control / test / inspection protocol for electric medical and sports devices

general information **details about inspection procedure available at instruction: "instruction_manual_cos11690en-03e_hpcosmos_electrical_measurements.docx"**

customer name, ZIP-code, city: _____ room temp.: _____ °C

control form for service report no. & date: _____ rel. humidity: _____ %

device type: _____ serial no.: _____ construction year: _____ UDI-PI:

☐ manufacturer: h/p/cosmos sports & medical gmbh / Germany ☐ manufacturer: _____

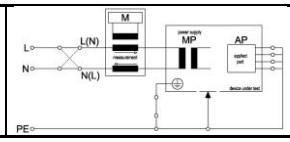
appliance class of device: ☐ I (one) ☐ II (two) ☐ III (three) ☐ first measurement ☐ repeat test ☐ test after repair

applied part type: ☐ B ☐ _____ power supply cord: ☐ NPS non-detachable ☐ DPS detachable ☐ PIE permanent installed equipment

measuring instrument: _____ serial-/inventory # _____ next calibration date: _____

technician name: _____ company: _____ measurement date: _____

checks & measurements	**passed**	**failed**
a) Check visually wall socket (outlet) for damage. Measure if earth conductor (protective conductor) PE, N and L1 (L2, L3) are correctly connected. Note: this is not a function test of the electric house circuit. A local electrician independently of this test must check the function and safety of the electric circuit of the building. **RCD must be type "B"** which is also measuring DC residual current, e.g. when operating frequency-controlled equipment like treadmills or motor driven devices with inverter drives.	☐	☐
b) Measured voltage at the wall socket: _____ V (without load). If accessible, note fuse at the electric circuit of the building: _____ A / Type: ____ RCD / RCCB Type _____	☐	☐
c) Separate device from the supply network (mains). Separate connections to host/peripheral equipment (e.g. via RS232 interface). Remove data lines, additional functional earthing (potential equalisation) temporarily. After measurements have been performed all connections have to be reconnected!	☐	☐
d) Visual check electrical system: Electrical assemblies, electrical parts, mains connection lead (power cord) incl. cord grip and power plug, ground wire connection and ground wire assemblies at device and accessories must not show any damages which are creating any safety risks.	☐	☐
e) Visually check mechanical system: Running-surface, rollers, belt spanner, running belt, elevation element with fixation screws, visible frame weld seams and fixation of screws and nuts, safety covers and motor hood at device and accessories must not show any damages which are creating any safety risks.	☐	☐
f) Visually check pollution: Cooling openings and cooling fins, cooling slots and perforated metal covers, light barriers, running belt and non-slip step-stripes, treads and footboards at device and accessories must not show any damages which are creating any safety risks.	☐	☐
g) Visual check of labels: Safety instructions and warning labels on device and accessories must be present, complete and legible according to instruction resp. device (running-machine) operation manual. Running belt marking is visible.	☐	☐
h) Fuses and micro-fuses, where applicable, which are accessible from the outside must be checked for the correct value and the correct labelling.	☐	☐
i) Check and – if necessary - adjust the belt re-entry zones at the back and at reverse belt rotation at the front as well. Gap must be below < 8 mm. Consider: standard IEC EN 60601-1, EN 957-6, see also "test-finger".	☐	☐
j) Latest version of the user/operation manual must be available on-site. User manual version must be compatible with the installed firmware and the installed accessories / options at the running machine. Download available @ https://www.hpcosmos.com/en/contact-support/media-downloads/manuals	☐	☐
k) Measurements: Users, patients and other third parties must stay away in safe distance (more than 1.5 meters) during measurements and must not touch the device under test! CAUTION! Device must be **„isolated"** (no touch, no interface linkage, no potential equalization). ME-Systems have to be measured as a complete system as well.	☐	☐

l) Check according to actual DIN VDE 0701-0702 (DIN EN 50699) Applicable for all h/p/cosmos devices of the category sports with CE **m) Check according to actual VDE 0751-1 (actual IEC / DIN EN 62353) & IEC TR 62354** Applicable for all h/p/cosmos devices of the category medical with CE 0123		☐ **l) limit values** DIN VDE 0701- 0702	☐ **m) limit values** VDE 0751-1/ IEC 62353	**result of measurement** (through qualified and trained personnel and with calibrated measurement instruments only)	**passed**	**failed**
n) Protective Earth Resistance R_{PE} Measurement: Device with solid mains connection lead resp. device incl. removable mains connection lead in composite at min. 0.2 A DC (according to VDE 0701-0702 the limit value is effective up to 5 m power cord and <16 A)		≤ 0.3 Ω	≤ 0.3 Ω	_____ Ω	☐	☐
o) Protective Earth Resistance R_{PE} for devices with removable mains connection lead (power cord) Measurement: **only removable mains connection lead** (power cord) medical devices (VDE 0751-1) at min. 0.2 A DC		-----	≤ 0.2 Ω	_____ Ω	☐	☐
p) Protective Earth Resistance R_{PE} for devices with removable mains connection lead (power cord) at min. 0.2 A DC calculation: **only device** (between power plug and earth protected, tangible, conductible parts of the device) only med. devices (VDE 0751-1). calculation: measurement (n) minus measurement (o) = result (p) only device [(n): _____ Ω minus (o) _____ Ω = (p): _____ Ω]		≤ 0.3 Ω	≤ 0.3 Ω	_____ Ω	☐	☐
q) Insulation resistance R_{ISO} measurement at U_{ISO} 500 volts DC. No insulation breakdown shall occur during the test.	appliance class I	> 1 MΩ	> 2 MΩ	_____ MΩ	☐	☐
	appliance class II	> 2 MΩ	> 7 MΩ	_____ MΩ	☐	☐
r) Touch current I_{HL} or I_{TOUCH} (= I_{PL} patient-leakage current for medical devices) same measurement for sports & medical devices, at mains voltage, AC based on VDE 0701-0702 according to direct measurement procedure. For medical treadmills the entire device is an applied part, so I_{HL} or I_{TOUCH} = I_{PL}	appliance class I	----	≤ 0.1 mA	_____ mA	☐	☐
	appliance class II	≤ 0.5 mA	≤ 0.1 mA	_____ mA	☐	☐
s) Earth-leakage-current I_{EA} I_{Δ} at mains voltage, AC, according to differential-current measurement. Info: I_{EA} I_{Δ} = Device-leakage-current I_{LC} because device is isolated. 	appliance class I	≤ 3.5 mA	≤ 0.5 mA	_____ mA	☐	☐
					☐	☐

t) Safety regulations: Running machine / device is directly plugged into the wall socket and the use of extension cables or multiple plug sockets is not permitted (except medical systems). A clear safety zone of min. L 2 m x W 1 m behind the device must exist (at running-surface W: >1 m at least L: 2 m x width of running surface) ☐ ☐

u) Function checks: Function check speed, elevation and all existing emergency-off accessories at device and accessories have been performed. Check especially all emergency and safety functions and also visually the conditions, such as emergency stop devices, safety lanyard (pull-cord device) automatic stop through safety arch, safety arch harness, chest belts, buckles and carabiners, airwalk unweighting vests, step platforms, running belt, etc. ☐ ☐

v) Assessment of device check: checks & measurement results **OK (passed)**. Test badge placed with date-code for next check, date of next check: _____ ☐

w) Assessment of the check: 1) checks & measurement results **not OK (failed)**. ☐

2) Device put out of operation. Remarks: ☐

3) Safety is in doubt. device is _____ years old and replacement is recommended ☐

customer's signature _____ technician's signature _____

x) Device exceeded intended lifetime of 10 years / respective 20 years with refurbishment of power supply, isolation transformers and live voltage components after 10 years

☐ No ☐ Yes, but with refurbishment of power supply, isolation transformers and live voltage components after 10 years ☐ Yes

⚠ Disclaimer and Warning in general and especially for devices that have exceeded the intended lifetime:
An inspection can only determine the current status of the device and the measurable and detectable defects. Especially after the intended lifetime of max. 20 years, defects that cannot be measured or detected are possible. High voltage tests, which are more suitable to detect hidden defects of isolation, cannot be performed during field maintenance inspections.

Therefore the inspection cannot guarantee the safety of such devices. For devices, that have exceeded the intended lifetime, an inspection sticker will not be attached.