



Hospices Civils de Lyon

NéphroGones

Dialysis in pediatrics: what should we take into account before buying hemodialysis machines?

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ERKNet



Introduction

- No conflict of interest to declare
- Working with:
 - Hemodialysis machines Fresenius 5008 and 6008
 - CRRT machines Baxter Prismaflex/Prismax
 - Medtronic Carpediem



« Before » HD machines

- Need of ultrapure dialysis water
- Water treatment station with filtration with water softener charcoal and small sieving coefficient filters and double reverse osmosis
- Regular disinfections of dialysis water circuit and dialysis machine
- Regular controls (bacteria, endotoxins, biochemical) of dialysis water, dialysis bath and substitution fluid

Pediatr Nephrol 2005; 20: 1054-66,

<https://solidarites-sante.gouv.fr/fichiers/bo/2007/07-03/a0030058.htm>



Hemodialysis unit

- Pediatric dedicated unit? Or children dialysed in an adult hemodialysis unit?
- Medical
 - how many people?
 - which time dedicated for hemodialysis?
- Paramedical
 - how many people,
 - are they doing only hemodialysis
- Biomedical time dedicated to devices?
- How many children on chronic hemodialysis?
- more your means are limited, fewer children to dialyze
 - more difficult to have several types of hemodialysis machine
- Collaboration with a PICU and/or NICU? CRRT machine?



Which children do we need to dialyse ?

- Age and weight?

Most of centers: 0 to 18 years and 1 to 100 kilograms

Children on chronic HD (incident patients)

	Years	Age	N	< 10 kg	10-15 kg	15-20 kg	20-40 kg
Lyon	2008-21	0-18	73	15%			
ESPN registry	2007-16	0-15	821	12%	18%	15%	55%
IPHN registry	2012-21	0-21	1054	6%	8%	10%	40%

Infants are not rare!

Bonthuis M. *Pediatr Nephrol* 2021; 36: 2337 and courtesy of E Vidal (ESPN registry)

Courtesy CP Schmitt (IPHN registry)

- Renal failure type: acute and/or chronic



Extracorporeal volume

- Guidelines
 - ≤10% of blood volume
 - 10 ml/kg before 1 month
 - 8 ml/kg thereafter

In clinical practice: possible (even absolutely not perfect) up to 16 ml / kg
if no ultrafiltration required



The old good times

Dialysis machine	Double needle	Single needle	Blood line volume (ml)	oIHDF	BVM
Gambro AK 2005	yes	no	32	no	no
	yes	no	87	yes	yes
		yes	132		no
Fresenius 4008	yes		56	yes	no
	yes		126	yes	yes
		yes	88		no
Nikkiso DBE-07	yes		56	yes	no
	yes		86	yes	yes
	yes		113	yes	yes
		yes	93		no
		yes	123		yes
		yes	150		yes

Lines volume
in « old » chronic
machines

Not available in Europe
anymore



Dialysis machine	Double needle	Single needle	Blood line volume (ml)	Extracorporeal Volume (ml)	Theoretical minimal weight
Baxter AK 98	yes	no	36	53	6.6
	yes	no	85	102	12.7
	yes	no	100	117	14.6
		yes	132	149	18.6
Baxter Artis Physio	yes		132	149	18.6
		yes	227	244	30.5
Braun Dialog iQ	yes		122	139	17,4
		yes	186	203	25.4
Fresenius 5008	yes		108	125	15.6
	yes		136	153	19,1
		yes	169	186	23.2
Fresenius 6008	yes	no	83	100	12.5
	yes		122	139	17,4
		yes	137-187	154-200	25
Nikkiso DBB-EXA	yes		143	160	20
		yes	202	219	27.4
Nipro Surdial-X	yes		132	149	18.6
		yes	231	248	31

Lines volume
in 2021: machines
for chronic dialysis

+ dialyzer priming volume

Smallest ones:

Gambro Polyflux2H: 17 ml

Fresenius FxPaed : 18 ml

Pediatric lines



Lines volume in 2021: machines for chronic dialysis

Adult lines

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Lines volume
in 2021: machines
for chronic dialysis

Recommendations and
line volumes:
only one device for
children under ten
kilograms



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Lines volume
in 2021: machines
for chronic dialysis

Local experience since 2008
with Fresenius 5008
11 children < 10 kg
4 children < 8.5 kg (7.6-8.3)
All residual diuresis
15% of total
6 oxalosis

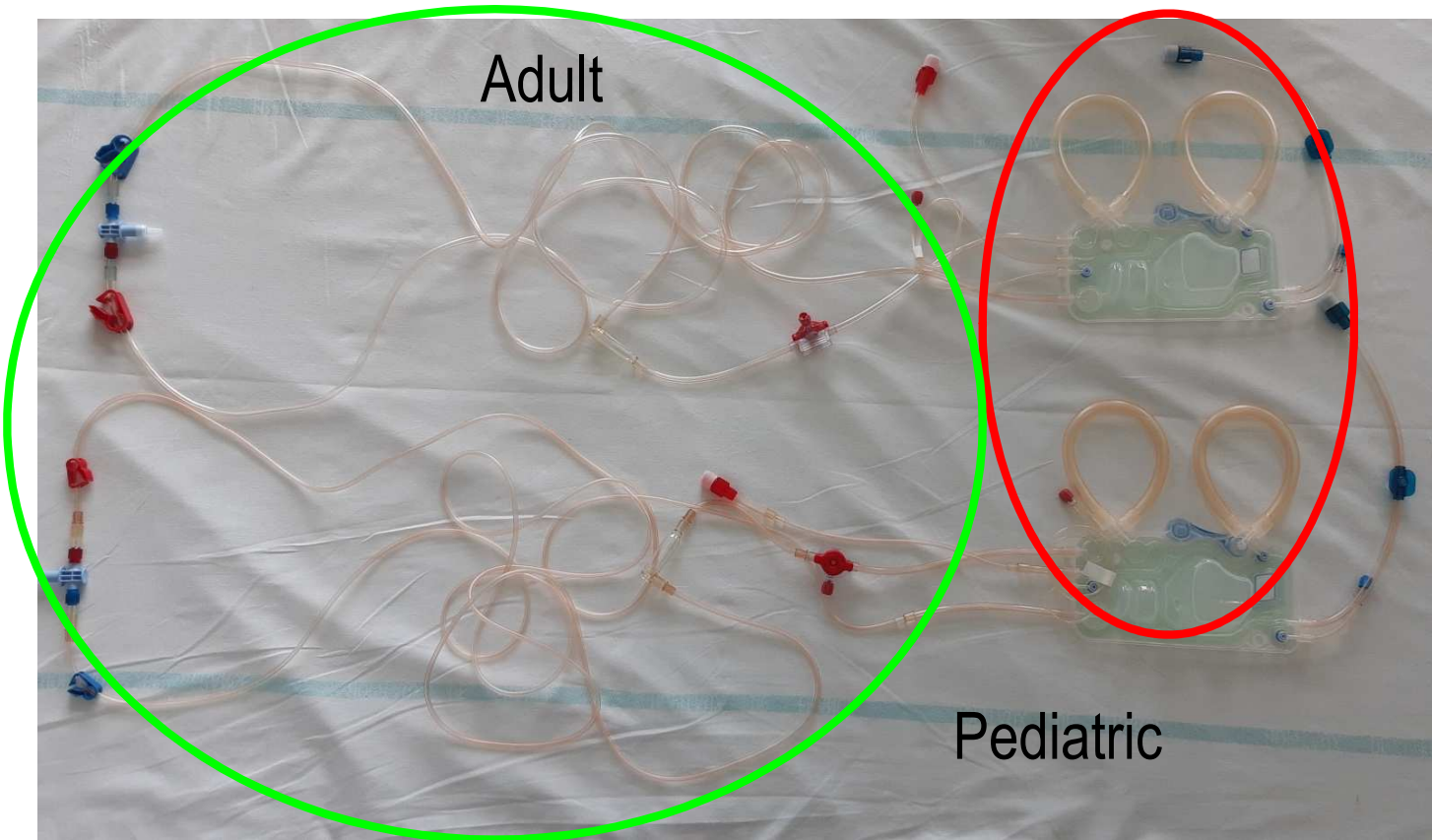


Fresenius 6008 sets

Adult

Pediatric

Pediatric lines
in 2021:
new generation
machines for chronic
dialysis





Pediatric

Pediatric lines
in 2021:
new generation
machines for chronic
dialysis

Adult

Fresenius 6008 sets



AK98 Baby lines



Pediatric lines
in 2021:
new generation
machines for chronic
dialysis

Thinner lines:

In the pump : 3.9 x 7.9 mm vs 6.35 x 10.35 mm

Outside the pump : 2 x 4 mm vs 3.5 x 5.8 mm

Shorter lines: 505 cm vs 520 and 536 cm

Courtesy of Dr Theresa Kwon
Robert Debre Hospital, Paris,
6.6 kilograms at HD start



Blood flow

- Guidelines

150–200 mL/min/m², 5–7 mL/min/kg

arterial aspiration pressure > - 200 mmHg

venous pressure < 200 mmHg

recirculation < 10% if catheter, < 15% if arteriovenous fistula

Pediatr Nephrol 2005; 20: 1054-66



Which blood flow with these lines ?

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	yes	no	85	no	no
	yes	no	100	no	no
		yes	132		no
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	yes		136	yes	yes
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Fresenius 6008	yes	no	83	yes	yes
	yes		122	yes	yes
		yes	137-187		yes
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		yes	231		yes

AK98 neonatal line: 20 to 80 ml/min
 85 ml line: 20 to 150 ml/min

6008 pediatric set : 30 to 90 ml/min

Lines: not the only limiting factor

Catheters:
 Medcomp 8Fr tunneled catheter
 max Qb of 110 ml/min
 In US Bard Glide Path 7.5 Fr
 max Qb of 128 ml/min?



Lines volume in 2021: CRRT machines

Dialysis machine	Extracorporeal volume (ml) dialyzer included
Neonatal devices	
Nidus (not yet available)	9-17
Carpediem Medtronic	27-33 or 42
Others	
HF440 Infomed	55
Prismaflex/Prismax Baxter HF20 set	58
Multifiltrate Fresenius	72
Plasauto S Asahi Kasei	87
Aquarius Nikkiso	96



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Which blood flow with these CRRT machines?

Nidus	5 ml/min	single lumen 2.7Fr of CVL
Carpediem	5-50 ml/min	dual lumen 5Fr catheter
HF440 Infomed	0-100 ml/min	dual lumen 6.5 Fr catheter
Prismaflex/Prismax HF20	20-100 ml/min	dual lumen 6.5 Fr catheter
Multifiltrate	10-100 ml/min	dual lumen 6.5 Fr catheter



Dialysis machine	Extracorporeal volume (ml) dialyzer included
Neonatal devices	
Nidus (not yet available)	9-17
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Maximum dialysate and substitution flow rate with CRRT machines (ml/min)



Dialysate flow

- Recommendations in chronic HD

1,5 to 2 times blood flow rate
and probably > 300 ml/min



Dialysis machine	Extracorporeal volume (ml) dialyzer included
Neonatal devices	
Nidus (not yet available)	9-17
Carpediem Medtronic	27-33 or 42
Others	
HF440 Infomed	55
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Maximum dialysate and substitution flow rate with CRRT machines (ml/min)

	dialysate	substitution	
Carpediem:	10	10	(not simultaneous)
Infomed HF440	67	33	
Prismaflex/Prismax HF20	41	24	
Multifiltrate	25	8	



Precise fluid control

- Ultrafiltration and fluid control have to be extremely precise in the smallest children
- 10 ml/kg/h
 - 4 kilograms 40 gr
 - 10 kilograms 100 gr
 - 30 kilograms 300 gr
 - 60 kilograms 600 gr



Precise fluid control

- Carpediem $\pm 7.5\%$ of dialysate flow
- Infomed HF440 ± 10 ml/h
- Prismaflex and Prismax HF20 ± 30 ml/h (possible stop session if > 60 ml/3h)
- Multifiltrate $\pm 1\%$

- Fresenius 5008 $\pm 1\%$ (and $\pm 0.1\%$ of substitution+dialysate flow)
- Fresenius 6008 $\pm 1\%$ (and $\pm 0.1\%$ of substitution+dialysate flow)
- Braun iQ $\pm 1\%$ (and $\pm 0.1\%$ of substitution+dialysate flow)
- Nikkiso DBB-Exa ± 30 ml/h (with dialysate flow 300-500 ml/min)
- Nipro Surdial-X ± 30 ml/h
- Baxter AK98 ± 50 ml/h or $\pm 2.5\%$ of the cumuled UF volume
- Baxter Artis Physio plus ± 50 ml/h or $\pm 2.5\%$ of the cumuled UF volume

+ In CRRT machines alarm when ultrafiltration deviates from the target



Precise fluid control in optimal situation but also ... in case of vascular access dysfunction or ultrafilter leak

Baxter AK 98 v1

25 September, 2018

Dear Healthcare Provider,

Problem Description Baxter is communicating important safety information regarding the potential for AK 98 Hemodialysis Devices to generate excessive ultrafiltration (UF) in certain situations where treatment-related alarms occur, or where there is an ultrafilter leak. As discussed below, excessive UF may present hazards for sensitive patients, such as low-weight patients, for whom target UF values of zero or very low volumes are desired. **Due to the potential for excess fluid loss, when treating low-weight or other sensitive patients, weight loss should be monitored during treatment and the attached mitigating instructions should be followed (Refer to Attachment 1).**

Baxter is initiating a design improvement for all AK 98 devices to mitigate cases of excessive fluid loss in patients.

**URGENT DEVICE
CORRECTION**



Information Importante de Sécurité

Restriction d'utilisation avec l'option 5008 CorDiax HD-Pédiatrique

No more use of Fresenius 5008 in children less than 17 kg

Date: 29 Juin 2018



Fresenius Medical Care
47 Avenue des
Pépinières 94832-
Fresnes

A l'attention des Pharmaciens des Etablissements de Santé et des cadres de Santé

Reuse authorization between 10 and 17 kg

Le 03/02/2020

Objet :

Fin de restriction à 17 kg - 5008 Cordiax / 5008 S Cordiax Version logiciel 4.63

Baxter AK 98 v2

**INFORMATION
IMPORTANTE DE SECURITE
CORRECTION**

A l'attention du Correspondant de Matérovigilance

Guyancourt, le 03 février 2020

Code produit	Dispositif médical	Numéro de série
955403	AK 98 V2 230V BIO VERSION	Tous
955404	AK 98 V2 230V SELF-CARE	Tous



FDA or EC certification

- Carpediem 2.5 to 10 kg (FDA and EC)
- Infomed HF440 > 5 kg (EC)
- Prismaflex > 8 kg (FDA and EC)
- Multifiltrate no weight specified (EC)
- Fresenius 5008 > 10 kg (EC)
- Fresenius 6008 > 10 kg (EC)
- Nikkiso Aquarius > 20 kg (EC)
- Nikkiso DBB-Exa > 20 kg (EC)
- Baxter AK98 > 25 kg (FDA and EC)
- Baxter Artis Physio > 25 kg (FDA and EC)
- Braun iQ > 30 kg (FDA and EC)
- Nipro Surdial-X > 30 kg (EC)



Which machines in 2021?

Dialysis machine	Double needle	Single needle	Blood line volume (ml)	oIHDF	BVM
Baxter AK 98	yes	no	32	no	no
	yes	no	85	no	no
		no	100	no	no
		yes	132		no
Baxter Artis	yes		132	yes	yes
		yes	227		yes
Braun Dialog iQ	yes		122	yes	yes
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	yes		136	yes	yes
		yes	169		yes
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	yes		122	yes	yes
		yes	137-187		yes
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		yes	231		yes

Single needle possible?

In the two devices not with the lowest volume lines
And in 6008 machine not possible with low volume settings (< 40 kg)

Adults' machines: around 200 ml

Same lines as double needle?

Yes in 6008 but with adult set, and normal volume settings (> 40 kg): switch from double needle to single needle during a session without changing lines



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Online Hemodiafiltration possible?



Dialysis machine	Double needle	Single needle	Blood line volume (ml)	oIHDF	BVM
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Which machines in 2021?

Which substitution flow ?

Goals

Post-dilution > 23 L/1.73m²

Pre-dilution > 33 L/m²

75- 100% du Qb

Post-dilution automated in 5 devices

≤28% of Qb with Nikkiso DBB-EXA

≈ 30% of Qb with Fresenius

≈ 30% of Qb with Artis

No data with Nippro Surdial-X

Pre-dilution

Nikkiso DBB-EXA, Artis and

NipproSurdial-X: manual

5008 Automated and < 100% Qb

manual 75-100%

6008 Automated and not optimal

manual < 75% Qb



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Blood volume monitoring ?
Online clearance measurement?

Access recirculation evaluation

Fresenius 6008: Yes but ...
only if $Q_b > 100$ ml/min
« Q_b optimal: 250 ml/min »
validated only in pts > 40 kg

Warning
Urea distribution space calculated
with Watson formulae not suitable,
Use Morgenstern



Which machines in 2021?

Blood restitution without line disconnection ?

Nikkiso DBB-EXA

Fresenius 6008: Yes but ... not in pre-dilution ol-HDF

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Which machines in 2021?

Na monitoring and management module ?

Fresenius 6008: Yes but ...

Na control (management module) only if > 20 kg (possible) to 40 kg (advised)





Summary

- Bad news: fewer and fewer pediatric lines
- Good news: more and more efficient devices for adults
- But without validation in children and off-label use by paediatricians in many children
- How to choose ?

Know performance and characteristics of each machine

Take into account regulation authorities agreement for weight

Match the weight, needs of the child and machine's characteristics

Capacity of your team to use more than one device

- Need of collaboration between
 - pediatric nephrologists
 - pediatric and adult nephrologists
 - pediatric nephrologists and intensivists
 - pediatric nephrologists and industrial partners



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