CARDIOLOGY 2024

Berlin Heart EXCOR Active Experience at CHOP

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BERLIN HEART EXCOR

- Only pulsatile pediatric VAD
- Paracorporeal VAD system





BERLIN HEART EXCOR CONSOLE COMPARISON

<u>IKUS</u>

- Pneumatic pump for pulsatile blood flow
 - Compressor
 - Pressure and suction limiter
 - Pressure and vacuum cylinders
 - Control electronics
 - Control valve
- Triple redundancy of core components
- Driving pressures 30-150bpm
- Up to 30-minute battery life

<u>ACTIVE</u>

- Electro-pneumatic pump for pulsatile blood flow
 - Cylinder with pistons
 - Motor
 - Control electronics
 - Control valve
- Driving pressure 5-130bpm
- Different modes
 - Manual vs. Automatic
- Up to 13-hour battery life



BERLIN HEART CONSOLE COMPARISON

<u>IKUS</u>







ACTIVE







ACTIVE DRIVER ACCESSORIES







ACTIVE DRIVER

VR Modes Manual Automatic



Three different logins with PC Local Medical Expert





WHEN TO BE IN MANUAL MODE?

- When thorax is open
 - Increased diastole pressures in automatic mode
 - Risk of air entrapment
- Recommended when replacing a blood pump
- Not intended to stay in manual mode, should stay connected to main power while in manual mode
 - Significantly louder when in manual mode

	Left 30 mL	Right 25 ml.	point
Dystale (wnHg)	180	120	87 10 10
Diaston (neverg)	-20.	-20	EAAAAAAAAA
Ourutizer systole (%)	50	50	
Rate (tipes)	-00	00	
Flow alarm Streaticki	1.8	1.5	Manual Synchronous 000

Fig. 0-41	semilys ior	the blood pump	parameters.	- manual	pressure control view	

1	Parameter	Overview
2	Pressure Curves	Display of pressure curves
3	Pressure Control	Manual/automatic pressure control
4	Synchronization	Synchronous mode, Asynchronous mode, Separate mode.
5	Start/Stop	Starting and stopping of blood pumps

Time until the driving unit finishes self-regulation; maxinter mum pressure levels will be adjusted step by step during this period





FINE TUNING AUTOMATIC MODE

- The values for the piston stroke and suction pressures can not be set directly
- They can be optimized indirectly using the ++/-- for diastole and systole
 - It will first adjust the piston stroke and then regulate the average driving pressure

=		¥			0
	Left 30 mL	Right 25 mL	provide (
Systole	-+;-	-44-	400 500 300		
Diastole	+/-	+/-	A M M	RAAR	M
Duration systele (%)	50	50	JUU	UJUU	1
Rate (bpm)	90	90	······································	1 25 30 31 40	45 58 9
Flow alarm threshold (j./min)	2.0	1.5	Automatic	Synchronous	00
			Paaneen - n	essenteres 6	
				4	B





DISPLAY OF VALUES ON THE ACTIVE DRIVER









ACTIVE DRIVER

- Design of the Pneumatic System
 - LVAD- if the pneumatic system fails the right pneumatic system will drive the pump
 - BIVAD- if one pneumatic system fails the remaining pneumatic system will drive both pumps at 45% of the former pumping performance
 - Will have to switch to backup unit





FLOW SENSOR

- New addition, ultrasonic flow sensor
- Need to save 55mm cannula length
- Mirror allows inspection of the underside of the cannula



SONOFLOW





SAME PUMP DIFFERENT LIMITATIONS

• IKUS

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10.1.10 Maximum rates for the pump-cannula combination	16.1	0 Maximum rates for	r the p	ump-cannula	combination
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Cannulation		Blood pumps						
Ø inflow cannula	Ø outflow cannula	10 ml	15 ml	25 ml	30 ml	50 ml	60 m	
5 mm	5 mm	130 bpm						
6 mm	5 mm	130 bpm	130 bpm					
6 mm	6 mm	130 bpm	130 bpm	80 bpm	65 bpm			
9 mm	6 mm		130 bpm	100 bpm	90 bpm			
9 mm	9 mm		130 bpm	130 bpm	130 bpm	130 bpm	105 bpm	
12 mm	9 mm					130 bpm	105 bpm	
12 mm	12 mm					130 bpm	125 bpm	





¹ With cannulae having multiple diameters, the smaller diameter determines the classification. This also applies to the use of connecting sets.

110 possible combination and maximum possible rate in [bpm]

95

80 ml blood pump not on driving unit REF: 1502210 selectable



PATIENTS AT CHOP

7 implants from 2/23-12/23

2 transplanted

1 explanted

1 converted to centrimag





PATIENTS









PATIENTS

- 2 transplanted
 - 3.5kg HLHS & TGA- Hybrid VAD on for 8 months
 - Driver changed because of PC syncing issues
 - Couldn't download data
 - 4 pump changeouts due to fibrin deposits
 - 18kg DCM on for 4 months
 - Driver changed for S4 alarm; pump never stopped
 - Driving unit is disconnected from the mains and immediately reconnected to the mains.
 - No pump changeouts





PATIENTS

- 1 Explanted
- 4.4kg ALCAPA repair
- S/P ECMO 11 days
- Berlin Heart with Active Driver 77 days
- 2 pump changes
- Turn down with ECHO in manual mode, off couple minutes and hand pumped





TRANSPORTATION WITH ACTIVE DRIVER

- Longer battery life
- Easier?
- Different attachments for strollers
- Light weight 15kg
- Patients can take trips outside of the hospital







FLOW SENSOR ALARM

- Things to look out for
 - Overheating
 - Cath lab
 - Overnight with a lot of blankets
 - Flow probe position
 - Right size flow probe for the tubing
 - Always face vent away from the patient skin



Flow Sensor

The flow sensor measures the amount of blood flow inside the cannula. **Warning:** Flow probe is sensitive to warm environments so if covered, it can cause a TS alarm.





PC MONITOR CONNECTION



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Three main parts of the Panel:

- Panel PC
- Docking Station
- USB connection to driver

PC will show flow rate while in locked screen and show colored alarms

Keep docking station charged at all times

• PC must be connected to the driver during self test everyday



NURSE CALL ALARM

- Compatibility issues with German plugs
- Communication of different priority alarms







TURNING OFF BACKUP DRIVER CORRECTLY





MONTHLY CHECK CHARGE EMERGENCY BATTERY FOR INACTIVE DRIVING UNIT

IF BACKUP DRIVER ISN'T TURNED OFF CORRECTLY IT WILL DRAIN THE EMERGENCY BATTERY





MAINTENANCE

- Every day the driver is unplugged from AC power to drain the batteries
- Back up batteries are swapped every 2 weeks

Driver Changeout

- 34 million pump cycles or 1 year, whichever comes first
 - IKUS was every 2000 hours
 - Less driver changeouts





REFERENCES

- *EXCOR Active driving system* instructions for clinical use 4.0. (n.d.). https://www.berlinheart.de/fileadmin/user_upload/Berlin_Heart/Dokumente/Dow nloads/Downloads_IFU/EXCOR_Active/clinic/1015002x03_A04_EXCOR_Active_ GA_Klinik_en.pdf
- *EXCOR Pediatric VAD with Stationary Driving Unit Ikus Rev. 2.1*. Downloads. (n.d.). https://www.berlinheart.de/en/mediaroom/downloads/



