OŚRODEK BADAŃ ATESTACJI I CERTYFIKACJI OBAC Sp. z o.o.
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Laboratorium L A B O R E x
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AB 1340

Gliwice 08.04.2021

TEST REPORT

from test No. LL/003/2021/A

Subject: **Research of PSS Liana sitting position stabilizer**

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NIP: PL 631-21-53-136 z 24.04.2004 r.
REGON: 273725355
Kapitał zakładowy – 400 000,00 PLN
KRS: 0000161774 Sąd Rejonowy w Gliwicach
X Wydział Gospodarczy Krajowego Rejestru Sądowego

1. **Client name and address:**
   ASP Polska Sp. z o. o.
   21 Wierzbowa street,
   67-200 Głogów.

2. **Contract/errand/order/number:**
   0008/OBAC/2393/KM/21

3. **Case identification number given by Laboratory:**
   LL/003/2021

4. **Place of performing tests:**
   LABOREx Laboratory
   4 Aronii street,
   44-102 Gliwice.

5. **Date of delivery of object for testing:**
   21.12.2020

6. **Description, status and identification of tested object:**
   Tested object: PSS Liana sitting position stabilizer
   Serial number: ASP20201201,
   Year of production: 2020,
   Sample delivered by the client.

7. **Date(s) of performing tests:**
   27.01÷08.04.2021

8. **Tests range and identification of method applied:**

No.	Tested magnitude	Standards applied	Accredited method
1	Checking the risk management process	PN-EN 60601-1:2011 +A1:2014+ A12:2014+Ap1:2014+Ap2:2019+ AC:2015 point 4.1 ÷ 4.10 Analysis of risk management file	no
2	Checking the single fault condition	PN-EN 60601-1:2011 +A1:2014+ A12:2014+Ap1:2014+Ap2:2019+ AC:2015 point 4.7	yes
3	Checking components	PN-EN 60601-1:2011 +A1:2014+ A12:2014+Ap1:2014+Ap2:2019+ AC:2015 point 4.8	no
4	Checking of power consumption	PN-EN 60601-1:2011 +A1:2014+ A12:2014+Ap1:2014+Ap2:2019+ AC:2015 point 4.11	no

5	Checking access to applied parts and accessible parts	PN-EN 60601-1:2011 +A1:2014+ A12:2014+Ap1:2014+Ap2:2019+ AC:2015 point 5.9	no
6	Checking identification and marking	PN-EN 60601-1:2011 +A1:2014+ A12:2014+Ap1:2014+Ap2:2019+ AC:2015 point 7 and annex „C"	yes
7	Checking protection against electric shock	PN-EN 60601-1:2011 +A1:2014+ A12:2014+Ap1:2014+Ap2:2019+ AC:2015 point 8	yes
8	Checking the limitation of voltage, current or energy	PN-EN 60601-1:2011 +A1:2014+ A12:2014+Ap1:2014+Ap2:2019+ AC:2015 point 8.4	no
9	Checking the separation of parts	PN-EN 60601-1:2011 +A1:2014+ A12:2014+Ap1:2014+Ap2:2019+ AC:2015 point 8.5	no
10	Checking the protective earthing, functional earthing and potential equalization (if applicable)	PN-EN 60601-1:2011 +A1:2014+ A12:2014+Ap1:2014+Ap2:2019+ AC:2015 point 8.6	yes
11	Checking the leakage currents and patient auxiliary currents	PN-EN 60601-1:2011 +A1:2014+ A12:2014+Ap1:2014+Ap2:2019+ AC:2015 point 8.7	yes
12	Checking the clearances by permanent insulation and the use of thin insulating spacers (if applicable)	PN-EN 60601-1:2011 +A1:2014+ A12:2014+Ap1:2014+Ap2:2019+ AC:2015 point 8.8.2	yes
13	Checking the dielectric strength	PN-EN 60601-1:2011 +A1:2014+ A12:2014+Ap1:2014+Ap2:2019+ AC:2015 point 8.8.3	yes
14	Checking the insulation other than wire insulation	PN-EN 60601-1:2011 +A1:2014+ A12:2014+Ap1:2014+Ap2:2019+ AC:2015 point 8.8.4	yes
15	Checking the creepage distances and air clearances	PN-EN 60601-1:2011 +A1:2014+ A12:2014+Ap1:2014+Ap2:2019+ AC:2015 point 8.9	yes
16	Checking the equipment components and general assembly	PN-EN 60601-1:2011 +A1:2014+ A12:2014+Ap1:2014+Ap2:2019+ AC:2015 point 8.10 and 15.4	no
17	Checking the mains parts, components and layout	PN-EN 60601-1:2011 +A1:2014+ A12:2014+Ap1:2014+Ap2:2019+ AC:2015 point 8.11	no

18	Checking the protection against mechanical hazards	PN-EN 60601-1:2011 +A1:2014+ A12:2014+Ap1:2014+Ap2:2019+ AC:2015 point 9	yes
19	Checking the hazards associated with moving parts	PN-EN 60601-1:2011 +A1:2014+ A12:2014+Ap1:2014+Ap2:2019+ AC:2015 point 9.2	yes
20	Checking the hazard associated with surfaces, corners and edges	PN-EN 60601-1:2011 +A1:2014+ A12:2014+Ap1:2014+Ap2:2019+ AC:2015 point 9.3	yes
21	Checking the hazard caused by instability	PN-EN 60601-1:2011 +A1:2014+ A12:2014+Ap1:2014+Ap2:2019+ AC:2015 point 9.4	yes
22	Checking the hazard associated with ejected parts	PN-EN 60601-1:2011 +A1:2014+ A12:2014+Ap1:2014+Ap2:2019+ AC:2015 point 9.5	no
23	Checking the hazard associated with support systems	PN-EN 60601-1:2011 +A1:2014+ A12:2014+Ap1:2014+Ap2:2019+ AC:2015 point 9.8	no
24	Checking the protection against excessive temperatures	PN-EN 60601-1:2011 +A1:2014+ A12:2014+Ap1:2014+Ap2:2019+ AC:2015 point 11.1	no
25	Checking of fire protection and design requirements for fireproof device enclosures	PN-EN 60601-1:2011 +A1:2014+ A12:2014+Ap1:2014+Ap2:2019+ AC:2015 point 11.2, 11.3	no
26	Checking the overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the equipment	PN-EN 60601-1:2011 +A1:2014+ A12:2014+Ap1:2014+Ap2:2019+ AC:2015 point 11.6	yes
27	Checking the power continuity	PN-EN 60601-1:2011 +A1:2014+ A12:2014+Ap1:2014+Ap2:2019+ AC:2015 point 11.8	no
28	Checking the accuracy of controls and instruments and protection against hazardous outputs	PN-EN 60601-1:2011 +A1:2014+ A12:2014+Ap1:2014+Ap2:2019+ AC:2015 point 12.1 ÷ 12.4	no
29	Checking the hazardous situations and fault conditions	PN-EN 60601-1:2011 +A1:2014+ A12:2014+Ap1:2014+Ap2:2019+ AC:2015 point 13	no
30	Checking the construction of equipment	PN-EN 60601-1:2011 +A1:2014+ A12:2014+Ap1:2014+Ap2:2019+ AC:2015 point 15	no

31	Checking the serviceability	PN-EN 60601-1:2011 +A1:2014+ A12:2014+Ap1:2014+Ap2:2019+ AC:2015 point 15.2	no
32	Checking the mechanical strength	PN-EN 60601-1:2011 +A1:2014+ A12:2014+Ap1:2014+Ap2:2019+ AC:2015 point 15.3 and 9.2.2.4.1	no
33	Checking the mains supply transformers of equipment and transformers providing separation	PN-EN 60601-1:2011 +A1:2014+ A12:2014+Ap1:2014+Ap2:2019+ AC:2015 point 15.5	no
34	Checking the static stability	PN-EN 12183 point 7.1.2	no
35	Checking the supports for the body parts	PN-EN 12183 point 8.1.2	no
36	Checking the flammability of plastic materials present in the device construction	PN-EN 12183 point 8.5	no
37	Checking the brakes	PN-EN 12183 point 9.1.2; 9.2.2	no
38	Checking the pushing force	PN-EN 12183 point 9.3.2	no
39	Checking the requirements for handles	PN-EN 12183 point 10.4.2	no
40	Determining the value of forces	PN-EN 12183 point 10.5.2	no
41	Measurement of noise during operation of the electric drive	EN ISO 3746	no
42	Temperature of the surface that may come into contact with the human skin	PN-EN ISO 13732-1	no
43	Checking the safe distances between moving and stationary parts	PN-EN 12182 point 12.1; 13.1	no
44	Checking the dimensions including ergonomics	PN-EN 12182 point 23	no
45	Checking the static strength	PN-EN 12184 point 8.2.2	no

9. Equipment used to perform tests

Equipment name	Identification number
Finger probe	C/099/LL
Electronic calliper	A/006/LL
SECULIFE ST device for testing medical devices	A/236/LL
FLUKE multimeter	A/044/LL
Climatic chamber	C/081/LL
Dynamometer FC-200	A/200/LL
Test circuit UP-2	A/126/LL
High voltage probe	A/125/LL
Digital multimeter BM 867	A/105/LL
Electronic stopwatch	A/136/LL
Temperature recorder HD32.8.16	A/228/LL
Thermocouple 20-K-1	A/228/A4/LL
Thermocouple 20-K-1	A/228/B4/LL
Thermocouple 20-K-1	A/228/C1/LL
Thermocouple 20-K-1	A/228/C2/LL
Thermocouple 20-K-1	A/228/C3/LL
Thermocouple 20-K-1	A/228/C4/LL
Thermocouple 20-K-1	A/228/D1/LL
Thermocouple 20-K-1	A/228/D2/LL
Hythergraph type LB522B	A/207/LL
Probe - Hythergraph type LB701H	C/074/LL
Measurement panel LB-706B with a barometric module	C/073/LL
Oscilloscope	A/023/LL
Voltage probe	A/023/01/LL

Apparatus was inspected prior to the tests- apparatus works correctly.

10. Test performance and results

The results and associated uncertainties relate only to the tested sample and may not relate to any part of product / substance / material.

Measurement uncertainty was determined according to the document EA-4/02. These uncertainties are expanded uncertainty at the 95% confidence level and coverage factor k = 2.

Delivered documentation:

- Instruction for use PSS Liana Patient sitting position stabilizer on the edge of the LIANA bed, Edition 01/05.12.2020
- Usability analysis rev.:1 of 24.11.2020
- Risk analysis acc. to ISO 14971 of the PSS Liana/2020

The test results are presented in the table.

Evaluation marks used in the test results:

P – positive result,
N – negative result,
NA – the research doesn't apply to the device.

Point of the standard	Test	Result	Assessment acc. to the requirements of the standard
4	**General requirements**		-
4.1	Conditions for using ME equipment and ME systems		-
4.2	Risk management process for ME equipment and ME systems - the manufacturer should have an established risk management process - the process should be carried out in accordance with ISO 14971 - the manufacturer should set acceptable risk levels	The risk analysis procedure was provided by the manufacturer. The file complies with ISO 14971.	P
4.2.1.	Introduction to risk management		
4.2.2.	General risk management requirement - inspection of the manufacturer's policy for determining criteria for risk acceptability - inspection of the risk management plan for the particular ME equipment or ME system under consideration - confirming the manufacturer has prepared a risk management file containing the risk management notations and other documentation required by this standard for the particular ME equipment or ME system under consideration		
4.2.3.	Evaluating risk		
4.2.3.1.	Hazards identified in the IEC 60601- series - compliance is checked by confirming that the notations in the risk management file demonstrate that, after applying the specific requirements of this standard, the acceptance criteria determined by the manufacturer are satisfied. Only the relevant parts of the risk management file need to be reviewed, e.g. the manufacturer's calculations or test results or the determination of risk acceptability.		
4.2.3.2.	Hazards not identified in the IEC 60601 series - the manufacturer shall address those hazards in the risk management process as specified in 4.2.2, compliance is checked by inspection of the risk management file.		
4.3	Essential performance - compliance is checked by inspection of the risk management file	PSS Liana stabilizer of the patient's position (sitting or standing) is the medical product supporting rehabilitation, intended for use in short and long- term care facilities, hospitals, hospices, rehabilitation centres.	P
4.4	Life expectancy	Information included in the User's manual of the device: *"The product life is 36 months from the date of purchase"*	P

4.5	Equivalent safety for ME equipment or ME systems - compliance is checked by inspection the risk management file	Risk management file	P
4.6	ME equipment or ME system parts that contact the patient - compliance is checked by inspection of the risk management file	Risk management file	P
4.7	Single fault condition in the ME equipment	Tests acc. to point 13.2	-
4.8	Components of ME equipment	Tests acc. to point 13.2.8 and 15.5.3	-
4.9	The use of high reliability components in the ME equipment	NA	NA
4.10	Power supply		-
4.10.1	Power source of the ME equipment The device should be adapted to: - connection to the supply mains - connection to the separate power source - from an internal power source - power supply combination of the above connections	The device is powered by the internal battery. The battery is charged outside the device with the use of charger compliant with the test standard.	P
4.10.2	Supply mains for ME equipment and ME systems. Nominal voltage value must not exceed: - 250 V for hand-held ME equipment - 250 V for single-phase constant or alternating voltage - 500 V for multi-phase AC voltage at power <= 4 kVA - 500 V for all other ME equipment	100-240 V, 50/60 Hz for mains charger 24 V DC battery powered	P
	Mains overvoltage category (II, unless the manufacturer specifies a higher one)	Overvoltage category II has been defined for the charger	P
4.11	Power input Measure the power in units in which it was declared by the manufacturer	The device is powered from the internal source. The maximum power consumption when charging the battery outside the device, measured on the power supply of the dedicated charger from the 230 V mains was: P = 25 W I = 0,18 A	P
5	**General requirements for testing ME equipment**		-
5.1	Type tests	Tests were carried out which are type tests according to annex B of the standard.	P
5.2	Number of samples	The tests were carried out on one sample of the device.	P
5.3	Ambient temperature, relative humidity, atmospheric pressure	Ambient temperature: 20,4÷24,5 ℃ Relative humidity: 38÷70% RH Pressure: 989÷1020 hPa	P
5.4	Other conditions	Relative humidity stabilization 93% RH	P
5.5	Supply voltages, type of current, type of supply, frequency	100-240 V, 50/60 Hz for the mains charger	P

5.6	Repairs and modifications	NA	NA
5.7	Humidity preconditioning treatment	93% RH for 168 h	P
5.8	Tests order	Order of tests in accordance with annex B of the standard.	P
5.9	Determination of applied parts and accessible parts		-
5.9.1	Applied parts	Application parts: - headrest - backrest - lumbar support - knee support - hand grip - armrest	P
5.9.2	Accessible parts		-
5.9.2.1	Finger probe access	No access to live parts	P
5.9.2.2	Test hook	Lower cover of the stabilizer-pulling the cover did not cause loosen it	P
5.9.2.3	Actuating mechanisms - compliance is checked by tests according to 5.9.2.1 and 15.4.6.1	Conductive parts of the actuating mechanisms cannot be accessed without removing the covers with the tool	P
7	**ME equipment identification, marking and documents**		-
7.1	General requirements		-
7.1.1	Usability of the identification, marking and documents. - compliance is checked in accordance with IEC 60601-1-6	Usability analysis rev.:1 of 24.11.2020 The document refers to the IEC 60601-1-6 standard	P
7.1.2	Legibility of markings	Marking legible from a distance of 1m	P
7.1.3	Durability of markings	After rubbing with distilled water, 96% ethyl alcohol and isopropyl alcohol, no legibility was lost	P
7.2	Marking on the outside of ME equipment		-
7.2.1	Minimal requirements for marking on ME equipment and on interchangeable parts	Nameplate placed on the device	P
7.2.2	Identification	The device is marked with the nameplate, view of the nameplate attached.	P
7.2.3	Use of accompanying documentation	Symbol ISO 7000-1641 located on the nameplate	P
7.2.4	Accessories	The only equipment of the tested device is the mains charger compliant with the IEC 60601-1 standard	P
7.2.5	ME equipment intended to receive power from other equipment	NA	NA
7.2.6	Connection to the supply mains	Supply voltage : 100 V - 240 V 50/60 Hz for mains charger	P

7.2.7	Electrical input power from the supply mains	NA- device powered from the internal source. The power consumption of the charger while charging the battery is: P=25 W, I=0,18 A	NA
7.2.8	Output connections		-
7.2.8.1	Supply mains output power	NA	NA
7.2.8.1	Other power sources	NA	NA
7.2.9	IP classification	Entire device IPX2	P
7.2.10	Applied parts	Type B applied parts	P
7.2.11	Type of operation	Fill factor 10% or 2 min continuous operation / 18 min break	P
7.2.12	Fuses	NA	NA
7.2.13	Physiological effects (safety signs and warnings)	NA	NA
7.2.14	High voltage terminal devices	NA	NA
7.2.15	Cooling conditions	NA	NA
7.2.16	Mechanical stability	Tests acc. to point 9.4	-
7.2.17	Protective packaging	NA	NA
7.2.18	External pressure source	NA	NA
7.2.19	Functional earth terminal	NA - no functional earth terminal	NA
7.2.20	Removable protective measures	NA	NA
7.2.21	Mass of mobile ME equipment	Information included in the instruction for use Total weight of the device: 120kg Maximum load: 120kg	P
7.3	Marking on the inside of ME equipment or ME equipment parts		-
7.3.1	Heating elements and lamp holders	NA	NA
7.3.2	High voltage parts	NA	NA
7.3.3	Batteries	2.9 Ah battery compliant with test standard. The instruction for use contain the warning regarding the failure to connect the battery contacts.	P
7.3.4	Fuses, thermal cut-outs and over-current releases	NA	NA
7.3.5	Protective earth terminals	NA - no protective earth terminal	NA
7.3.6	Functional earth terminals	NA - no functional earth terminal	NA
7.3.7	Power terminals	NA	NA
7.3.8	Power terminals temperature	NA	NA
7.4	Marking of controls and instruments		-

7.4.1	Power switches	The power button is located on the controller module. The device is turned on by pressing the button on the remote control or the control panel in column with the door closed, which closes the circuit of the control module.	P
7.4.2	Control devices	NA	NA
7.4.3	Units of measure	NA	NA
7.5	Safety signs	Information signs: ISO 7000-0434A, ISO 7000-1641, EIC 60878, ISO 3864-1 pattern with hand	P
7.6	Symbols		-
7.6.1	Explanation of symbols	The symbols on the nameplate of the device are explained in the instruction for use	P
7.6.2	Symbols according to annex D	Symbols consistent with annex D	P
7.6.3	Symbols for controls and performance	NA	NA
7.7	Colours of the insulation of conductors		-
7.7.1	Protective earth conductor	NA	NA
7.7.2	Protective earth connections	NA	NA
7.7.3	Yellow-green insulation	NA	NA
7.7.4	Neutral conductor	NA	NA
7.7.5	Cores in the supply mains conductor	NA	NA
7.8	Light indicators and buttons		-
7.8.1	Light indicator colours	The device is equipped with signal diodes: mains charger turned on- green charging the battery in the mains charger- orange remote control high charge- green remote control low charge- yellow	P
7.8.2	Button colours	Only the emergency shutdown button of the device is red	P
7.9	Accompanying documents		-
7.9.1	General	Risk analysis acc. to ISO 14971 of the PSS Liana/2020 Instruction for use PSS Liana Patient sitting position stabilizer on the edge of the LIANA bed Edition 01/05.12.2020	P
7.9.2	Instruction for use		-

7.9.2.1	General	The instruction describes the purpose and device functions	P
7.9.2.2	Warnings and notes about safety	Warnings and notes regarding safe use can be found in section 1.2 General safety instruction in the Instruction for use	P
7.9.2.3	ME equipment intended for connection to the separate power source	NA	NA
7.9.2.4	Electrical power source	There is the internal battery with the capacity 2.9 Ah compliant with standard. The instruction for use including warnings about using the battery.	P
7.9.2.5	Description of the ME equipment	Instruction includes the description and operation of the ME device	P
7.9.2.6	Installation	NA - The device does not require any special installation	NA
7.9.2.7	Isolation from the supply mains	During operation, the device is powered from the internal source. The battery is charged in the mains charger outside the device. The mains charger is compliant with the standard.	P
7.9.2.8	Operational start procedure	The procedure is described in point 7 of the device's instruction for use	P
7.9.2.9	Instruction for use	Instruction for use of the PSS Liana sitting position of the patient on the edge of the LIANA bed edition 01/05.12.2020	P
7.9.2.10	Messages	Messages are generated by signalling diodes on the remote control. The explanation of the meaning of the messages are included in the instruction for use of the device.	P
7.9.2.11	Ending procedure	The procedure is described in point 7 of the instruction for use of the device	P
7.9.2.12	Cleaning, disinfection and sterilization	The cleaning and disinfection process is described in point 8 Cleaning and disinfection in the Instruction for use	P
7.9.2.13	Maintenance	In point 9. Service in the Instruction for use it is written "All repair and maintenance works may be performed only by the manufacturer or the recognized service".	P
7.9.2.14	Accessories, supplementary equipment, used material	Equipment described in point 5. Construction	P

7.9.2.15	Environmental protection	Relevant information is included in point 11 Environmental protection in the Instruction for use.	P
7.9.2.16	Reference to the technical description	The technical description is part of the instruction for use	P
7.9.3	Technical description		-
7.9.3.1	General		-
7.9.3.2	Replacement of fuses, supply mains cables and other parts	In point 9 Service in the instruction for use was included "All repair and maintenance works may be performed only by the manufacturer or the recognized service"	NA
7.9.3.3	Circuit diagrams, parts lists etc.		
7.9.3.4	Supply mains insulation	During operation the device is separated from the mains because it is powered from the internal source. While charging the battery, separation takes place at the mains charger.	P
8	**Protection against electrical hazards from ME equipment**		-
8.1	Fundamental rule of protection against electric shock	8.1 Fundamental rule of protection against electric shock. Tests according to point 8.7; 8.8; 8.9; 8.10; 13.1; and the accessible parts according to point 5.9.	P
8.2	Requirements related to power sources		-
8.2.1.	Connection to the separate power source	NA	NA
8.2.2.	Connection to an external d.c. power source	NA	NA
8.3	Classification of applied parts	The applied parts used in the device are type B	P
8.4	**Limitation of voltage, current or energy**		-
8.4.1	Patient connections for power supply	Annex No. 1	P
8.4.2	Accessible parts including applied parts	Annex No. 1	P
8.4.3	ME equipment intended to be connected to a power source by the plug	Integrated mains plug with the mains charger which is compliant with the test standard.	P
8.4.4	Internal capacitive circuits	NA	NA
8.5	**Separation of parts**		-
8.5.1	Means of protection		-
8.5.1.1	General: The medical device should have two protection means to protect the applied parts and other accessible parts against exceeding the permissible leakage currents		-

8.5.1.2	Means of patient protection (MOPP)	The device is powered from the internal source with the safe voltage of 24 V DC	P
8.5.1.3	Means of operator protection (MOOP)	1. The device is powered from the internal source with the safe voltage of 24 V DC 2. During the battery charging process, separation from the power supply is carried out by the AC adapter compliant with standard	P
8.5.2	Separation of patient connections		-
8.5.2.1	Type F applied parts	NA	NA
8.5.2.2	Type B applied parts	Tests acc. to 8.7.4 and 8.8.3	-
8.5.2.3	Patient leads or patient cables	NA	NA
8.5.3	Maximum supply mains	250 V - adopted acc. to the standard	P
8.5.4	Operating voltage	230 V for mains charger	P
8.5.5	Defibrillation-proof applied parts		-
8.5.5.1	Defibrillation protection	NA	NA
8.5.5.2	Energy reduction test	NA	NA
8.6	**Protective earthing, functional earthing and potential equalization of medical device**		-
8.6.1	Applicability of requirements	Requirements from 8.6.2 to 8.6.9	-
8.6.2	Protective earth terminal	NA	NA
8.6.3	Protective earth for moving parts	NA	NA
8.6.4	Impedance and current-carrying capability	NA	NA
8.6.5	Surface coverage	NA	NA
8.6.6	Plugs and sockets	NA	NA
8.6.7	Potential equalization conductor	NA	NA
8.6.8	Functional earth terminal	NA	NA
8.6.9	Class II medical device	NA	NA
8.7	**Leakage currents and patient auxiliary currents**	Annex No. 1	P
8.8	**Insulation**		-
8.8.1	General Only insulation that is relief upon as a means of protection, including reinforced insulation, shall be subject to testing		-
8.8.2	Clearance through permanent insulation and the use of thin insulating spacers	Annex No. 2	P
8.8.3	Dielectric strength	NA - device powered from the internal source with 24 V DC	NA
8.8.4	Insulation other than wire insulation		-

8.8.4.1	Mechanical strength and resistance to heat	NA	NA
8.8.4.2	Resistance to environmental exposure	The device is resistant to environmental exposure that may occur during its use in accordance with the user manual	P
8.9	Creepage distances and air clearances	Annex No. 2	P
8.10	Components and wiring		-
8.10.1	Fixing of components	The device components are securely fixed	P
8.10.2	Fixing of wiring	Cables and connectors properly secured	NA
8.10.4	Wired, manual and foot control units		-
8.10.4.1	Operating voltage limits	Remote control HB330VCXD056-2102C1E000 compliant with IEC 60601-1	P
8.10.4.2	Connection cords	Remote control HB330VCXD056-2102C1E000 compliant with IEC 60601-1	P
8.10.5	Mechanical protection of wiring	Cables and connectors properly secured	P
8.10.6.	Castors guides for insulated cords	NA	NA
8.10.7	Internal wiring insulation	a) internal wiring does not require the use of insulating sleeves b) in places where cables are subjected to mechanical stress, the cable cover is not used as a protection measure within the meaning of this standard c) the temperature of the cables during normal use does not exceed 70 °C	P
8.11	Mains parts, components and placement		-
8.11.1	Isolation from the supply mains		-
	a) disconnection from the supply mains at all poles at the same time	The device is powered by the internal power source. The mains charger is compliant with test standard.	P
	b) disconnection means should be built into the device	Connection socket- plug from the mains charger	P
	c) the switch should meet the requirements regarding insulation clearances acc. to IEC 61058-1	NA	NA
	d) the switch should not be installed in the hose	NA	NA
	e) direction of the switch move acc. to IEC 60447	NA	NA
	f) connection in ME equipment not permanently installed	Connection socket- plug from the mains charger	P

	g) fuses should not be used as disconnecting devices	NA	NA
	h) ME equipment should not have a device that causes shutdown by causing the short circuit and tripping of the circuit breaker	There is no device turning off by causing a short circuit	P
	i) any part of the circuit with a voltage above 42.4V that is not disconnected from the power supply via the power mains switch should be protected against contact with additional covers	NA- powering the device with the internal 24 V DC source Mains charger connected to the mains and it is compliant with the test standard	NA
8.11.2	Multiple sockets	NA	NA
8.11.3	AC mains cord		-
8.11.3.1	Application The power plug should not be connected to more than one power cord	NA	NA
8.11.3.2	Mains power cord requirements	NA	NA
8.11.3.3	Cross-section of the power cord	NA	NA
8.11.3.4	Equipment terminal	NA	NA
8.11.3.5	Cord anchorage	NA- the mains power cable is located in the mains charger which is compliant with the test standard	NA
8.11.3.6	Cord strain relief		NA
8.11.4	Mains terminal blocks		-
8.11.4.1	Requirements for mains terminal blocks	NA - the device does not have a non-detachable cable	NA
8.11.4.2	Arrangement of mains terminal assemblies	NA - the device does not have a non-detachable cable	NA
8.11.4.3	Installation of the mains terminals	NA	NA
8.11.4.4	Connection to the mains terminals	NA	NA
8.11.4.5	Connection accessibility	NA	NA
8.11.5	Mains fuses and over-current releases	NA	NA
8.11.6	Internal wiring of the mains part	NA	NA
9	**Protection against mechanical hazards of ME equipment and ME systems**		-
9.1	Mechanical hazards of ME devices	Tests acc. to 9.2, 9.3, 9.4 and 9.8	-
9.2	Mechanical hazards associated with moving parts		-
9.2.1	General: The risk arising from contact with moving parts should be reduced to the acceptable level using protective means, taking into account freedom of access, function of the ME equipment, shape of parts, energy and speed of movement and benefits for patient.	Tests acc. to 9.2	-
9.2.2	Trapping zone		-

9.2.2.1	General The device with trapping zone should meet one or more of the following requirements: - gaps as specified in 9.2.2.2 or - safe distances as specified in 9.2.2.3 or - guards and other risk control measures as specified in 9.2.2.4 or - continuous activation as specified in 9.2.2.5	Tests acc. to 9.2.2.2, 9.2.2.3, 9.2.2.4	-
9.2.2.2	Gaps	The dimensions of the gaps are not compliant with table 20. Movement takes place in the operator's field of view, there is continuous activation.	NA
9.2.2.3	Safe distances	NA	NA
9.2.2.4	Guards and other risk control measures		-
9.2.2.4.1	Access to trapping zones	There is access to the trapping zone. Movement takes place in the operator's field of view, there is continuous activation .	NA
9.2.2.4.2	Guards permanently fixed	NA	NA
9.2.2.4.3	Movable guards	NA	NA
9.2.2.4.4	Other risk control measures	The warning sign is located near to adjustment of the patient's headrest.	P
9.2.2.5	Continuous activation	Movement take's place in the operator's field of view, there is continuous activation.	P
9.2.2.6	Speed of movements	Movement is slow and the operator has control over its positioning.	P
9.2.3	Other mechanical hazards associated with moving parts		-
9.2.3.1	Unintended movement	No possibility of the unintentional movement of the device	P
9.2.3.2	Overtravel end stops	NA	NA
9.2.4	Emergency stopping devices	The device has one emergency switch meeting the requirements of this point of the standard.	P
9.2.5	Release of patient	The device was inspected and the risk management file.	P
9.3	Mechanical hazards associated with surfaces, corners and edges	There are no sharp edges	P
9.4	Instability hazards		-
9.4.1	General	Mobile device. Tests acc. to: 9.4.2 to 9.4.4	-
9.4.2	Instability - overbalance		-
9.4.2.1	Instability in transport position	The device does not lose balance when placed on the surface inclined from the horizontal at an angle of 10°.	P

9.4.2.2	Instability excluding transport	The device does not lose balance when placed on the surface inclined from the horizontal at an angle of 5°.	P
9.4.2.3	Instability from horizontal and vertical forces	Weight of the device > 25kg The force of 150 N was applied to: - arms - device column The device did not lose its balance in any of the cases. The force of 800 N was applied at the point of the maximum torque. The device did not lose its balance.	P
9.4.2.4	Castors and wheels		-
9.4.2.4.1	General		-
9.4.2.4.2	Force to move off	The force required to slide the device over the hard and flat horizontal plane is less than 200 N.	P
9.4.2.4.3	Movement over a threshold	The test was performed in accordance with the standard. The device is capable of pass over the threshold. Drive over the threshold does not cause loss of stability of the device.	P
9.4.3	Instability from unwanted lateral movement (including slip)		-
9.4.3.1	Instability in transport position	NA- the device brakes are not mechanically driven	NA
9.4.3.2	Instability excluding transport position		-
	a) mobile ME equipment	The research was carried out in accordance with the provisions of the standard. There was no displacement greater than 50 mm.	P
	b) stationary ME equipment		
9.4.4	Grips and other handling devices		-
	a) ME equipment other than portable or it's parts with mass bigger than 20 kg	The device is equipped in the operator's grip, the method of moving the device is obvious and does not introduce any hazards.	P
	b) portable devices	NA - mobile device	NA
	c) requirements for portable device holders	NA - mobile device	NA
9.5	Hazards associated with ejected parts		-
9.5.1	Means of protection	NA	NA
9.5.2	Tube lamps	NA	NA
9.8	Hazards associated with support systems		-
9.8.1	General	The risk analysis included the breaking of the patient's support slings and the collapse of the bed.	P

9.8.2	Tensile safety factor	The risk analysis states that the design of the support slings was calculated with the factor of 2,5.	P
9.8.3	Strength of patient or operator support or suspension systems		-
9.8.3.1	General	The maximum load specified in the instruction for use is 120 kg	P
9.8.3.2	Static forces due to loading from persons	NA	NA
9.8.3.3	Dynamic forces due to loading from persons	NA	NA
9.8.4	Systems with mechanical protective devices		-
9.8.4.1	General	NA	NA
9.8.4.2	Use after mechanical protection device has worked	NA	N
9.8.4.3	Mechanical protective device intended for single activation	NA	NA
9.8.5	Systems without mechanical protective devices	The risk analysis included the breaking of the patient's support slings and the collapse of the bed. The risk analysis states that the design of the support slings was calculated with the factor of 2,5.	P
11	**Protection against excessive temperatures and other hazards**		-
11.1	Excessive temperatures in ME equipment	Annex No. 3	P
11.1.1	Maximum temperatures in normal use		
11.1.2	Temperature of applied parts		
11.1.2.2	Applied parts not intended to supply heat to a patient		
11.1.3	Measurements		
11.1.4	Guards		
11.2	Fire prevention		-
11.2.1	Strength and rigidity required to prevent fires in the ME equipment	Tests acc. to 15.3	P
11.2.2	ME equipment and ME systems used in the oxygen-rich environment	NA	NA
11.2.2.1	Risk of fire in the oxygen-rich environment	NA	NA
11.2.2.2	External outlet sockets in the oxygen-rich environment	NA	NA
11.2.2.3	Electrical connections in the oxygen-rich environment	NA	NA
11.2.3	Single fault conditions related to the oxygen-rich environment including ME equipment and ME systems	NA	NA
11.3	Construction requirements for ME equipment enclosure	NA	NA
11.6	Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME equipment		-

11.6.1	General		-
11.6.2	Overflow in ME equipment	NA	NA
11.6.3	Spillage on ME equipment and ME system	NA	NA
11.6.4	Leakage	NA	NA
11.6.5	Ingress of water or particulate matter into ME equipment and ME systems	Equipment marked with IPX2 protection degree was tested acc. to IEC 60529 in the worst position in normal use: no traces of water was found inside the housing of the device, which could create the hazardous situation	P
11.6.6	Cleaning and disinfection	In the risk analysis provided, the effects of the loss of legibility of the marking caused by cleaning the device were assessed.	P
11.6.7	Sterilization of ME equipment	NA	NA
11.6.8	Compatibility with substances used with the ME equipment	NA	NA
11.7	Biocompatibility of ME equipment and ME systems	NA	NA
11.8	Interruption of the power supply/ supply mains to ME equipment	The break in the power supply circuit followed by the power return does not cause the hazardous situation	P
12	**Accuracy of controls and instruments and protection against hazardous outputs**		-
12.1	Accuracy of controls and instruments	NA	NA
12.2	Usability of ME equipment	Usability analysis rev.:1 of 24.11.2020 The document refers to the IEC 60601-1-6 standard	P
12.3	Alarm systems	NA	NA
12.4	Protection against hazardous output		-
12.4.1	Intentional exceeding safety limits	NA	NA
12.4.2	Indications relevant to safety	NA- the product has no measuring functions	NA
12.4.3	Accidental selection of the excessive output parameters values	NA	NA
12.4.4	Invalid values of the output parameters	NA	NA
12.4.5	Radiation for diagnostic or therapeutic purposes		-
12.4.5.1	Limit values	NA	NA
12.4.5.2	Diagnostic x-ray device	NA	NA
12.4.5.3	Radiotherapy equipment	NA	NA
12.4.5.4	Other ME equipment producing diagnostic or therapeutic radiation	NA	NA

12.4.6	Diagnostic or therapeutic sound pressure	NA	NA
13	**Hazardous situations and fault conditions for ME equipment**		-
13.1	Specific hazardous situations		-
13.1.1	General	Tests acc. to 13.2	-
13.1.2	Emissions, deformation of enclosure or exceeding maximum temperature	Annex No. 3 and Annex No. 4 - no hazardous state described in the point occurred	P
13.1.3	Leakage current or voltage limits exceeded	Annex No. 1	P
13.1.4	Special mechanical hazards	Conditions according to the specific mechanical hazards described in points 9.1 to 9.4 There is no hazardous situation	P
13.2	Single fault conditions		-
13.2.1	General		-
13.2.2	Electrical single fault condition	The break in the pilot circuit does not cause the hazardous situation. Annex No. 4	P
13.2.3	Overheating of transformers in the ME equipment	The mains charger with the transformer complies with IEC 60601-1	NA
13.2.4	Damage of thermostats	NA	NA
13.2.5	Damage of temperature limiting devices	NA	NA
13.2.6	Fluid leakage	NA	NA
13.2.7	Impairment of cooling that could result in a hazardous situation	NA	NA
13.2.8	Blocking of moving parts	NA - the device is controlled by the continuous activation in the operator's field of view at low speed of movement. Small possibility of the block of drives while device operation.	NA
13.2.9	Interruption of the circuit and short-circuit of the motor starting capacitors	NA	NA
13.2.10	Additional criteria for testing the ME equipment with the motor drive	NA	NA
13.2.11	Damage of components in ME equipment operating in the oxygen-rich environment	NA	NA
13.2.12	Damage of parts that can cause the mechanical hazard	Tests acc. to point 9 and 15	-
13.2.13	Overload		-
13.2.13.1	General overload test conditions		-
13.2.13.2	Me equipment with heating elements	NA	NA

13.2.13.3	ME equipment with motors	NA	NA
13.2.13.4	ME equipment with nominal values suitable for discontinuous operation	NA	NA
15	**Construction of ME equipment**		-
15.1	Arrangements of controls and indicators of ME equipment	NA	NA
15.2	Vulnerability to service-related activities	Installation and placement of replacement parts designed in such way that service operations do not cause the unacceptable risk.	P
15.3	Mechanical strength		-
15.3.1	General	Mobile device : Tests acc. to 15.3.2, 15.3.3, 15.3.5, 15.3.6	-
15.3.2	Push test	Pressure through a round flat surface with a diameter of 30 mm with a force of 250 N on the device housing No damage of the housing	P
15.3.3	Impact test	Impact with a ball with a diameter of 50 mm and weight of 500 g from a height of 1.3 m on the device enclosure. There was no unacceptable risk.	P
15.3.4	Drop test		-
15.3.4.1	Hand-held ME equipment	NA	NA
15.3.4.2	Portable ME equipment	NA	NA
15.3.5	Rough handling test	The test was performed in accordance with the standard. No damage which causes the unacceptable risk.	P
15.3.6	Post-assembly tension loss test	NA	NA
15.3.7	Environmental influences	Environmental influences do not cause unacceptable risk (based on accompanying documentation and specification of materials used)- while using the device in accordance with the manufacturer's instructions.	P
15.4	Equipment components and general assembly		-
15.4.1	Construction of connectors	NA	NA
15.4.2	Temperature and overload control devices		-
15.4.2.1	Application		
	a) thermal switches and circuit breakers with automatic reset should not be used in the device, if their use may cause a hazardous situation during such reset	NA	NA

	b) thermal switches with safety function	NA	NA
	c) in the device in which damage of the thermostat may cause a hazard, an additional thermal switch should be used with unassisted return	NA	NA
	d) loss of device function caused by a thermal or overcurrent switch should not cause a hazardous situation	NA	NA
	e) capacitors should not be connected to thermal switch contacts	NA	NA
	f) the use of a thermal or overcurrent switch in the design should not affect the safety of the medical device	NA	NA
	g) the tank heated with liquid should have protection against overheating when there is no liquid in the tank	NA	NA
	h) the device containing tubular heating elements should have overheating protection	NA	NA
15.4.2.2	Temperature setting	No thermostats with temperature setting	NA
15.4.3	Batteries	BAJ1 battery	-
15.4.3.1	Housing	The device has the separate place for the battery. The device has been designed to avoid accidental short circuit of the battery.	P
15.4.3.2	Connection	The battery and the port connector used to connect it are designed in such a way that they prevent it from being connected incorrectly	P
15.4.3.3	Overcharge protection	Based on the documentation, it was state that both Based the BAJ1 battery and the charger declared to charge it are compliant with IEC 60601-1	P
15.4.3.4	Lithium batteries	Based on the documentation, it was state that the BAJ1 battery complies with IEC 60601-1 standard. Battery capacity: 2,9 Ah.	P
15.4.3.5	Excessive current and voltage protection	Based on the documentation, it was state that the BAJ1 battery complies with IEC 60601-1 standard	P
15.4.4	Indicators	When the battery chamber door is closed, the device is ready for operation, after press the button on the remote control or the control panel, the diode on the remote control lights up. The diode lights up constantly and indicates the battery charge status.	P

15.4.5	Elements of pre-adjustment	NA	NA
15.4.6	Actuating parts of controls of ME equipment		-
15.4.6.1	Fixing, prevention of maladjustment	NA	NA
15.4.6.2	Limitation of movement	NA	NA
15.4.7	Cord-connected hand-held and foot-operated control devices		-
15.4.7.1	Mechanical strength	Remote control HB330VCXD056-2102C1E000 compliant with IEC 60601-1	P
15.4.7.2	Accidental operation of the ME equipment	No accidental operation of the device	P
15.4.7.3	Entry of liquids	NA	NA
15.4.8	Internal wiring of the ME equipment	No aluminium cords are used inside the device	P
15.4.9	Oil tanks	NA	NA
15.5	Mains supply transformers of ME equipment and transformers providing separation in accordance with 8.5		-
15.5.1	Overheating		-
15.5.1.1	Transformers	The mains charger with the transformer complies with IEC 60601-1	P
15.5.1.2	Short-circuit test		
15.5.1.3	Overload test		
15.5.2	Dielectric strength		
15.5.3	Construction of transformers used to provide separation as required by 8.5		
7.1.2 acc. to PN-EN 12183	Test method (checking the static stability)	NA	NA
8.1.2 acc. to PN-EN 12183	Test method (checking the supports for the body parts)	NA	NA
8.5 acc. to PN-EN 12183	Resistance to ignition	NA	NA
9.1.2 acc. to PN-EN 12183	Test method for determination of brake operating forces	NA	NA
9.2.2 acc. to PN-EN 12183	Test methods	NA	NA
9.2.2.1 acc. to PN-EN 12183	Test for determination of effectiveness of parking brakes	NA	NA
9.2.2.2 acc. to PN-EN 12183	Test method for protrusion of parts of parking brakes	NA	NA
9.2.2.3 acc. to PN-EN 12183	Test method for fatigue strength of parking brakes	NA	NA

9.3.2 acc. to PN-EN 12183	Determining the pushing force	The averaged value of the pushing force is 48 N The maximum load of 120 kg has been assumed in accordance with the manufacturer's documentation	P
10.4.2 acc. to PN-EN 12183	Test method (checking the requirements for handles)	NA	NA
10.5.2 acc. to PN-EN 12183	Test (determining the value of forces)	Arm adjustment lever: 28N Headrest adjustment lever: 39N Numerical value of the torque is less than 0,05 times the numerical value of the diameter of the knob: - knee support adjustment lever: - armrest adjustment lever:	P
EN ISO 3746	Measurement of noise during operation of the electric drive	Sound power level: 48,90 dB	P
PN-EN ISO 13732-1	Temperature of the surface that may come into contact with the human skin	Annex No. 3	P
12.1 acc. to PN-EN 12182	Checking the safe distances between moving and stationary parts	- there is the continuous activation - the patient has difficult access to the trap zone	P
13.1 acc. to PN-EN 12182		For stationary parts: - hole near to adjustment of the headrest 34,93 x 175 mm - hole on the lumbar support connection with position adjustment 39,77 x 19,94 mm Safety distances are not maintained acc. to table 3 (the manufacturer has placed the warning sign) - push handle for device, distance less than 120 mm, safe distances maintained against entrapment of head	P
23 acc. to PN-EN 12182	Checking the dimensions including ergonomics	a) distance greater than 35 mm b) NA c) diameter of the patient's handle: 39,12 mm operator handle 21,37×40,26 mm d) NA e) controls at a height of 838 mm f) operator handle at a height 1078 mm	P
8.2.2 acc. to PN-EN 12184	Checking the static strength	NA	NA

Annex No. 1 (Leakage currents).

Annex No. 1	Leakage currents			
Type of measured current and switch configuration	Voltage [V]	Frequency [Hz]	Current measurement before moisture [µA]	Current measurement after moisture [µA]
Touch current Pic. 14				
(S1=1, S5=0)	24	-	0,3	0,5
(S1=0, S5=0)	24	-	0,6	0,7
(S1=1, S5=1)	24	-	0,5	0,6
(S1=0, S5=1, S7=1, S12=1)	24	-	0,7	0,9

white - normal condition
grey - single fault condition

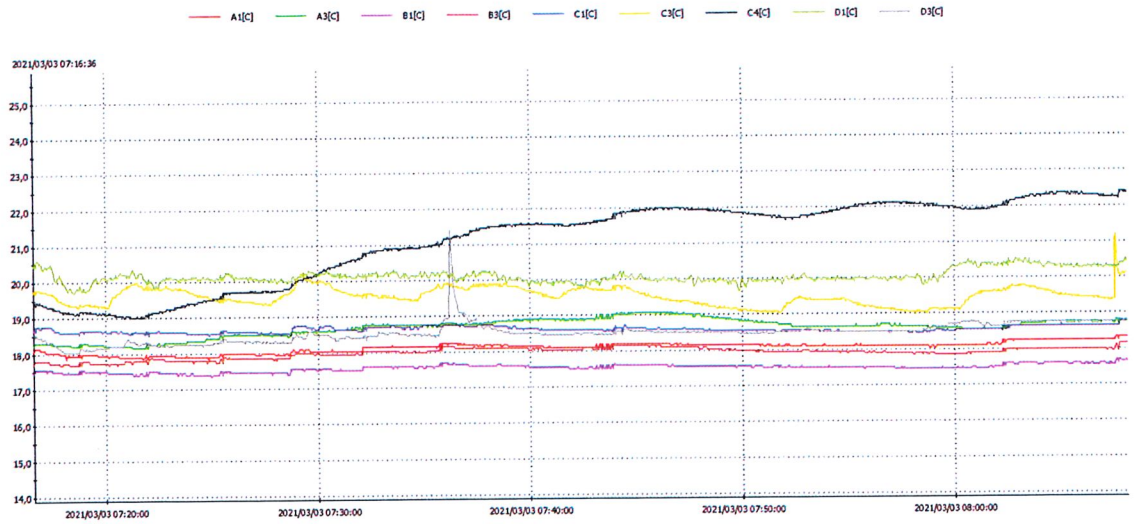
Annex No. 2 (Insulation clearance).

Annex No. 2	Insulation clearance				
Measurement location acc. to electric shock protection diagram	Voltage	Creepage distance		Air clearance	
		Required value	Measured value	Required value	Measured value
Socket on the PCB plate	24 V DC	1	1,86	2,0	-
Solder connection on the PCB plate	24 V DC	1	1,39	2,0	2,08

Annex No. 3 (Temperature tests).

Annex No. 3	Temperature tests		
	Supply voltage:		24 V DC
	Ambient temperature		20,45 ° C
	Test conditions		The device operated acc. to the fill factor described in the instruction for use
Place of measurements	Measured temperature		Allowable temperature ° C
	in temp. 20,45 ° C	for temp. 40 ° C	
Switch	---	---	86,0
Parts of the device enclosure touched by :			
t < 1 s	---	---	86,0
1 s ≤ t < 10 s	20,2	39,8	71,0
10 s ≤ t < 1 min	---	---	60,0
1 min ≤ t	21,2	40,8	48,0
Applied parts that come into contact with the patient through :			
t < 1 min	---	---	60,0
1 min ≤ t < 10 min			48,0
10 min ≤ t	18,4	38,0	43,0
Touch panel	21,2	40,8	48,0
Test angle wall on the back of the device	---	---	90,0
Floor angle testing	18,6	38,2	90,0

Recorder channel No.	Location of temperature sensors
A1	Floor testing
A3	Controller housing
B1	Distribution box
B3	Electric wire
C1	Stationary control panel
C3	Manual control panel
C4	Electric drive
D1	Environment
D3	Hand held by the patient



Annex No. 4. (Fault conditions).

Annex No. 4	Fault conditions	
Fault	Duration	Description of the action
Break in the pilot circuit	Any duration of fault	Stopping the device (if it was in motion at the time of damage)
Unintentional device movement when accidentally pressing the button on the remote control	Any duration of fault	The device is equipped in the safety switch located within the operator's range, near the patient area so that the drives can be disconnected from the power supply during any unintentional movement of the device. Device movements are slow. Situation described in the provided risk analysis.

Annex No. 5 (List of the basic device components).

Annex No. 5	**List of the basic device components**			
Name	**Company**	**Model / Type**	**Technical data**	**Standard**
PSS Liana sitting position stabilizer	ASP Polska Sp. z o.o.	PSS Liana	Total weight: 120 kg Maximum load: 120 kg	-
Remote control	LIANA	HB330VCXD056-2102C1E000	-	IEC 60601-1
Battery	LINAK	Baj1	Voltage: 24 V DC, Capacity: 1x 2,9 Ah	IEC 60601-1
Control box	LINAK	CBJ2	Output voltage : 24 V DC	IEC 60601-1
Mains charger	LINAK	CHJ20000030A151	Input voltage: 100-240 V~ / 50-60 Hz	IEC 60601-1

Estimation of uncertainty of measurements results.

Estimation of uncertainty of length measurement results by using calliper No. A/006/LL

$U(L)= (0,0149 +0,000011 \times w_{wsk})\ mm$

w_{wsk} - value indicated by the calliper

Estimation of uncertainty of AC voltage measurement results by using multimeter FLUKE No. A/044/LL

$U(U)=(0,0011+0,0012 \times w_{wsk})\ V$

w_{wsk} - value indicated by the multimeter

Estimation of uncertainty of AC measurement results by using multimeter FLUKE No. A/044/LL

$U(U)=(0,005+0,0043 \times w_{wsk})\ A$

w_{wsk} - value indicated by the multimeter

Estimation of uncertainty for the contact method (recorder) No. A/228/LL

$U(T)= (0,33 + 0,011 \times w_{wsk})\ ^0C$

w_{wsk} - value indicated by the recorder

Estimation of uncertainty of the resistance measurements results by using TMT-5 type Thomson bridge No. A/026/LL

$U(R)=(0,2+0,02 \times w_{wsk})\ m\Omega$

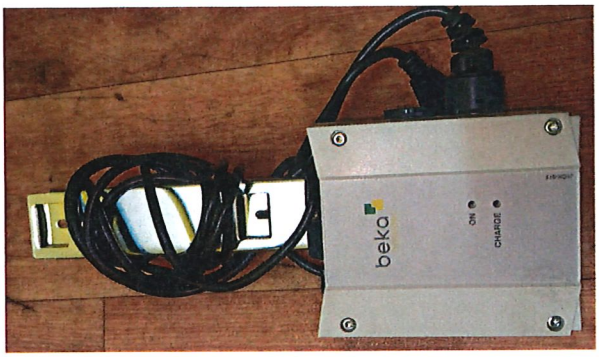
w_{wsk} - value indicated by the device

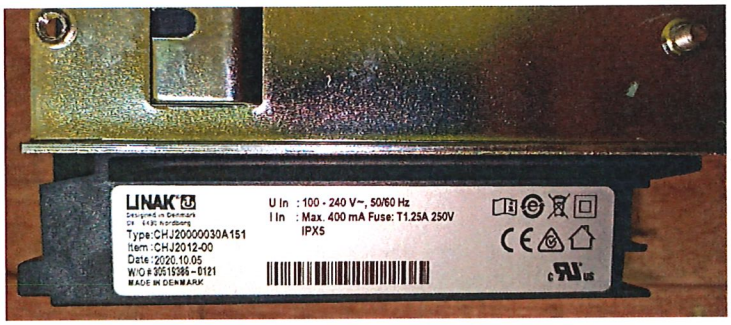
Estimation of uncertainty of force measurements results by using dynamometer No. A/200/LL

$U(F)=(2,89+0,0077 \times w_{wsk})\ N$

w_{wsk} - value indicated by the dynamometer

Photographic documentation.





	ASP Polska Sp. z o.o. Ul. Wierzbowa 21 PL 67-200 Głogów Tel. 0048 76 831 39 44 www.systems-for-life.com
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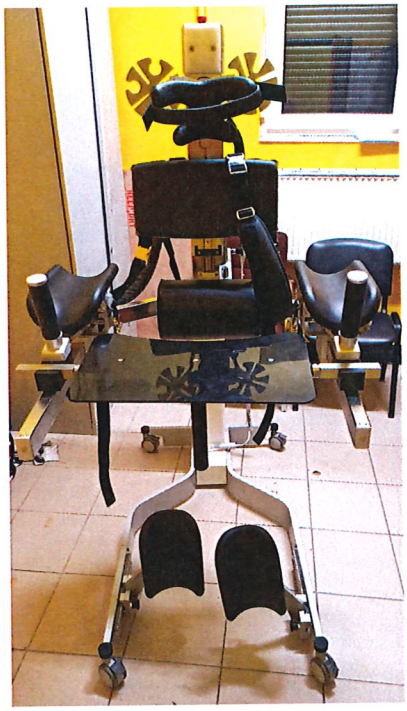

Tests performed by:

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Date	name and surname	position	signature
08.04.2021	Marcin Jaśkiewicz	Research assistant	.....
Date	name and surname	position	signature

Checked and verified by:

08.04.2021	Wojciech Bobecki	Laboratory Manager	.....
Date	name and surname	position	signature

END OF REPORT