Strategies for Implementing and Managing Multiple Mechanical Circulatory Support Platforms at One Center

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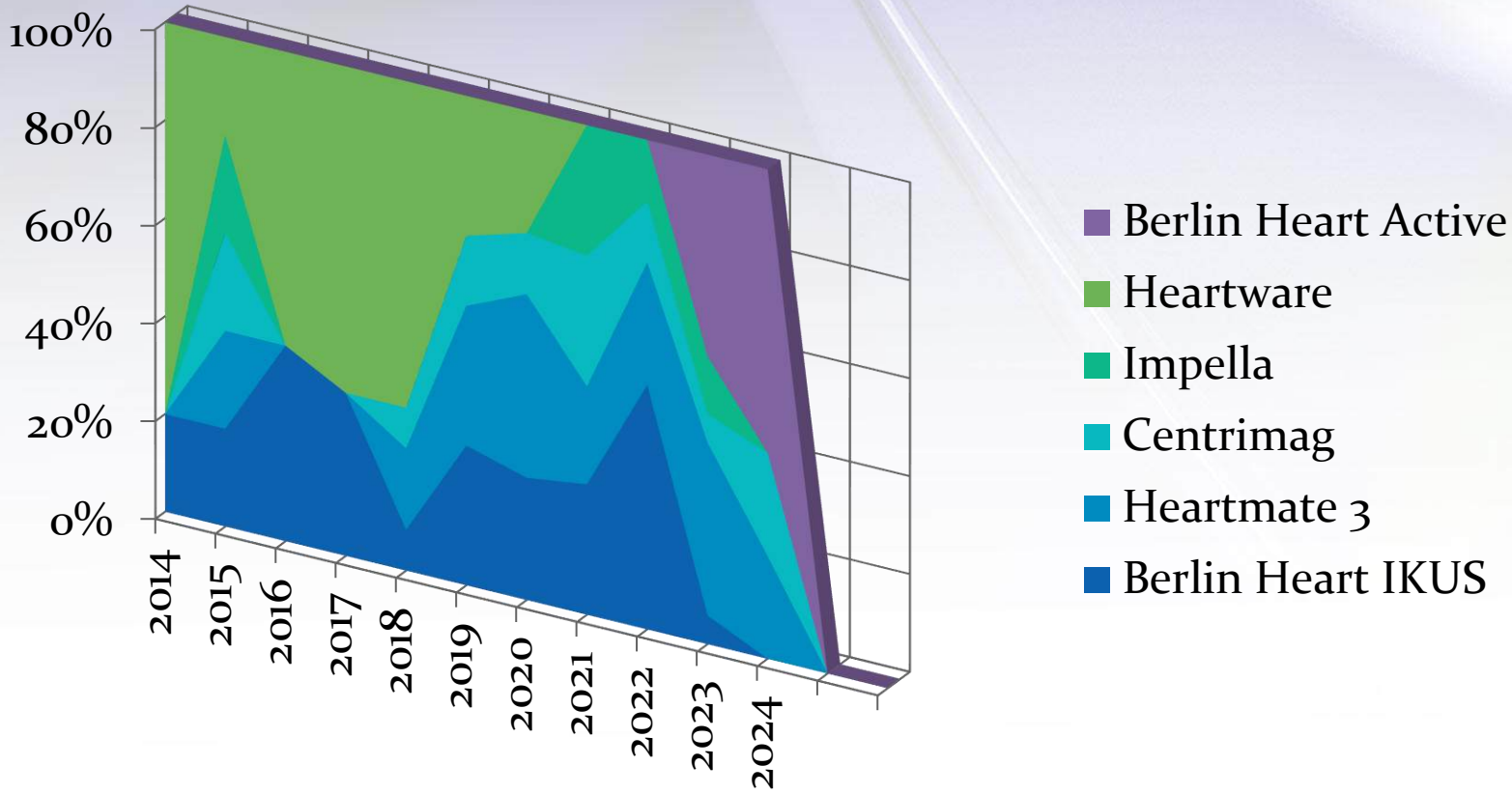
The Children's Hospital of Philadelphia
CHOP Cardiology Disney 2025

Preview…

- Roles and Responsibilities
- Challenges with multiple devices
- Adding a new device
- Troubleshooting
- Keys to Success

Mechanical Circulatory Support at CHOP



MCS Program Roles and Responsibilities

- Ordering, logistics, supplies and equipment, work with vendor, training, troubleshooting
- Protocols, just-in-time training, family education
- Anticoagulation, rounding, troubleshooting, care plan
- Discharge planning, clinic visits, supporting the outpatient/long term inpatient

Roles and Responsibilities

- Perfusion
- Nursing
- Surgery
- Cardiology/Heart failure team
- Support staff

Roles and Responsibilities

At CHOP-Divide and Conquer

- *Perfusion*- ordering, logistics, supplies and equipment, work with vendor, training, troubleshooting
- *Nursing*- protocols, just-in-time training, family education
- *Surgery/Cardiology/Heart failure*- anticoagulation, rounding, troubleshooting, care plan, discharge planning, clinic visits, support outpatient

VAD Coordinator!

Introduction to Advanced Cardiac Therapies for Heart Failure (ACT)

Advanced heart failure in CHD is the **greatest challenge** and **unmet need** in our field

Clinical Pathways	Current State	Future State
Medications	• No pediatric-specific therapies • No targeted therapies for right ventricular failure* • Poor long-term survival with medical therapy alone	*Provision of **targeted medical therapies** informed by cutting-edge research*
Mechanical Circulatory Support	• Limited devices for infants and small children • No dischargeable pediatric device • Underutilized setting of CHD	***Heart Failure ICU**, an innovative care delivery model, w/ **rehabilitation integration** into complex care*
Heart Transplantation	• Outcomes inferior in patients with CHD • Prolonged waiting times result in ~20% waitlist mortality • Limited long-term survival	***Innovative use of mechanical circulatory support** to improve post-transplant outcomes*

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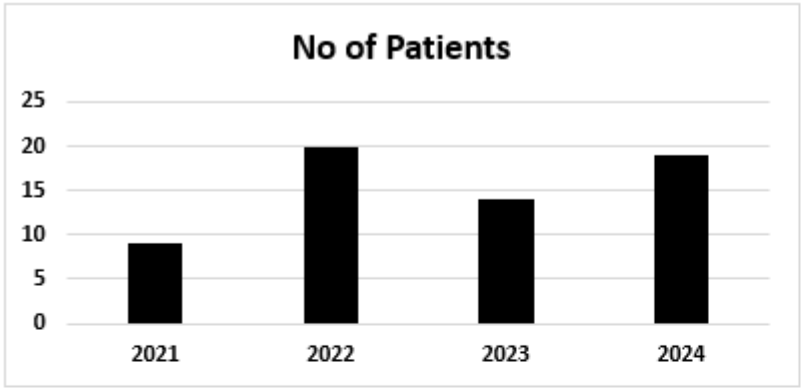
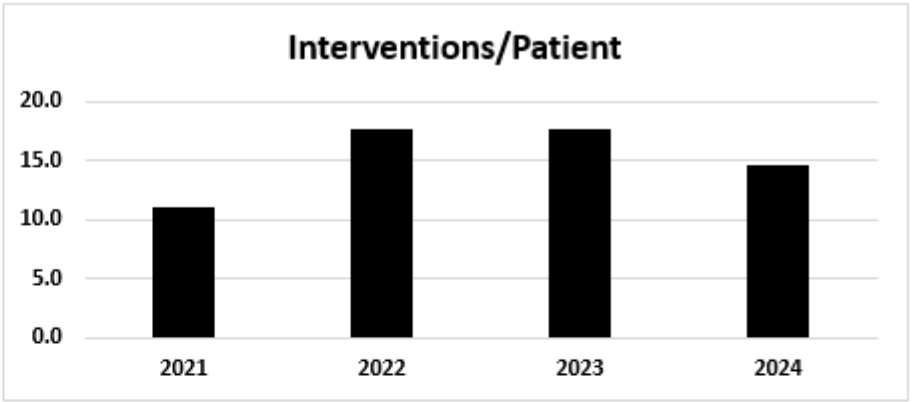
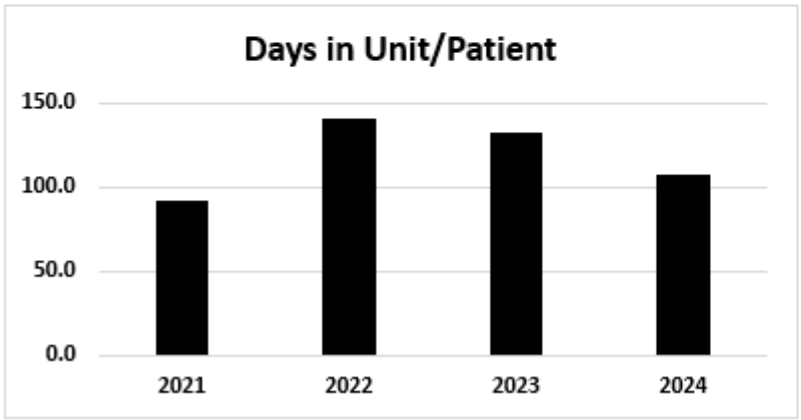
Clinical Approach- ACT

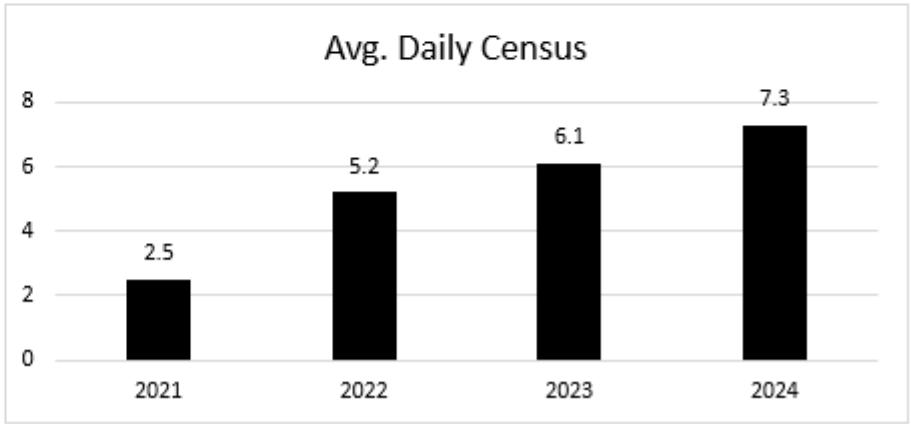
VAD Management	Targeted Heart Failure Medical Management	Comprehensive Care Model	Intensive Rehab Program	Specialized Care Team
Novel approaches for VAD and mechanical circulatory support management for single ventricle patients Earlier use of VAD for heart failure patients as clinically indicated	Focus on implementation of reverse-remodeling agents / RESTAGE protocol Current research on targeted, evidence-based strategies to treat pediatric and specifically RV heart failure	Device support, medical management, nursing care, nutrition, PT/OT/Speech developmental care, behavioral health, social work, child life, school services	Early mobilization and intensive rehabilitation with PT/OT/PM&R services Transition to conditioning phase / rehab gym once intensive rehab complete Transition to outpatient therapy services on discharge Weekly Rehab rounds	Surgical team, Perfusion, Medical team, APP/CNS/ENS/nursing teams, VAD coordinator, PT/OT/Rehab Focus on continuity of care

Growth of the ACT Program









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Challenges With Multiple Devices

- Different technology
- Low usage
- Equipment management
- Timing- urgent need
- Training- time, space, availability
- Troubleshooting

Challenges With Multiple Devices

- Super users
- Just in time training
- Troubleshooting plan/communication
- Reference tools

Berlin Heart EXCOR® Active

OPS

Pump Settings

Rate: The rate of the pump

Diastolic Pressure: The pump's suction pressure *(Usually -20 to -70 mmHg)*

Systolic Pressure: The pump's ejection pressure *(Aegs: LVAD=180–250 mmHg, RVAD= 80–150 mmHg)*

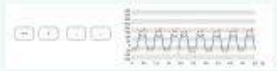
% Systole: Time the pump spends ejecting blood *(Usually >30% and <50%)*

Flow: Blood flow monitored by the flow sensor in the cannula *(L/min)*

Flow Alarm Threshold: The driving unit will emit an alarm if the flow drops below this value

Automatic Mode: The systolic and diastolic settings change to achieve the least amount of pressure needed to fill or eject the pump. Optimize the settings by using + or – symbol.

Manual Mode: All settings remain the same unless changed by the clinician—mode primarily used when chest is open.



System Components

1. Power supply
2. Adapter for external alarm (nurse call)
3. Batteries
4. Driving Unit
5. USB Cable
6. USB stick
7. Panel PC
8. Docking station
9. Panel PC Power supply unit
10. Battery charging unit
11. Flow sensor (R)
12. Flow sensor (L)
13. Power cable
14. Applied parts: blood pumps (defibrillation protected, cardiac floating)

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 T5 alarm.

Panel PC

The panel PC connects to the driver, stores all the settings, and communicates alarms. Clinicians can log in expert or medical mode to make settings adjustments, download data, and monitor parameters.

Operation Panel

1. Display
2. Maintenance LED
3. Battery LED
4. System LED
5. Button – audio pause, paging through views
6. Driving tube connector
7. Flow sensor connector
8. Seal plug
9. Power connector *(with seal cap)*

Optimizing Pump Function

		CVP (Central Venous Pressure)	C.O. (Cardiac Output)	Patient Treatments	
POOR FILL	Hypovolemia	↓	↓	Give Fluid	Decrease Rate
	Inflow Cannula Obstruction	↑	↓	Evaluate Further	Increase Diastolic Pressure
	Tamponade	↑	↓	Surgical Drainage	Decrease % Systole
	Right Heart Failure	↑	↓	+/- Nitric Oxide & Inotropes	
POOR EJECT	Hypertension	↑	↓	Reduce Afterload	Increase Systolic Pressure
	Outflow Cannula Obstruction	↑	↓	Evaluate Further	Increase % Systole
	Agitation	↑	↓	Pain Control/Sedation	

CAUSES — PUMP FIXES

Power Sources

General Power:

Batteries: Two batteries should last 6–13 hours depending on settings. It takes 3–4 hours to charge batteries in the docking station. **Do NOT remove both batteries at one time while driver is supporting a patient*

Power Outlet: Plug in while the patient is in bed. While plugged in, driver batteries should charge.

Emergency Power:

Internal Back Up Battery: Can power Driver for 30 minutes

Manual Pump: Pump at a speed of 60–80 BPM *(per IFU)*

Active Driver Accessories

Caddy: The driver can be removed from the caddy but it must remain upright at all times on a stable even surface.

Accessory Bag: Holds an extra set of batteries, the hand pump, and a tire pump.

Alarm Levels

Low, medium, and **high** alarms have different audio and visual cues and require user to press silence button to acknowledge alarm

S4 Alarm: Occurs if driver system is defective—may require the active driver to be replaced

- Contact your Berlin Heart representative to troubleshoot
- Prepare to switch driving unit

Alarm Types

Temperature: Temperature is too high or too low

Hemodynamics: Patient is receiving insufficient amount of support

System: Driving unit is not functioning properly

Power: Power supply is not functioning properly

Potential Emergencies

Power Failure: *(Manual Pump)*

- Switch driving tubes from the driver to the manual pump according to the color code
- Operate manual pump rhythmically with approximately 60–80 BPM
- Make sure membrane is moving completely

Switching Driver: *Contact the Berlin Heart Rep for assistance.*

- Place batteries into the replacement driver, ensure pump turns on and immediately starts pumping
- Confirm settings
- Switch driving tubes to the replacement driver
- Switch flow sensor to the replacement driver
- Watch for hemodynamic changes

CPR: Chest compressions and defibrillation/cardioversion can be used if needed

Membrane Rupture

- Watch for change in membrane movement on air or blood side
- Watch for a dark area or air bubbles on the blood side
- Watch for hemodynamic changes or heart failure signs and symptoms
- Treat heart failure
- Perform emergency pump exchange

Clinical Emergency Hotline: 1-800-826-9466

Scan QR code for **Berlin Heart Algorithms & Emergency Care**

action

actionlearningnetwork.org
myactioneducation.org

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Adding a New Mechanical Assist Device

Considerations

- Business plan
- Initial training
- Supplies/Equipment
- Vendor support
- Nursing/FLOC etc. training

Business Plan

Strategic Vision

- Financial implication-charges, reimbursements, operating expenses…
- How many devices, period of time
- Staffing, additional FTE's?
- Ancillary staff- OT, PT, hematology, home care, etc.

Initial Device Training

On Site- Scheduled or Urgent Need

- Clinical specialist
- Multiple times a day/at least week
- Space
- Train the trainer

Staying Competent

- Annual competencies/Skills fair
- Routine in-services

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Staying Competent

Just-In-Time Training

- Identified all high risk, low volume therapies
- Minimum skill set, competency checklists
- Education day for the charge nurses
- Start of every shift review a competency based checklist with the charge nurse or their designee

Staying Competent- Just in Time Training

Berlin Heart VAD Active Driver Competency Checklist- revised 10/2024

☐ ☐ Understand **electrical power** for Berlin Active Driver

- Each battery can last for 6-13.5 hours; time to drain depends on size of patient and demand on machine, ex: BIVAD v. SVAD, size of pump, etc.); batteries drain simultaneously.
- Recommend being on battery during the day to promote mobility/activity; plug in at night
- Check battery level hourly by pressing Charge Level Button on top of the battery
- Change battery when charge level reaches 50% (2 bars). Batteries must be changed at least every two weeks to maintain battery health.
- *If you disconnect power cord connection at the box, disconnect cord from driving unit (patient) and then reconnect cords at the box, and then connect back to patient. This is important to prevent a power surge to the driver which would generate an alert "S4 Driving alarm defective".*
- Battery charges in 3 hours on docking station
- Alarm sounds 5 minutes before battery dies; internal battery has 30 minutes battery life
- Tablet can be unplugged during the day once settings are set

☐ ☐ Understand miscellaneous **nursing care** associated with device

- Flow probe with vent
  - On cannula between metal and dressing
  - Does not need to be repositioned
  - **Clean with alcohol wipe daily, when performing a dressing change, or when soiled**; not approved for any other cleanser, including Oxivir. Remove vent from flow probe to clean both components with alcohol swab each time.
  - Alarm will trigger if overheats, move sensor PRN for optimal positioning of probe vent
- ACTION VAD Stroke Prevention Daily Rounds Checklist should be at bedside and up-to-date
- Perform dressing change every day for POD 1-7, then perform twice weekly
- Ensure VAD is in nurse call during safety checks by unplugging the nurse call cable from the wall briefly to ensure you get an alarm to your phone
- If patient is ordered for safety observer (1:1), be sure to give report and review safety measures

☐ ☐ Understand **pump settings and order**

- Review VAD order for mode
  - Can operate in two modes: Manual or Automatic/Adaptive
  - Manual Mode: set rate, systolic pressure, diastolic pressure, percent systole, and flow alarm
    - Pump will be louder in manual mode
    - Use when chest is open and during surgery
  - Automatic/Adaptive Mode: set rate, percent systole, and flow alarm; driveline will make changes in response to patient condition
    - Maintain hourly documentation of all parameters, including systolic and
- Review VAD order for settings
  - Rate (beats per minute): generally set 30-100bpm
  - Systolic pressure: ejection pressure (the pressure required to eject blood from the VAD). Generally set between 60 to 350 mmHg in manual mode.
  - Diastolic pressure: Assists with the filling of the VAD. Generally set between 0 to -100 mmHg in manual mode
  - % systole: length of time in diastole to allow filling of the VAD

☐ ☐ Understand **pump assessment**.

- Assess blood pump and visible cannulae for visible deposits every hour. Ensure the blood pump is clean prior to assessment. Utilize a flashlight to illuminate the blood pump which makes it easier to detect deposits.
  - Dark red area of discoloration may indicate a clot in the pump, white area of discoloration may indicate a calcification in the pump.
- Assess blood pump filling and ejection every hour. A completely smooth pump membrane at the end of systole and end of diastole indicates optimal filling and emptying. Wrinkles during filling may indicate decreased preload (hypovolemia, right ventricular failure, tamponade) or a need to increase diastole pressure. Wrinkles during ejection may indicate increased afterload (hypertension or agitation) or a need to increase systolic pressure.

☐ ☐ Understand nursing actions when **patient is mobile (therapies, travel, etc.)**

- Ensure back-up batteries are fully charged
- Bring back-up batteries on any walk outside of the patient's room
- Nursing should help ensure patient safety during transition to different surfaces (ex. Bed to stroller)
- Procedure: Transporting Patients within the Hospital
- Transportation within the unit:
  - CICU: requires an RN and another healthcare professional or caregiver and discussion with frontline provider
  - For a stable, identified patient without other medical needs that require additional support:
    - Okay to walk halls with parents but must be with staff member if on bridge, playroom, or gym (outside of unit)
- Transportation off the unit: Notify Perfusion, follow all existing VAD transport policies

☐ ☐ Understand **emergency care** for the Active driver

- The Active driver has two pneumatic drivers. For an LVAD if the primary driver fails, it will automatically switch to the second driver. For a BIVAD, both drivers are in use and would need to be switch to the back-up driver in the event of a driver failure.
- Emergency hand pump is located in accessory bag. To hand pump, remove seal plug from driving tube connector and pump at the set VAD rate. For an LVAD, driving tubing can be

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Supplies

Disposable Supplies

- Inventory, expiration, pre-implant check, post-implant reorder
- Point person/team
- System in place

How many supplies??

BERLIN HEART DISPOSABLES					
Item #	Article #	Description	LOT #	EXP	QTY
1	P10P-001x01	Blood Pump PU Valves 10ml	1320605	Mar-17	1
2	P10P-001x01	Blood Pump PU Valves 10ml	1320606	Mar-17	1
3	P10P-001x01	Blood Pump PU Valves 10ml	1320608	Mar-17	1
4	P25P-001x01	Blood Pump PU Valves 25ml	1320300	Oct-16	1
5	P25P-001x01	Blood Pump PU Valves 25ml	1220934	Aug-16	1
6	P25P-001x01	Blood Pump PU Valves 25ml	1220933	Aug-16	1
7	P30P-001x01	Blood Pump PU Valves 30ml	1320394	Sep-16	1
8	P30P-001x01	Blood Pump PU Valves 30ml	1320413	Jul-17	1
9	P15P-001x01	Blood Pump PU Valves 15ml	1420633	Jul-17	1
10	P15P-001x01	Blood Pump PU Valves 15ml	1420637	Jul-17	1
11	C85G-004	Arterial Cannula 12/9 mm 85°	32930	Feb-17	2
12	C85G-004	Arterial Cannula 12/9 mm 85°	31082	Feb-17	1
13	C80G-021	Arterial Cannula 6mm	25695	Jul-16	3
14	C60G-004	Arterial Cannula 12/9mm 60°	24514	Jun-16	2
15	C60G-004	Arterial Cannula 12/9 mm 60°	24972	Jun-16	1
16	C19V-020	Atrial Cannula 6mm	21972	Oct-16	2
17	C22V-004	Atrial cannula 12/9 mm 22mm	17673	Mar-16	2
18	C25V-004	Atrial cannula 12/9 mm 25mm	31039	Feb-17	2
19	C18A-020	Apex Cannula 6 mm	29941	Dec-16	2
20	C22A-004	Apex Cannula 12/9 mm	29943	Dec-16	2
21	C22A-004	Apex cannula 12/9 mm	26532	Aug-16	1
22	A06-006	Connecting Set for cannulas 6/6 mm	36566	Jun-16	1
23	A06-009	Connecting Set for cannulas 6/9 mm	27237	Sep-16	1
24	T00L-002	Accessory Set PU Valves	32794	Jan-17	2
25	T00L-002	Accessory Set PU Valves	31502	Nov-16	1
26	L20H-003x01	Driving Tube, blue	25343	Sep-16	2
27	L20H-003x01	Driving Tube, blue	35022	May-17	2
28	L20H-002x01	Driving Tube, red	26578	Feb-17	1
29	L20H-002x01	Driving Tube, red	26577	Nov-16	1
30	L20H-002x01	Driving Tube, red	29425	Jan-17	1
		updated on 12/22/2014			

Heart Mate 3 Disposable List			
	Product Description	Part Number	Par
Needed for Implant	Implant Kit (inc. 1 Controller)	106524US	3
	Controller (inc. EBB)	106531US	2
	Box of Lithium Ion Batteries (set of 4 per box)	2465	12 Batteries (3 Boxes) Patient gets 8 batteries
	Box of Battery Clips (set of 2)	2865	4 Clips 2 Boxes)
	Mini Cuff	10005877	2
	Battery Charger	1440	2
Needed Before Discharge	Consolidated Bag (Left)	106449	0
	Mobile Power Unit	107754	0
	Shower Bag (box of 2)	104323	0
	Large Holster Vest	104231	0
	Medium Holster Vest	104230	0
	Small Holster Vest	104229	0
	Battery Holster	104234	0
Extras	Modular Cable	106525US	0
	Outflow Graft	105581US	0
	Tunneling Tools	106533US	2
	Surgical Hand Tools	10002222US	2
	Surgical Accessory Spare Kit	10006827	0
	Functional Training Kit	10008189	1
	Power Module Patient Cable	103426	3

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Equipment

- Location/space
- Service/maintenance
- Tracking

Troubleshooting

There is an issue…Who needs to know?

- Perfusion/VAD Coordinator
- Surgeon
- Cardiologist/Heart Failure/Transplant attending

Final decision lies with..?

Consistency!

Troubleshooting

Know Your Resources

- Super user
- Smart phone- Pics/video
- Vendor

Berlin Heart

- Troubleshooting tool

Berlin Bedside Trouble Shooting (Active Driver)

Alarm Code: H1 H2

Cause: Kinking of drive line or cannula

Troubleshoot: Try to reposition patient, and cannula.

Assure driveline is not kinked. Attempt to clear alarm with silence button.

Need to call Perfusion? No, if the issue resolves. Yes if it does not.

Alarm Code: P alarms = Power issue (#1-8)

Cause: replace battery, connect to power supply

Troubleshoot: Replace batteries or connect to AC power

Need to call Perfusion? No if issue resolves. Yes if it does not or seems to be defected battery.

Alarm Code: S Alarms = System issue S2

Cause: Manual Mode for prolonged period

Troubleshoot: Silence every 24hrs until clinical team indicates switch to Automatic mode

Need to call Perfusion? No

Alarm Code: S Alarms = System issue S6

Cause: Flow sensor not connected

Troubleshoot: Connect flow sensor. If Connected attempt to remove and reconnect

Need to call Perfusion? No, if the issue resolves. Yes if it does not ** *Other S Alarms indicate system issue, notify perfusion.*

Alarm Code: T Alarms = Temperature issue T6

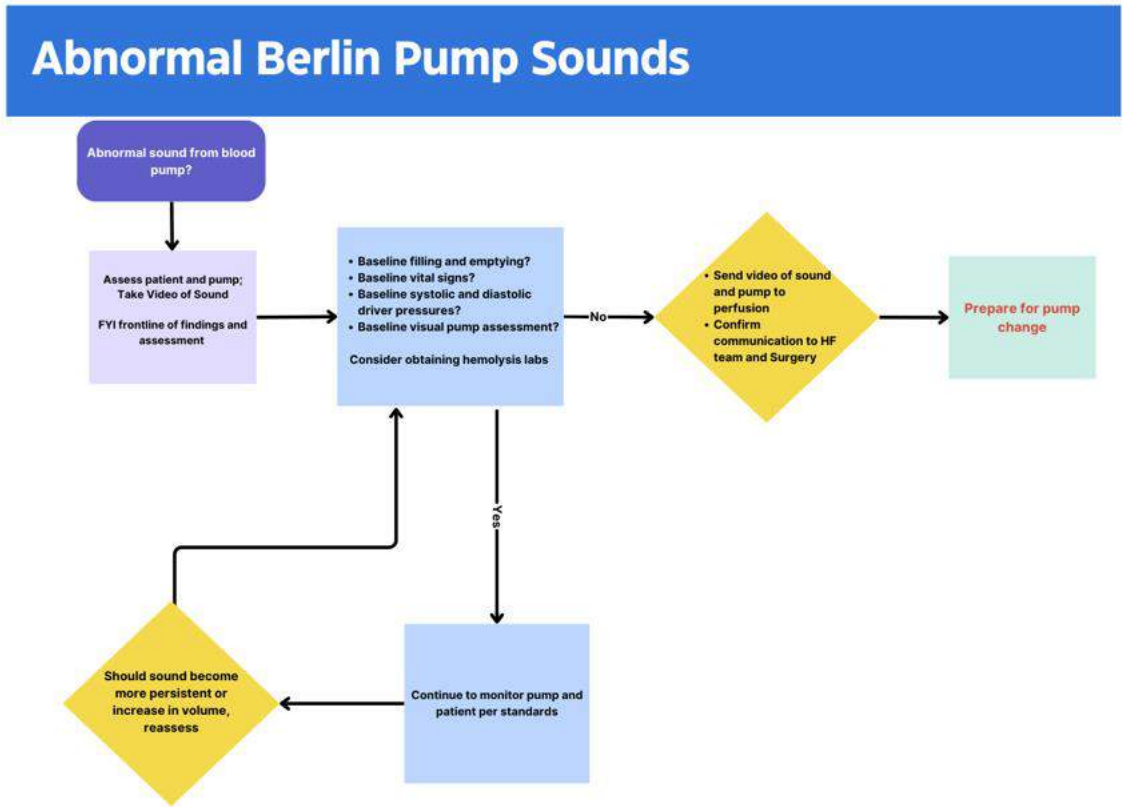
Cause: Flow sensor too hot

Troubleshoot: Remove excess blankets or heat surrounding flow probe if possible. Briefly remove sensor from driving unit. Remove and replace position of flow probe on cannula.

Need to call Perfusion? No, if the issue resolves. Yes if it does not.

*** *Other T Alarms notify perfusion*

Berlin Heart-Troubleshooting Tool



Keys to Troubleshooting Success

- Clear plan
- Team approach
- Strong communication
- Use all available tools

Don’t Panic…Call Perfusion!!

Keys to Success Managing Multiple Assist Devices

- Use your experts
- Establish resources
- Communication
- Competency
- Team approach