	C/ Battery status – no general requirement.		N/A
+56.8	Indicators (if not any other indication possible):		P
	-indication that appliance is on,		P
	-indication that heating elements are on,		N/A
	-indication that appliance is activated		P
	Appliance equipped with a charging device of internal power supply.		N/A
+56.9	Not used.		N/A
+56.10	Controls		N/A
	A/ Protection against injury caused by electrical discharge – requirements in accordance with 16c).		N/A
	B/ Mechanical locking and prevention of fault setting.		N/A
	C/ Movement limitations.		N/A
+56.11	Controls and pedals with electrical cord.		N/A
	A/ Limitations of operation voltage.		N/A
	B/ Mechanical strength.		N/A
	C/ Undesired operation.		N/A
	D/ Ingress of liquids.		N/A
	E/ Electrical cords.		N/A
57	NETWORK PARTS, COMPONENTS AND ORGANIZATION		P

+57.1	Insulation of network distribution		N/A
Chapter	Requirements of the chapter of ČSN EN 60601-1	Notes	*H
	A/ Insulation		N/A
	-devices to disconnect from the mains at all poles simultaneously,		N/A
	-external device for disconnection must be specified in documentation.		N/A
	B/, C/ Not used.		N/A
	D/ Switches must meet the requirements for air and creepage distances		N/A
	E/ Not used.		N/A
	F/ Mains switches must not be built into the mains supply input or into external bendable conducting wires.		N/A
	G/ Movement directions of functional parts of switches.		N/A
	H/ Plug used to insulate the appliance from mains supply.		N/A
	J/, K/, L/ Not used.		N/A
	M/ Fuse and semi-conducting elements.		N/A
+57.2	Extensions, sockets and alike.	USB connector	P
	A/, B/, D/ Not used.		N/A
	C/ Construction – no general requirement.		N/A
	D/ Not used.		N/A
	E/ Auxiliary mains sockets.		N/A
	G/ Extensions of protection type I in appliances of protection type II.		N/A
+57.3	Mains supply		N/A
	A/ Design.		N/A
	B/ Types.		N/A
	C/ Cross section of conducting wires.		N/A
	D/ Preparation of conducting wires.		N/A
57.4	Connection of mains distribution inputs.		N/A
	A/ Anchoring of cable attachment		N/A
	-Conducting wires must be protected against tension and twisting, insulation must be protected against abrasion.		N/A
	-Design of mains distribution cord attachment.		N/A
	-Attachment of cord by screw gripping		N/A
	-Cord attachment screws must not be used for attachment of other components.		N/A
	Tensile test of cord, 25 times, 1 second.		N/A
	Test of twisting.		N/A
	B/ Test of cord protection.		N/A
	Test of bending.		N/A
	C/ Accessibility of connection inside the appliance for fixed line or repairable power supply.		N/A
+57.5	Connection terminals for mains voltage and mains conducting wires		N/A
	A/ General requirements		
	A continuously connected appliance or one connected via repairable non-separable input must have a connection terminal		N/A
	Keeping conducting wires in a required position.		N/A
	Terminals of other components.		N/A
	Screws and nuts gripping external leading wires.		N/A
	B/ Organization of connection terminals.		N/A
	Organization of connection terminals in appliance with repairable cord		N/A
	Connection of protective conducting wire – chapter 58		N/A

Chapter	Requirements of the chapter of ČSN EN 60601-1	Notes	*H
	Connection terminals must be accessible only by using a tool.		N/A
	Loose wire test.		N/A
	C/ Attachment of connection terminals.		N/A
	Test of attachment and release of conducting wire.		N/A
	D/ Connection to connection terminals.		N/A
+57.6	Mains-side fuse and overcurrent switch		N/A
	Use of fuse in each supply conducting wire in appliance of class I and II with functional earthing.		N/A
	Use of fuse at least in one supply conducting wire in one-phase appliances of class II.		N/A
	Nominal values of mains-side fuse and its maximal size.		N/A
	Protective earthing wire must not be equipped with a fuse.		N/A
	Neutral wire must not be equipped with a fuse in a fixed conducting wire		N/A
+57.7	Placement of suppression elements in the mains circuit – not used.		N/A
+57.8	Conducting wires of the mains circuit		N/A
	A/ Insulation		N/A
	Test of dielectrical strength in electrically equal insulation.		N/A
	B/ Crosscut		N/A
	Test of insulation by short-cut voltage.		N/A
+57.9	Mains transformers		N/A
+57.9.1	Overheating - tests as in 57.9.1a/b/.		N/A
	A/ Short-circuit		N/A
	Winding temperature.		N/A
	B/ Overloading		N/A
	Winding temperature		N/A
+57.9.2	Dielectrical strength – performed on an assembled appliance in accordance with chapter 20 and must not be repeated.		N/A
+57.9.3	Not used.		N/A
+57.9.4	Structure		N/A
	A/ Division of input and output winding.		N/A
	B/ Not used.		N/A
	C/ Shift of end thread out of insulation.		N/A
	D/ Protective earthing shielding		N/A
	E/ Isolation of transformers with reinforced or double insulation.		N/A
	F/ Creepage distances between input and output winding		N/A
	G/ Conducting wires output from internal winding of toroidal transformers.		N/A
57.10	Creepage and air distances	see supplement #1	P
	A/ Values – at minimum correspond to the values in table 16.		P
	B/ Usage.		N/A
	C/ Not used.		N/A
	D/ Measuring of creepage and air distances.		N/A
58	PROTECTIVE EARTHING – CLIPS AND CONNECTIONS		N/A
+58.1	Clips must comply with the requirements in 57.5c/.		N/A
	They can be loosened only with a tool.		N/A
+58.2	Internal protective earthing connection.		N/A
+58.3	Not used.		N/A
+58.4	Not used.		N/A

+58.5	Not used.		N/A
Chapter	Requirements of the chapter of ČSN EN 60601-1	Notes	*H
+58.6	Not used.		N/A
+58.7	Plug earthing pin.		N/A
+58.9	Protective earthing when pins and plug connection is used.		N/A
59	DESIGN STRUCTURE ORGANIZATION		P
+59.1	Internal links		N/A
	A/ Mechanical protection		N/A
	-Must be protected against contact with moving parts.		N/A
	-Must be sleeve-protected if in contact with metal parts.		N/A
	-Must not be exposed to damage when assembled.		N/A
	B/ Bending – radius of pulley \geq five times the outside diameter of conducting wire.		N/A
	C/ Insulation		N/A
	-Sleeve must be secured.		N/A
	-Bendable wire coat as extra insulation.		N/A
	-Insulation of conducting wires at $> 70^{\circ}\text{C}$.		N/A
	Test of dielectrical strength.		N/A
	D/ Material – aluminum wires must be $\geq 16\text{mm}^2$.		N/A
	E/ Not used.		N/A
	F/ Connecting cords between parts of appliance are considered appliance components.		P
59.2	Insulation (for other parts than insulation of conducting wires).		P
	A/ Not used.		N/A
	B/ Mechanical strength and heat and fire resistance		P
	-moisture resistance test (chapter 44),		P
	-test of dielectrical strength (chapter 20),		P
	-mechanical strength test (chapter 21)		P
	Heat resistance		P
	Brinell hardness test of covers and external insulating parts at the temperature of $+75^{\circ}\text{C}$ (or $40^{\circ}\text{C} + \Delta t$) for 1 hour.	75°C	P
	Brinell hardness test of material carrying non-insulated elements of mains distribution part at the temperature of 125°C (or $40^{\circ}\text{C} + \Delta t$) for 1 hours.		N/A
	C/ Protection		N/A
	-Insulation for settling of dust and other particles created by the wear of internal parts.		N/A
	-Ceramics and similar which are not sintered or individual beads should not be used.		N/A
	-Natural or synthetic rubber parts used as additional insulation in protection of class II must be aging resistant.		N/A
	Aging test in oxygen atmosphere.		N/A
+59.3	Protection against excessive current and voltage.		N/A
	-see article 57.6.		N/A
	-Device for protection against possible fire hazard when internal power supply is used.		N/A
	-Fuse elements, changeable without opening the cover of appliance.		N/A
	-Protective devices to secure against excessive voltage.		N/A
	-Thermal fuse and overcurrent switches – article 56.6		N/A
+59.4	Oil containers		N/A
	SUPPLEMENT A – LEGEND AND GENERAL EXPLANATIONS		P
	SUPPLEMENT B – TESTS DURING PRODUCTION OR INSTALLATION		P
	SUPPLEMENT C – ORDERING OF TESTS		P

	SUPPLEMENT D – ICONS COMPENSATING FOR SIGNS		N/A
	SUPPLEMENT E – OVERVIEW OF INSULATION PATHS AND TEST CIRCUITS		P

3 CONCLUSION

***Electroimpedance computer mamograph MEIK® complies with the requirements of the following norms:**

- ČSN EN 60601-1

Test results refer solely to the tested object.