Acceptance/maintenance protocol

Date		Report-No.		Serial-number		Operating-hrs.	

Checklist for all Wellsystem massagers and SPA hoods

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

Basics of the test			
Legal basis	☐ DGUV-V3	☐ Equipment and Product Safety Act	☐ BetrSichV/TRBS 1201
Norms:	☐ DIN EN 50678 (VDE 0701)		☐ DIN EN 62353 (VDE 0751)
	☐ DIN EN 50699 (VDE 0702)		
Other:			
Information about the test			
Reason for testing:	☐ Assembly/acceptanc ☐ Change	☐ Maintenance	☐ Repeat test, annually

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/mechanical testing**					
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	Damage to the connection lines	X			
1.3	Complete Device	Insulation damage	X			
1.4	Complete Device	Proper selection and use of cables and connectors	X			
1.5	Complete Device	Condition of the mains plug, connection terminals and wires	X			
1.6	Complete Device	Defects in the bending protection	X			
1.7	Complete Device	Defects in the strain relief of the connecting cable	X			
1.8	Complete Device	Condition of the mounting, cable holders, fuse switches accessible to the user, etc.	X			
1.9	Complete Device	Damage to the housing and protective covers	X			
1.10	Complete Device	Signs of overloading or improper application/operation	X			
1.11	Complete Device	Signs of unauthorized interventions or modifications	X			
1.12	Complete Device	contamination, corrosion, discoloration or aging that inadmissibly impairs safety	X			
1.13	Complete Device	contamination, blockage of the openings used for cooling	X			
1.14	Complete Device	Air filter condition	X			
1.15	Complete Device	Tightness of tanks for water, air or other media, condition of overpressure valves	X			
1.16	Complete Device	Operability of switches, controls, adjusters, etc.	X			
1.17	Complete Device	All markings required in the operating instructions are present and legible	X			
1.18	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 *
1.19	Pump/FU	Check pump for leaks	X		Check all hose clamps and couplings for tight fit. Replace the pump after approx. operating hours 8000/max. 8 years.	
1.20	Rubber matt	Check top and bottom for damaged areas	X		Check for discoloration and deformation. Rubber mat must be renewed after 3 years	
1.21	Timing belt	Check timing belt for wear (brittle, released nylon threads, etc.), replace if necessary.	X		Timing belt must be replaced after 5000 h.	
1.22	Ball bearing of the Nozzle carriage	Check concentricity and freedom from play	X		Function control	
1.23	Drive engine	Remove drive engine and check bearing clearance, check engine for tight fit on retaining plate	X		The ball bearings must be replaced after 5000 h.	
1.24	Drive engine Arms + nozzle carriage	Check Function	X		Test with MAN card	
1.25	Plug/ Coupling (internal)	Check for discoloration and braising	X		Replace in pairs if a fault is found	
1.26	Hoses (internal)	Check for leaks, chafing, kinks, etc.	X		Replace individually if a fault is detected. The hoses must be replaced after 5000 h.	
1.27	Frequency converter	Check elbows and push-in fittings, as well as cooling hoses	X		Replace in case of corresponding fault detection	
1.28	Gear/ Nozzle trolley	Check gear wheel for damage	X		Replace if the fault is detected. The gear must be replaced after 3000 h.	
1.29	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 service PC.	
1.30	Rack	Check rack for tight fit	X		The rack must be replaced after 5000 h.	
1.31	Water inlet	If water cooling is connected, check if the water hose is tested and approved.	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.	
1.32	Water stop valve (water quantity control)	Check if water stop valve is present	X		The use of a water stop valve (water volume control) is recommended	
1.33	Water change	Perform during maintenance	X		Check device for contamination and clean if necessary	
1.34	Fan FU	Optical inspection/function test	X			
1.35	Fan device cooling	Optical inspection/function test	X			
1.36	Software	Check and update if necessary	X			
1.37	Filter air/ Water cooling		X		Cleaning	

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 *
1.38	Heat exchanger		X		Check heat exchanger for contamination and clean if necessary.	
2	**SPA**	**SPA present?** ☐ **Yes** ☐ **No** **Device number:_____**				
2.1	SPA	Velcro properly attached?		X		
2.2	SPA	Holder properly attached?		X		
2.3	SPA	Measurements according to DIN EN 50678 (VDE 0701) / DIN EN 62353 (VDE 0751) / performed and recorded?	X	X		
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**		
3.2	Test point 2: Heating	X	X	**≤0,3 Ω**		
3.3	Test point 3: Pump housing	X	X	**≤0,3 Ω**		
3.4	Test point 4: Tub support at the front (located valve unit)	X	X	**≤0,3 Ω**		
3.5	Testing insulation resistance corrugated system	X	X	**≥ 2 MΩ**		
3.6*	Testing devices leakage current corrugated system **Attention:** *no substitute leakage current measurement allowed*	X	X	**≤3,5 mA**		
3.6.1**	Testing devices leakage current corrugated system **Attention:** *no substitute leakage current measurement allowed*	X	X	**≤5 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	Testing line impedance	X	X	**<= 0,14 Ω**	If value is exceeded, pulse massage **must not** be switched on	
3.10	Type measuring device	X	X			
	Validity calibration date until	X	X			
4	**Final inspection for new assembly**					
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		

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 ***
4.4	Pump	Is the transport lock / pump lock correctly attached? Important if the unit has been disassembled		X		
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		
4.8	Blanket	Aligned and fastened with clamping bar and clamping claws?		X	The terminal strips must be replaced after 5000 h.	
4.9	Operating unit	Check function		X		
4.10	Complete Device	Vented and vent checked for leaks?		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		
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 with IO/NIO/N/A or a value.
**For Medwave/Medwave Touch/Medical_Plus/Medical/Relax Hydrojet Medical according to Medical Product Book (MPB) (or **For Wellsystem clinic devices according to Medical Product Book (MPB)).

The completely filled out acceptance protocol has to be sent to the Global Service Department
Fax: 02224-818205 EMail: Service@jk-globalservice.de (PDF)

☐ No defects detected ☐ Defects detected	Next inspection date:
Customer: ☐ The list of defects has been/is noted. The equipment contained therein is withdrawn from further use. Location, date Signature	**Responsible inspector/technician/contractor:** ☐ Operating equipment with defects that could lead to a hazard has been identified. This equipment is to be withdrawn from further use. They have been marked accordingly and compiled in the list of defects. I hereby confirm that the equipment has been properly installed Location, date Company, Signature

Legend:
IO = in order
NOK = not in order
N/A = not applicable, e.g. function not present, device is not present, etc.

* Measuring point 3.6 is only valid for measurement according to DIN EN 50678 and DIN EN 50699
** Measuring point 3.6.1 is only valid for measurements according to DIN EN 62353.