Acceptance/maintenance protocol

Date		Report-number		serial-number		Operating-hrs.	

Checklist for all Wellsystem massagers and SPA hoods

Note: if the device has been in operation for more than 10 years, it must be evaluated by a trained service technician.

Information about the test

Reason for testing: ☐ Assembly/Acceptance ☐ Change ☐ Maintenance ☐ Repeat test, annually

Basics of the test ***

Legal basis:	DGUV-V3	Product Safety Act - ProdSG
Norms:	DIN EN 50678 (VDE 0701)	DIN EN 62353 (VDE 0751)
	DIN EN 50699 (VDE 0702)	
Others:		

No.	Components	Description of the inspection and Maintenance work	Retest/ Modifications/ Repair (interval annually)	New assembly (Enter as required)	Notes	Result OK/Not OK/ N/A *
Optical testing according to DIN EN 50678(VDE 0701) / DIN EN 50699(VDE 0702) and EN 62353 (VDE 0751) for medical devices						
1	**Visual inspection**					
1.1	Complete Device	The device documentation is completely available	X		Inspect safety-related markings, signs and labels for legibility and completeness.	
1.2	Complete Device	mechanical parts are intact	X			
1.3	Complete Device	Damage to the cables/insulation	X			
1.4	Complete Device	Condition of the mains plug, connection terminals and wires	X			
1.5	Complete Device	Defects in the strain relief of the connecting cable	X			
1.6	Complete Device	Condition of the mounting, cable holders, fuse switches accessible to the user, etc.	X			
1.7	Complete Device	Damage to the housing and protective covers	X			
1.8	Complete Device	Signs of overloading or improper application/operation	X			
1.9	Complete Device	Signs of unauthorized interventions or modifications	X			
1.10	Complete Device	contamination, corrosion, discoloration or aging that inadmissibly impairs safety	X			
1.11	Complete Device	contamination, blockage of the openings used for cooling	X			
1.12	Complete Device	Tightness of tanks for water, air or other media, condition of overpressure valves	X			
1.13	Complete Device	Operability of switches, controls, adjusters, etc.	X			
1.14	Complete Device	All markings required in the operating instructions are present and legible	X			
1.15	Complete Device	Check the device for leaks	X			

No.	Components	Description of the inspection and Maintenance work	Retest/ Modifications/ Repair (interval annually)	New assembly (Enter as required)	Notes	Result OK/Not OK/ N/A *
1.16	Pump /FU	Check the pump for leaks and noise	X		Check all hose clamps and couplings for tightness (13Nm). Replacement of the pump after approx. 8000 h, or if necessary.	
1.17	Rubber Matt	Check top and bottom for damaged areas	X		Check for discoloration and deformation. Rubber mat must be renewed after 5000 h / 3 years, or if necessary.	
1.18	Timing belt	Check timing belt for wear (brittle, released nylon threads, etc.), replace if necessary.	X		Renew after 5000 h or if necessary.	
1.19	Ball bearing of the Nozzle carriage	Check concentricity and freedom from play	X		Function control	
1.20	Drive engine	Remove drive engine and check bearing clearance, check engine for tight fit on retaining plate	X		Drive motors are replaced after 3000 h, the ball bearings have to be replaced after 5000 h.	
1.21	Drive engine Arms + nozzle carriage	Check Function	X		Test with MAN card	
1.22	Plug/ Coupling (internal)	Check for discoloration and braising	X		Replace in pairs if a fault is found	
1.23	Hoses (internal)	Check for leaks, chafing, kinks, etc.	X		Renew after 5000 h or if necessary	
1.24	Frequency converter	Check elbows and push-in fittings, as well as cooling hoses	X		Replace in case of corresponding fault detection	
1.25	Gear/ Nozzle trolley	Check gear wheel for damage	X		Replace if the fault is detected.	
1.26	Magnetic switch	Check function	X		For Hydrojet Medical/Profi Wellsystem Measure Medical/Relax with multimeter. Test the Medical_plus /Relax_plus well system with the MAN card.	
1.27	Rack	Check rack for tight fit	X		The rack must be replaced after 5000 h.	
1.28	Water inlet	If water cooling is connected, check that the water hose is tested and approved. Check for leaks.	X	X	If the period of use exceeds 3 hours per day, the water cooling system must be connected. Untested or damaged water hoses must be replaced.	
1.29	Water drainage	If water cooling is connected, check whether a free outlet is guaranteed.	X	X	A free outlet must be provided, and a minimum distance must be maintained, which must be greater than twice the inner diameter of the inlet pipe. The free outlet (airlift) is the most effective way to prevent the backflow into the public water supply network.	
1.30	Water stop valve (water quantity control)	Check if water stop valve is present	X	X	The use of a water stop valve (water volume control) is recommended	
1.31	Water change	Perform during maintenance	X		Check device for contamination and clean if necessary	
1.32	Fan FU	Optical inspection/function test	X			
1.33	Fan device cooling	Optical inspection/function test	X			
1.34	Software	Check and update if necessary	X			
1.35	Filter air/ Water cooling	Optical inspection	X		Cleaning	
1.36	Heat exchanger	Optical inspection	X		Check heat exchanger for contamination and clean if necessary.	

No.	Components	Description of the inspection and Maintenance work	Retest/ Modifications/ Repair (interval annually)	New assembly (Enter as required)	Notes		Result OK/Not OK/ N/A *
2	**SPA**	**SPA present? ☐ Yes ☐ No Device number:_____**					
2.1	SPA	Velcro properly attached?		X			
2.2	SPA	Holder properly attached?	X	X			
2.3	SPA	Measurements according to DIN EN 50678 (VDE 0701) / DIN EN 62353 (VDE 0751) / performed and recorded?	X	X			
2.3.1	**Protective conductor test SPA**				**Limit value**	**Actual value**	
2.3.2	Test point 1: Housing back panel		X	X	**≤0,2 Ω**	**Ω**	
2.3.3	Test point 2: Lid upper part		X	X	**≤0,2 Ω**	**Ω**	
2.3.4	Testing insulation resistance SPA		X	X	**≥ 10 MΩ**	**MΩ**	
2.3.5	Testing devices leakage current SPA		X	X	**≤3,5 mA**	**mA**	
2.4	SPA	Check folding mechanism/gas strut	X		Function check; should be replaced by customer service after 5 years		
2.5	SPA	Check AROMA container	X		Check expiration date, replace aroma if necessary		
2.6	SPA	2 Fans	X	X	Function check and clean		
Electrical test according to DIN EN 50678(VDE 0701) / DIN EN 50699(VDE 0702) and EN 62353 (VDE 0751) for medical devices (the documented measured values are to be included in the service report in parallel)							
3	**Testing protective conductor wave system**				**Limit value**	**Actual value**	
3.1	Test point 1: Sheet metal control		X	X	**≤0,3 Ω**	**Ω**	
3.2	Test point 2: Heating		X	X	**≤0,3 Ω**	**Ω**	
3.3	Test point 3: Pump housing		X	X	**≤0,3 Ω**	**Ω**	
3.4	Test point 4: Tub support at the front (located valve unit)		X	X	**≤0,3 Ω**	**Ω**	
3.5	Testing insulation resistance corrugated system		X	X	**≥ 2 MΩ**	**MΩ**	
3.6*[2]	Testing devices leakage current corrugated system **Attention**: *no substitute leakage current measurement allowed*		X	X	**≤3,5 mA**	**mA**	
3.6.1*[3]	Testing devices leakage current corrugated system **Attention**: *no substitute leakage current measurement allowed*		X	X	**≤5 mA**	**mA**	
3.7	Type measuring device		X	X			
	Validity calibration date until		X	X			
3.8	The assembly was carried out according to the requirements of the assembly instructions.			X			
3.9	Get information on the line impedance from the electrician or operator of the system.			X	**<= 0,14 Ω**	If value is exceeded, pulse massage must not be switched on	
3.10	Type measuring device						
	Validity calibration date until						
4	**Final inspection**						
4.1	Complete Device	Aligned horizontally?		X			
4.2	Adjustable feet	All on the ground?		X			
4.3	Pump-carrier	Are they adapted to the soil?		X			
4.4	Pump	Is the transport lock / pump lock correctly attached? Important if the unit has been disassembled		X			

No.	Components	Description of the inspection and Maintenance work	Retest/ Modifications/ Repair (interval annually)	New assembly (Enter as required)	Notes	Result OK/Not OK/ N/A *
4.5	Water-cooling	Has the cooling been connected Yes/No?		X	If no, this must be justified in the KD report	
4.6	Solenoid valve	No cooling connected: Has the plug been disconnected?		X		
4.7	Tub	Filled to the top of the tub rim?	X	X	Check for correct water level, refill/drain if necessary.	
4.8	Rubber Matt	Aligned and fastened with clamping bar and clamping claws?		X		
4.9	Operating unit	Check function	X	X		
4.10	Complete Device	Vented checked for leaks?	X	X		
4.11	Mains voltage	In operation (pump on max) L1 V In Stand By (heating off) L1 V	X	X		
4.12	Type measuring device		X	X		
	Validity calibration date until		X	X		
4.13	Complete Device	Corrugated system was partially disassembled ☐ completely assembled ☐		X		
4.14	Hose-clamps	All hose clamps of the pump are to be tightened with 13 Nm (pressure side)		X	Only when disassembling the pump	
4.15	Check cooling function (if connected)		X	X		
4.16	Check heating function		X	X		
4.17	Check pressure control		X	X		
4.18	Check function of nozzle carriage		X	X		
4.19	Check the device for leaks		X	X		
4.20	Check massage programs		X	X		

☐ No defects detected

☐ Defects detected

Next inspection date:

Customer:

☐ The list of defects was/is noted.

☐ The device is withdrawn from further use.

Location, date

Signature

Responsible inspector/technician/contractor:

☐ Defects in the device were found that could lead to a hazard. The device must be withdrawn from further use. It was marked accordingly and compiled in the list of defects. I hereby confirm the proper assembly and positively completed final inspection.

Location, date

Company, Signature

Legend:
IO = in order
NIO = not in order
N/A = not applicable, e.g. function not present, device is not present, etc..
*² Measuring point 3.6 only applies to measurements in accordance with DIN EN 50678 and DIN EN 50699
*³ Measuring point 3.6.1 only applies to measurements in accordance with DIN EN 62353

5	**Device instruction after new installation**	
5.1	Device instruction carried out according to MPB** (part no./index) _____	
5.2	Device must not be used by several patients at the same time	
5.3	Patients with more than 210kg body weight must not use the device	
5.4	Infants and children up to and including the age of 7 may not be treated with Wellsystem medical devices. Children and adolescents from 8-17 years of age may only use Wellsystem medical devices in consultation with a parent or guardian and after consultation with a physician	
5.5	The maintenance intervals must be observed according to the operating instructions	
5.6	Device no. entered in operating instructions, device incl. accessories properly handed over according to delivery bill	
6.0	**Remarks**	
6.1	Device familiarization is not desired and is performed by the medical device consultant, the responsibility for familiarization lies with the operator	

Person(s) admitted:

Remarks:

Place _____ Date _____

_____ _____

Operator/person responsible for the device Signature/Customer

*Open fields must be filled in with IO/NIO/N/A or a value

** For Medwave/Medwave Touch/Medical_Plus/Medical/Relax Hydrojet Medical according to the medical device book (MPB) (or **for Wellsystem clinic devices according to the medical device book (MPB))

*** DIN EN 50678 (VDE 0701) is for repair DIN EN 50699 (VDE 0702) is for periodic testing

DIN EN 62535 (VDE 0751) is for periodic testing of medical devices Product Safety Act is for installation and maintenance

DGUV V3 is for maintenance and periodic testing

Please send the completed protocol to: service@jk-globalservice.de (PDF)