Edwards

Fakultní nemocnice Olomouc
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Kardiochirurgie
s.s. Drobiličová

Praha 17.5.2006

Potvrzení o provedení pravidelné kontroly a údržby přístroje pro kontinuální hemofiltraci a hemodialýzu Edwards Aquarius

Potvrzujeme provedení pravidelné kontroly a údržby přístrojů pro kontinuální hemofiltraci a hemodialýzu Edwards Aquarius, v.č. 0258.
Pravidelná kontrola a údržba přístrojů byla provedena autorizovanou servisní organizací **ALINEX Kácovská spol. s r.o., J. Masaryka 26, 120 35 PRAHA 2 tel./ fax: 224257865 a 222515291** a je prováděna vyškolenými techniky dle servisní dokumentace výrobce. Výsledky kontroly jsou uváděny v záznamu o kontrole, který je nedílnou součástí tohoto potvrzení. Při kontrole byly použity přístroje s platnými kalibračními listy, kalibračními značkami a speciální přípravky výrobce.

Datum provedení kontroly a údržby: 15.5.2006
Provedl: Petr Starý (autorizovaný technik)

Přístroj po kontrole a údržbě za oddělení
Převzal: s.s. Drobiličová

Závěr kontroly: **Zařízení bylo zkontrolováno, je bezpečné a schopné plnit správně funkci, pro níž bylo určeno.**
Doporučený termín příští kontroly: květen 2007

Za Edwards Lifesciences, AG: Petr Starý

Edwards Lifesciences AG,
organizační složka
Opletalova 55/1015, 110 00 Praha 1
Tel.: 221 602 251, Fax: 221 602 256

Seznam použitých měřicích přístrojů:
- multimetr Metex, v. č. EB292527, č. kalibračního listu KL318/2006, platnost do 01/2007
- tlakoměr Eva 200, v.č. 0291, č. kalibračního listu 240/2006, platnost do 01/2007
- závaží 5 kg, č. kalibračního listu 5052-KL-Z352-05, platnost do 12/2006
- váha Soehnle 8103.02, v.č. 2004/387381, č. kalibračního listu 426, platnost do 01/2007
- revizní přístroj REVEX 2051 v.č. 0401263, č.kalibračního listu 148/06, platnost do 01/2007

Technical Safety Check and Maintenance Aquarius

Interval: at least every 12 months.

Serial number	0258	Operating place	Olomouc
Software version	3.51.1.	FN Olomouc KCH	
Operating hours	481		

Use only calibrated measuring equipment, weights and measuring cylinder.

1.	**Cleaning**		
1.1	Cleaning the cabinet interior		✓
1.2	Cleaning the ventilation grids		✓
1.3	Cleaning the mirror and optical components of the blood leak detector		✓
2.	**Visual Check**		
2.1	Labels concerning safety must be attached to the machine, and readable		✓
2.2	Safety values must correspond with the data		✓
2.3	The mechanical condition of the device must ensure a safe operation (sealing, pump doors, attachments)		✓
3.	**Accessories**		
3.1	Hook and IV pole		✓
3.2	Power cable		✓
3.3	Machine data		✓
3.4	Operating manual		✓
4.	**Electrical Safety**		
4.1.1	Protective resistor power cable		0,09 Ω
4.1.2	Protective conductor resistance	(max. 0,1 Ω)	0,08 Ω
4.1.3	Enclosure leakage current	(in Range)	0,08 mA
4.1.4	Earth leakage current	(in Range)	0,3 mA
4.1.5	Patient leakage current	(in Range)	0,09 mA
4.1.6	Power failure test (power fail signal and switch to storage battery operation)		✓
4.2	*Battery check*		
4.2.1	Power fail battery (17V – 21V)		✓
4.2.2	PC104 battery (2.8V-3.2V) (only BG-E325-00)		3,186 V
4.3	*Power converter – primary voltage*		
4.3.1	+24 V ± 0,5 V		24,02 V
4.4	*Power converter – secondary voltage*		
4.4.1	+8 V ± 0,2 V		7,98 V
4.4.2	+5,5 V ± 0,2 V		5,5 V
4.4.3	+12,5 V ± 0,5V		12,50 V
4.4.4	+15 V ± 0,5 V		15,02 V
4.4.5	-15 V ± 0,5 V	–	14,98 V
4.4.6	+24 V ± 0,5 V		23,64 V

5.	Testing the Electronic Components	
5.1	**Access Pressure**	
5.1.1	Measured value at +100 mmHg (± 5 mmHg) Master	100 mmHg
5.1.2	Measured value at +100 mmHg (± 5 mmHg) Controller	100 mmHg
5.1.3	Measured value at -200 mmHg (± 5 mmHg) Master	– 198 mmHg
5.1.4	Measured value at -200mmHg (± 5 mmHg) Controller	– 198 mmHg
5.1.5	Offset (-45 < Offset < –10)	– 11 mmHg
5.2	**Pressure before Filter**	
5.2.1	Measured value at 300 mmHg (± 5 mmHg) Master	298 mmHg
5.2.2	Measured value at 300 mmHg (± 5 mmHg) Controller	298 mmHg
5.2.3	Measured value at 0 mmHg (± 5 mmHg) Master	0 mmHg
5.2.4	Measured value at 0 mmHg (± 5 mmHg) Controller	0 mmHg
5.2.5	Offset (-40 < Offset < -5)	– 7 mmHg
5.3	**Filtrate Pressure**	
5.3.1	Measured value at 250 mmHg (± 5 mmHg) Master	247 mmHg
5.3.2	Measured value at 250 mmHg (± 5 mmHg) Controller	247 mmHg
5.3.3	Measured value at - 250 mmHg (± 5 mmHg) Master	– 250 mmHg
5.3.4	Measured value at - 250 mmHg (± 5 mmHg) Controller	– 250 mmHg
5.3.5	Offset (-45 < Offset < -10)	– 10 mmHg
5.4	**Return Pressure**	
5.4.1	Measured value at 300 mmHg (± 5 mmHg) Master	300 mmHg
5.4.2	Measured value at 300 mmHg (± 5 mmHg) Controller	300 mmHg
5.4.3	Measured value at 0 mmHg (± 5 mmHg) Master	0 mmHg
5.4.4	Measured value at 0 mmHg (± 5 mmHg)	0 mmHg
5.4.5	Offset (-40 < Offset < -5)	– 22 mmHg
5.5	**Blood Pump**	
5.5.1	Flow rate 50 ml/min ± 1 ml/min	50 ml/min
5.5.2	Flow rate 430 ml/min ± 15 ml	430 ml/min
5.5.3	Stops when the pump doors are open	☐ ✓
5.5.4	Occlusion (< 10mmHg/10s at 600mmHg)	☐ ✓
5.6	**Filtrate Pump**	
5.6.1	Flow rate 30 ml/min ± 1 ml/min	30 ml/min
5.6.2	Flow rate 150 ml/min ± 2 ml/min	150 ml/min
5.6.3	Occlusion (< 10mmHg/10s at 600mmHg)	☐ ✓
5.7	**Pre-dilution Pump**	
5.7.1	Flow rate 30 ml/min ± 1 ml/min	30 ml/min
5.7.2	Flow rate 150 ml/min ± 2 ml/min	150 ml/min
5.7.3	Occlusion (< 10mmHg/10s at 600mmHg)	☐ ✓
5.8	**Post-dilution Pump**	
5.8.1	Flow rate 30 ml/min ± 1 ml/min	30 ml/min
5.8.2	Flow rate 150 ml/min ± 2 ml/min	150 ml/min
5.8.3	Occlusion (< 10mmHg/10s at 600mmHg)	☐ ✓
5.9	**Temperature after 15 – 17 min**	
5.9.1	Measured value at 37 °C ± 0,5 °C (Master)	37,2 °C
5.9.2	Measured value at 37 °C ± 0,5 °C (Controller)	37,2 °C
5.9.3	Δ t < 0,5°C	0,0 °C
5.9.4	Function of switch for substitution temperature sensor	☐ ✓
5.9.5	Δ t < 0,5°C (Substituate temperature sensor)	0,1 °C

5.10	**Substitution Scale**	
5.10.1	Measured value at 0 g ± 5 g (Master)	2 g
5.10.2	Measured value at 5000 g ± 10 g (Master)	5002 g
5.10.3	Measured value at 10.000 g ± 20 g (Master)	10001 g
5.10.4	Measured value at 0 g ± 5 g (Controller)	0 g
5.10.5	Measured value at 5000 g ± 10 g (Controller)	5000 g
5.10.6	Measured value at 10.000 g ± 20 g (Controller)	10001 g
5.11	**Filtrate Scale**	
5.11.1	Measured value at 0 g ± 5 g (Master)	0 g
5.11.2	Measured value at 5000 g ± 10 g (Master)	4999 g
5.11.3	Measured value at 10.000 g ± 20 g (Master)	10000 g
5.11.4	Measured value at 0 g ± 5 g (Controller)	1 g
5.11.5	Measured value at 5000 g ± 10 g (Controller)	5001 g
5.11.6	Measured value at 10.000 g ± 20 g (Controller)	10000 g
5.12	**Heparin Pump**	
5.12.1	Displayed ml with piston in lower position ± 1 ml (Master)	0.1 ml
5.12.2	Displayed ml with piston in lower position ± 1 ml (Controller)	0.1 ml
5.12.3	Displayed ml with piston in upper position ± 1 ml (Master)	49.9 ml
5.12.4	Displayed ml with piston in upper position ± 1 ml (Controller)	50.0 ml
5.12.5	Syringe detector	☐ ✓
5.13	**Blood Leak Detector**	
5.13.1	*Measured value with installed BLD chamber (conversion steps = CS)*	
5.13.1.1	Measured value AD-Master (LED on) >400	435 CS
5.13.1.2	Measured value AD-Master (LED off) 0 < value < 30	1 CS
5.13.1.3	Measured value alarm limit Master > 120	142 CS
5.13.1.4	Measured value AD-Controller (LED on) >400	517 CS
5.13.1.5	Measured value AD-Controller (LED off) 0 < value < 30	1 CS
5.13.1.6	Measured value alarm limit Controller > 120	142 CS
5.13.2	*Measured value with no BLD chamber installed*	
5.13.2.1	Measured value AD-Master (LED on) value < 1/3 5.13.1.1	123 CS
5.13.2.2	Measured value AD-Master (LED off) 0 < value < 30	1 CS
5.13.2.4	Measured value AD-Controller (LED on) value < 1/3 5.13.1.1	143 CS
5.13.2.5	Measured value AD-Controller (LED off) 0 < value < 30	1 CS
5.14	**Air Detector**	
5.14.1	Visible and audible alarm when air has been detected (clamp closes, pumps stop)	☐ ✓
5.14.2	Changing the operational mode from Connect patient mode to Disconnect patient mode when no blood has been detected.	☐ ✓
5.14.3	Output voltage (2-5V) GND – Pin 6 air detector module	4,34 V
5.15	**Venous Clamp**	
5.15.1	Clamp closes / opens	☐ ✓
5.15.2	Leak-tightness (pressure drop must be < 20 mmHg/min at 350 mmHg)	☐ ✓
5.15.3	Fluid detection (tube filled with water = 1)	☐ ✓
5.15.4	Blood detection (light beam interrupted = 0)	☐ ✓
5.16	**Time and Date**	
5.16.1	Time and Date checked	☐ ✓
5.17	**RS 232**	
5.17.1	Com 3 ok (Cal.version 2.1 or higher)	☐ ✓
5.18	**Self test**	
5.18.1	Self test successful passed	☐ ✓
5.18.2	LED's (all LED's are flashing during system test)	☐ ✓
5.18.3	Priming successful	☐ ✓
5.18.4	Clamp and pressure test passed	☐ ✓

5.19	**Test treatment (min. 5 minutes)**	
5.19.1	Test treatment without alarms	☐ ✓

Test result: Were any defects detected, which may cause risks for the patients, operators or other persons?
Yes ☐ No ☐ Ne

Remarks: _____

Are further works required? Ne

Olomouc
Place

16.5.2006
Date

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Signature technician