

multiFiltrate

Technical Manual

Edition: 5/02.06

Part no. M28 003 1



Fresenius Medical Care

4.2 TSC / MA Report multiFiltrate

Technician's name:	Device type including option(s) / software version:	
Customer/Customer no.:	Device no.:	Inventory no.:
Service report no.:	Operating hours:	Equipment code:

Type	No.	Description	Meas. value	✓
	1	Visual inspections		
TSC	1.1	Fuses accessible from the outside comply with the indicated values.		<input type="checkbox"/>
TSC	1.2	Labels and labeling are present and legible.		<input type="checkbox"/>
TSC	1.3	The mechanical condition permits further safe use.		<input type="checkbox"/>
TSC	1.4	There are no signs of damage or dirt.		<input type="checkbox"/>
TSC	1.5	The power cord is not damaged.		<input type="checkbox"/>
MA	1.6	Replace the lithium battery of operating and safety processors (P.C.B. LP 244) every 4 years.	_____	
	2	Extracorporeal components		
TSC	2.1	Pump checked for stopping with open door.		
		Blood pump		<input type="checkbox"/>
		Filtrate pump		<input type="checkbox"/>
		Substitute pump		<input type="checkbox"/>
		Dialysate pump		<input type="checkbox"/>
TSC	2.2	Pump rotors checked for damage and rolls for smooth running.		
		Blood pump		<input type="checkbox"/>
		Filtrate pump		<input type="checkbox"/>
		Substitute pump		<input type="checkbox"/>
		Dialysate pump		<input type="checkbox"/>
TSC	2.3	The venous occlusion clamp closes after an air detector alarm.		<input type="checkbox"/>
TSC	2.4	The pressure of 2 bar applied in the venous bubble catcher may not drop by more than 0.1 bar within 3 minutes.		<input type="checkbox"/>

Type	No.	Description	Meas. value	✓
MA	2.5	Air detector operation/calibration checked.		<input type="checkbox"/>
		Jumper J1-P.C.B. LP 450 set to the operation position. Place the checking block into the air detector. LEDs DI 5 and DI 10 are light.		<input type="checkbox"/>
		Jumper J1-P.C.B. LP 450 set to the operation position. Place the adjusting block into the air detector. LEDs DI 5 and DI 10 are dark.		<input type="checkbox"/>
MA	2.6	Pressure transducers: zero point and amplification as well as tightness checked.		<input type="checkbox"/>
		Arterial pressure (red) Zero point: Display within the range of ± 5 mmHg	_____	<input type="checkbox"/>
		Amplification: 300Apply 300 mmHg, tolerance ± 5 mmHg	_____	
		Tightness: 600 mmHg, drop max. 10 mmHg within 1 min	_____	
		Venous pressure (blue) Zero point: Display within the range of ± 5 mmHg	_____	<input type="checkbox"/>
		Amplification: 300Apply 300 mmHg, tolerance ± 5 mmHg	_____	
		Tightness: 600 mmHg, drop max. 10 mmHg within 1 min	_____	
		PHF pressure (white) Zero point: Display within the range of ± 5 mmHg	_____	<input type="checkbox"/>
		Amplification: 300Apply 300 mmHg, tolerance ± 5 mmHg	_____	
		Tightness: 600 mmHg, drop max. 10 mmHg within 1 min	_____	
		Filtrate pressure (yellow) Zero point: Display within the range of ± 5 mmHg	_____	<input type="checkbox"/>
		Amplification: 300Apply 300 mmHg, tolerance ± 5 mmHg	_____	
		Tightness: 600 mmHg, drop max. 10 mmHg within 1 min	_____	
MA	2.7	Blood leak detector values checked for red coloration and dimness.		<input type="checkbox"/>

Type	No.	Description	Meas. value	✓
	3	Mechanical components		
MA	3.1	Mechanical parts of scales checked for tight seat, parallelism and smoothness.		<input type="checkbox"/>
		Scale I		<input type="checkbox"/>
		Scales II		<input type="checkbox"/>
		Scales III		<input type="checkbox"/>
		Scales IV		<input type="checkbox"/>
MA	3.2	Zero load, calibration and ball weight of scales checked.		
		Scale I		<input type="checkbox"/>
		Zero load: display within a range from 60 g to 4500 g	_____g	
		Calibration: Test load on scales: display 5000 g ±1 g	_____g	
		Ball weight: display within a range from 43.8 g to 44.8 g	_____g	
		Scales II		<input type="checkbox"/>
		Zero load: display within a range from 60 g to 4500 g	_____g	
		Calibration: Test load on scales: display 5000 g ±1 g	_____g	
		Ball weight: display within a range from 43.8 g to 44.8 g	_____g	
		Scales III		<input type="checkbox"/>
		Zero load: display within a range from 60 g to 4500 g	_____g	
		Calibration: Test load on scales: display 5000 g ±1 g	_____g	
		Ball weight: display within a range from 43.8 g to 44.8 g	_____g	
Scales IV		<input type="checkbox"/>		
Zero load: display within a range from 60 g to 4500 g	_____g			
Calibration: Test load on scales: display 5000 g ±1 g	_____g			
Ball weight: display within a range from 43.8 g to 44.8 g	_____g			
MA	3.3	Rotary selector checked for easy movement and tight fit		<input type="checkbox"/>
MA	3.4	Brakes of wheel assy. checked		<input type="checkbox"/>

Type	No.	Description	Meas. value	✓
	4	Check of the electrical safety In Germany according to DIN VDE 0751-1, edition 10/2001. In other countries, observe the local regulations!		
TSC	4.1	Visual inspections performed according to item 1.		<input type="checkbox"/>
TSC	4.2	Protective earth resistance max. 0.3 Ω (with power cord)	_____ Ω	<input type="checkbox"/>
TSC	4.3	Leakage current measurement (device leakage current) <input type="checkbox"/> Differential current measurement according to figure C.6 <i>or</i> <input type="checkbox"/> Direct measurement according to figure C.5		<input type="checkbox"/>
		Nominal voltage of power supply: _____ V		
		Device leakage current mains polarity 1: _____ μ A		
		With line voltage: _____ V		
		Scaled to nominal voltage (maximum 500 μ A, see Additional conditions)	_____ μ A	
		Device leakage current mains polarity 2: _____ μ A		
		With line voltage: _____ V		
		Scaled to nominal voltage (maximum 500 μ A, see Additional conditions)	_____ μ A	
TSC	4.4	Patient leakage current measurement		
TSC	4.4.1	For degree of protection type "BF" according to fig. C.8		q
		Nominal voltage of power supply: _____ V		
		Patient leakage current _____ μ A		
		With line voltage: _____ V		
		scaled to nominal voltage (maximum 480 μ A, see Additional conditions):	_____ μ A	
TSC	4.4.2	For degree of protection type "CF" according to fig. C.8		q
		Nominal voltage of power supply: _____ V		
		Patient leakage current _____ μ A		
		With line voltage: _____ V		
		scaled to nominal voltage (maximum 34 μ A, see Additional conditions):	_____ μ A	
	5	Functional test		
TSC	5.1	Functional test (T1 test) checked for proper performance.		<input type="checkbox"/>

Type	No.	Description	Meas. value	✓
TSC	5.2	Power failure alarm executed.		<input type="checkbox"/>
	6	Final check		
TSC	6.1	Entries made in the Medical Device Register.		<input type="checkbox"/>

Test equipment used:
 Pressure
 (type, serial number): _____

Protective earth resistance, leakage current
 (type, serial number): _____

Comments:

Date:	Signature:	Stamp:
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The system has been released for the intended use. (Attach inspection sticker.)	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Next inspection date:		
Comments:		

Date:	Signature:	Stamp: