

Procedure

CCHMC ECMO Procedure	Procedure Number	ECMO-PR-017
Trial off Veno-arterial ECMO	Effective Date	11/22/2021
	Page	1 of 9

1.0 SCOPE

To assess the adequacy of the patient's cardio-pulmonary function without ECMO support. This procedure applies to all ECMO physicians, fellows, clinicians and specialists who provide ECMO to patients at CCHMC.

2.0 DEFINITIONS

N/A

3.0 PROCEDURES

Prior to clamping

3.1. ECMO Clinician will obtain VA ECMO Clamp Trial Job Aid and complete **time-out #1. This Job aid is to be used and documented on as indicated throughout the clamp trial process.**

3.1.1. Identify and **notify** the following roles who will be present for clamp trial

- 3.1.1.1. ECMO Clinician (presents required)
- 3.1.1.2. ECMO Specialist (presents required)
- 3.1.1.3. Bedside RN (presents required)
- 3.1.1.4. Fellow/NP (presents required)
- 3.1.1.5. Respiratory Therapist (RT) (presents required)
- 3.1.1.6. Attending (presents required)
- 3.1.1.7. Perfusion team (present only for surgical interventions in CICU)
- 3.1.1.8. CACN (Patients on add-on therapy, not required to be present)
- 3.1.1.9. Cardiac Surgeon (CICU only, not required to be present)
- 3.1.1.10. NICU medical team (NICU only, not required to be present)

3.2. **Managing attending** – in the setting of a clamp trial on a patient with an open chest and uncontrolled bleeding, there will be a discussion between the managing medical attending and cardiac surgeon to review risks and benefits regarding optimizing anticoagulation as described in this procedure.

3.3. **ECMO Specialist/Clinician** will:

- 3.3.1. Verify with ECMO fellow/Medical team lead the plan to perform clamp trial and time clamp trial will begin.
- 3.3.2. Provide laminated Job Aid to ECMO fellow/medical team lead (located in bedside ECMO cart)
- 3.3.3. Obtain a baseline Activated clotting time (ACT) and report results to ECMO Fellow/medical team lead.
- 3.3.4. Review most recent anticoagulation labs and confirm with ECMO fellow/medical team lead that the patient's anticoagulation is therapeutic/acceptable for a low flow state prior to weaning flows. (for patients with an open chest and uncontrolled bleeding, refer to section 3.2)
- 3.3.5. Notify CACN of clamp trial, if patient has add-on therapies running)
- 3.3.6. Confirm with bedside RN that patient has alternate heat source in place prior to clamp trial.
- 3.3.7. Remove hemofilter from shunt line
- 3.3.8. **Stop IV fluids infusing to ECMO circuit once they have been started to patient.**

3.4. **Fellow/NP** will:

- 3.4.1. Confirm if ECHO is needed for clamp trial and notify/order ECHO.
- 3.4.2. Place orders for two (2) 30units/kg heparin boluses **(Bivalirudin patients only)**

Procedure

CCHMC ECMO Procedure	Procedure Number	ECMO-PR-017
Trial off Veno-arterial ECMO	Effective Date	11/22/2021
	Page	2 of 9

- 3.4.3. Place orders for emergency medications to be available as appropriate.
- 3.4.4. Place orders for vasoactive infusions as appropriate.
- 3.4.5. Place orders for ventilator settings to be used at start of clamp trial.
- 3.4.6. Confirm with bedside RN that patient has appropriate IV access for clamp trial and place orders to obtain needed access if applicable.

3.5. **Bedside nurse** will:

- 3.5.1. Reorder all drips infusing to ECMO circuit that will continue infusing to patient during the clamp trial.
- 3.5.2. Confirm patient has appropriate IV access for all required infusions.
 - 3.5.2.1. Obtain appropriate IV access per orders.
- 3.5.3. To the patient, Start Bivalirudin and continuing ECMO circuit IV fluids.
- 3.5.4. Confirm with team lead need for vasoactive infusions for the clamp trial and confirm orders for medications are placed.
- 3.5.5. Place ordered vasoactive infusions in-line.
- 3.5.6. Prepare emergency medications as ordered.
- 3.5.7. Confirm with ECMO Specialist/Clinician that Bivalirudin has been started to patient.

3.6. **Respiratory Therapist (RT)** will:

- 3.6.1. Obtain baseline arterial blood gas (ABG) and report results to ECMO fellow/medical team lead
- 3.6.2. Confirm orders for initial ventilator settings for clamp trial and make changes per order.

Clamping Procedure

TIME OUT #2

3.7. **ECMO fellow/Medical team lead** will:

- 3.7.1. **Initiate Time out #2** by Calling "Time out: Everyone stop, focus and introduce name and role"
- 3.7.2. Representatives of roles noted in 3.1.1 will be present and introduce self, noting name and role.

3.8. **Managing Attending** will:

- 3.8.1. Be present at bedside for time outs

3.9. **Bedside RN** will:

- 3.9.1. Confirm emergency medications available as ordered
- 3.9.2. Confirm patient has appropriate access and medications are infusing to patient
- 3.9.3. Confirm vasoactive medications in-line as ordered
- 3.9.4. Confirm patient has alternate heat source in place.
- 3.9.5. Confirm Bivalirudin is infusing to patient and note time started. (**Bivalirudin patients only**)
- 3.9.6. Change all CRRT flow rates except blood flow, to zero and confirm setting with team. (for CRRT running via ECMO circuit only)

3.10. **ECMO Specialist/Clinician** will:

- 3.10.1. Report current circuit flows
- 3.10.2. Confirm Hemofilter has been removed from shunt line.

Procedure

CCHMC ECMO Procedure	Procedure Number	ECMO-PR-017
Trial off Veno-arterial ECMO	Effective Date	11/22/2021
	Page	3 of 9

3.11. **Respiratory Therapist (RT) will:**

- 3.11.1. Confirm vent settings as ordered
- 3.11.2. Confirm access for obtaining ordered ABGs during clamp trial.

3.12. **For patients on Bivalirudin:**

- 3.12.1. Do not wean Bivalirudin dose before or during wean
- 3.12.2. Bedside RN and ECMO Specialist/Clinician confirm two (2) bolus doses of heparin (30units/kg) are at bedside.
- 3.12.3. Bedside RN confirms Bivalirudin infusion started to patient and time started
- 3.12.4. ECMO Specialist/Clinician confirms Bivalirudin infusing to ECMO circuit has been stopped.
- 3.12.5. Give Heparin bolus 3-5 minutes prior to clamp trial starting (30units/kg) and chart in EMR
- 3.12.6. ECMO Specialist/Clinician to start **Heparin timer** in Spectrum
- 3.12.7. ECMO Specialist/Clinician obtains ACT after heparin bolus given and before clamp trial begins, and reports results to ECMO fellow/medical team lead.

Following completion of Time Out #2

3.13. **ECMO Specialist/Clinician** will wean flows as directed by ECMO fellow/medical team lead. If LA vent in place, clamp prior to weaning.

3.14. Once target flows and ventilator support are achieved:

3.14.1. **Managing attending** will:

- 3.14.1.1. Remain at bedside for first 15 minutes of clamp trial, acknowledging the first ACT results and ordered point of care lab values.
- 3.14.1.2. After the first 15 minutes of the trial, the attending may leave the bedside, but will remain within the unit/area of the patient's room.

3.14.2. **ECMO Specialist/Clinician** will:

- 3.14.2.1. Remove patient from ECMO support, clamp the Arterial cannula, and then clamp the venous cannula.
- 3.14.2.2. In Spectrum, select "clamp trial" to start timer, then select "ECMO off"
- 3.14.2.3. Adjust ECMO pump flows to prevent clotting of circuit during clamp trial
 - 3.14.2.3.1. Adjust circuit flow to a minimum of 500ml/min (0.5LPM) adult oxygenators
 - 3.14.2.3.2. Adjust circuit flow to a minimum of 200ml/min (0.2LPM) pediatric oxygenators
- 3.14.2.4. Stop circuit gasses (sweep gas and FI02)
- 3.14.2.5. Pause infusions still running to ECMO circuit.
- 3.14.2.6. Obtain ACT every 15 minutes until the conclusion of the clamp trial. Report values to ECMO fellow/medical team lead.
- 3.14.2.7. Notify ECMO fellow/medical team lead of time since last heparin bolus every 15 minutes until the clamp trial concludes. **(Bivalirudin patients only)**
- 3.14.2.8. Re-dose heparin bolus if the ACT falls below 160 seconds (30units/kg). **(Bivalirudin patients only)**
- 3.14.2.9. Note time of additional heparin boluses by stopping and restarting the Heparin timer in Spectrum. **(Bivalirudin patients only)**
- 3.14.2.10. ECMO fellow/medical team lead will order additional heparin boluses to bedside if 2nd dose is administered. **(Bivalirudin patients only)**

Procedure

CCHMC ECMO Procedure	Procedure Number	ECMO-PR-017
Trial off Veno-arterial ECMO	Effective Date	11/22/2021
	Page	4 of 9

3.14.2.10.1. **Flashing Cannulas**

- 3.14.2.10.1.1. Flash every 5 minutes or more often as needed
- 3.14.2.10.1.2. May need to reduce RPMs before flashing cannulas to prevent high flows to patient during cannula flash.
- 3.14.2.10.1.3. Open venous cannula, open arterial cannula, (open left atrial vent if present) for approximately 5 seconds and watch for color change, confirm forward arterial flow, then clamp the arterial cannula, then clamp the venous cannula and left atrial vent if present.)
- 3.14.2.10.1.4. Note “cannulas flashed” in Spectrum.

1.1.1. **Bedside RN** will:

- 1.1.1.1. Start/Adjust infusions to patient as ordered.
- 1.1.1.2. Obtain and send labs (except ABG) as ordered.
- 1.1.1.3. Monitor and report patient’s vital signs during clamp trial.

3.14.3. **Respiratory** Therapist will:

- 3.14.3.1. Adjust ventilator support as ordered.
- 3.14.3.2. Obtain patient arterial blood gas (ABG) as ordered and report results to ECMO fellow/medical team lead.
- 3.14.3.3. Make ventilator adjustments as ordered throughout the clamp trial.

At Conclusion of Clamp Trial

1.1. **ECMO Specialist/Clinician** will:

- 1.1.1. Return patient to ECMO support.
 - 1.1.1.1. Return RPMs to pre clamp trial RPMs.
 - 1.1.1.2. Initiate sweep gas flow at appropriate FiO₂.
 - 1.1.1.3. Open venous clamp, then open arterial clamp (if applicable, verify with physician if left atrial vent should be reopened)
- 1.1.2. Select “clamp trial” to stop timer and “bypass on” in Spectrum
- 1.1.3. Increase sweep gas and oxygen as flows are increased
- 1.1.4. Increase flows until desired flows/patient support is achieved
- 1.1.5. Restart anticoagulation infusions to ECMO circuit
- 1.1.6. Confirm with bedside RN that Bivalirudin infusion to patient is stopped. **(Bivalirudin patients only)**
- 1.1.7. Send coagulation labs within 4 hours following last heparin bolus and as ordered thereafter.
 - 1.1.7.1. Obtain labs from ECMO circuit following procedures: *ECMO-PR-002 Infusion and Sampling Sites on the ECMO Circuit and ECMO-PR-012 Drawing Blood Samples from the ECMO Circuit.*
- 1.1.8. Document clamp trial event in EMR.

1.2. **Bedside RN** will:

- 1.2.1. Remove alternative heat source and monitor patient temperature
- 1.2.2. Decrease/Stop vasoactive medications as ordered
- 1.2.3. Return CRRT to ordered rates.

1.3. **Respiratory Therapist** will:

- 1.3.1. Decrease ventilator settings as ordered
- 1.3.2. Obtain ABG as ordered.

Procedure

CCHMC ECMO Procedure	<i>Procedure Number</i>	ECMO-PR-017
Trial off Veno-arterial ECMO	<i>Effective Date</i>	11/22/2021
	<i>Page</i>	5 of 9

2.0 LIST OF ATTACHED FORMS

VA ECMO Clamp-Cap trial Job Aid Heparin
VA ECMO Clamp trial Job Aid Bivalirudin

3.0 REFERENCES

N/A

4.0 APPROVALS

All revisions of this procedure are approved by the ECMO Department. This procedure is reviewed every three years or sooner if deemed necessary. Authority for this document resides with the ECMO Department. This procedure is approved by the ECMO Manager, ECMO Clinical Director, ECMO Medical Director, Clinical Program Manager, Director of Professional Practice, Assistant Vice President of Patient Services and the Vice President of Patient Services.

HISTORY
Original Date
8/2015
Revision Date
5/2018, 5/2021, 11/2021, 4/5/2022
Review Date

Procedure

CCHMC ECMO Procedure	Procedure Number	ECMO-PR-017
Trial off Veno-arterial ECMO	Effective Date	11/22/2021
	Page	6 of 9



VA ECMO CLAMP TRIAL JOB AID

Date: _____

HEPARIN

Patient Sticker

Personnel present during clamp trial: (*presents required)

Notified:	Role:	Name:	Notified:	Role:	Name:
☐	*ECMO clinician	_____	☐	*Bedside RN	_____
☐	*ECMO specialist	_____	☐	*RT	_____
☐	*Fellow/NP	_____	☐	*Attending	_____
☐	Perfusion (CICU only)	_____	☐	CT Surgery (CICU only)	_____
☐	NICU Med Team (NICU only)	_____	☐	CACN (w/CRRT only)	_____

PRIOR TO CLAMPING Time out #1

- ☐ Time clamp trial to begin _____
- ☐ Laminated Job aide provided to Lead
- ☐ ECHO ordered/notified (if applicable)
- ☐ Current anticoagulation levels reviewed and acceptable for low flow state
- ☐ Remove Hemofilter from shunt line
- ☐ Base line ACT: _____ seconds
- ☐ IV fluids infusions reordered

Identified Lead

- ☐ Alternative heat source available
- ☐ Patient has sufficient IV access.
- ☐ Vasoactive infusions ordered: Infusions ordered _____
- ☐ All fluids moved to patient access
- ☐ Confirm initial vent settings for trial
- ☐ Emergency medication ordered
- ☐ Baseline ABG prior to clamping obtained

Time out #2

- | | |
|--|---|
| <ul style="list-style-type: none"> ☐ Team Lead Calls Time out ☐ All members introduce self and role ☐ All personnel present ☐ Emergency medications available ☐ All ordered infusions running to patient or in-line ☐ Current circuit flows: _____ | <ul style="list-style-type: none"> ☐ Alternative heat source in place ☐ All CRRT rates to "0", except blood rate ☐ Confirm starting vent settings ☐ Confirm access for AGBs during clamp ☐ All concerns addressed |
|--|---|

CLAMPING

- | | |
|---|---|
| <ul style="list-style-type: none"> ☐ Clamp patient off ECMO (arterial-venous, LAV vent if applicable) Time: _____ ☐ Select "Clamp Trial" in Spectrum ☐ Stop Sweep gases | <ul style="list-style-type: none"> ☐ Select "ECMO OFF" in Spectrum ☐ Turn off all IV infusions to circuit ☐ Increase pump flows
(pedi oxy ≥ 0.2Lpm, adult oxy ≥ 0.5Lpm) |
|---|---|

DURING CLAMP TRIAL

- ☐ Monitor ACT levels **q15 minutes until completion of trial**
- ☐ Flash Cannulas q 5 minutes, and select "Lines Flashed" in Spectrum
- ☐ Notify Lead of time since last heparin bolus every 15 minutes until conclusion of clamp trial
- ☐ Monitor ABG and CBC/platelets as ordered

Cont. on next page

Procedure

CCHMC ECMO Procedure	Procedure Number	ECMO-PR-017
Trial off Veno-arterial ECMO	Effective Date	11/22/2021
	Page	7 of 9



VA ECMO CLAMP TRIAL JOB AID

Date: _____

HEPARIN

Patient Sticker

POST CLAMP TRIAL

- ☐ Return to ECMO support (confirm with lead before unclamping LA/V vent if present)
- ☐ Restart sweep gases
- ☐ Select "Clamp Trial" in Spectrum to stop timer
- ☐ Select "ECMO On" in Spectrum
- ☐ Restart Heparin and AT3 infusions to ECMO circuit
- ☐ Remove alternative heat source
- ☐ Decrease/stop vasoactive infusions as ordered
- ☐ Return CRRT flows to ordered rates
- ☐ **Send Coagulation labs within 4 hours following last heparin bolus**
- ☐ Document Clamp Trial in EMR
- ☐ Wean Ventilator settings as ordered

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Procedure

CCHMC ECMO Procedure	Procedure Number	ECMO-PR-017
Trial off Veno-arterial ECMO	Effective Date	11/22/2021
	Page	8 of 9



VA ECMO CLAMP TRIAL JOB AID

Date: _____

BIVALIRUDIN

Patient Sticker

Personnel present during clamp trial: (*presents required)

Notified:	Role:	Name:	Notified:	Role:	Name:
☐	*ECMO clinician	_____	☐	*Bedside RN	_____
☐	*ECMO specialist	_____	☐	*RT	_____
☐	*Fellow/NP	_____	☐	*Attending	_____
☐	Perfusion (CICU only)	_____	☐	CT Surgery (CICU only)	_____
☐	NICU Med Team (NICU only)	_____	☐	CACN (w/CRRT only)	_____

PRIOR TO CLAMPING Time out #1

- ☐ Time clamp trial to begin _____
- ☐ Laminated Job aide provided to Lead
- ☐ ECHO ordered/notified (if applicable)
- ☐ Current anticoagulation levels reviewed and acceptable for low flow state
- ☐ Remove Hemofilter from shunt line
- ☐ Base line ACT: _____ seconds
- ☐ IV fluids and **Bivalirudin** infusions reordered
- ☐ Alternative heat source available
- ☐ Patient has sufficient IV access.

Identified Lead _____

- ☐ Vasoactive infusions ordered: Infusions ordered _____
- ☐ **Start Bivalirudin infusion to patient**
- ☐ **Stop Bivalirudin infusion to ECMO circuit**
- ☐ All fluids moved to patient access
- ☐ Confirm initial vent settings for trial
- ☐ **Confirm 2 Heparin bolus doses ordered (30units/kg)**
- ☐ Emergency medication ordered
- ☐ **Baseline ABG prior to clamping obtained**

Time out #2

- | | |
|---|---|
| ☐ Team Lead Calls Time out | ☐ Heparin boluses at bedside (30units/kg) |
| ☐ All members introduce self and role | ☐ Alternative heat source in place |
| ☐ All personnel present | ☐ Confirm starting vent settings |
| ☐ Emergency medications available | ☐ Confirm access for AGBs during clamp |
| ☐ Bivalirudin infusing to patient | ☐ Heparin timer started in Spectrum |
| ☐ Bivalirudin to ECMO circuit stopped | ☐ ACT post heparin bolus _____ |
| ☐ Ordered infusions running to pt. or in-line | ☐ All CRRT rates to "0", except blood rate |
| ☐ Current circuit flows _____ | ☐ All concerns addressed |
| ☐ Heparin Bolus (30units/kg) given Time (3-5 minutes prior to clamp): _____ | |

CLAMPING

- | | |
|--|---|
| ☐ Clamp patient off ECMO (arterial-venous, LAV vent if present) Time: _____ | ☐ Select "ECMO OFF" in Spectrum |
| ☐ Select "Clamp Trial" in Spectrum | ☐ Turn off all IV infusions to circuit |
| ☐ Stop Sweep gases | ☐ Increase pump flows
(pedi oxy ≥ 0.2 Lpm, adult oxy ≥ 0.5 Lpm) |

Cont. on next page

Procedure

CCHMC ECMO Procedure	Procedure Number	ECMO-PR-017
Trial off Veno-arterial ECMO	Effective Date	11/22/2021
	Page	9 of 9



VA ECMO CLAMP TRIAL JOB AID

Date: _____

BIVALIRUDIN

Patient Sticker

DURING CLAMP TRIAL

- ☐ Monitor ACT levels **q15 minutes until completion of trial**
- ☐ Flash Cannulas q 5 minutes, and select "Lines Flashed" in Spectrum
- ☐ Notify Lead of time since last heparin bolus every 15 minutes until conclusion of clamp trial
- ☐ Re-dose Heparin bolus to circuit if ACT<160 (30units/kg) Time _____
- ☐ Restart Heparin timer in Spectrum if re-dosed
- ☐ Monitor ABG and CBC/platelets as ordered
- ☐ Order additional Heparin bolus to bedside if 2nd dose is given

POST CLAMP TRIAL

- ☐ Return to ECMO support (confirm with lead before unclamping LA/V vent if present)
- ☐ Restart sweep gases
- ☐ Select "Clamp Trial" in Spectrum to stop timer
- ☐ Select "ECMO On" in Spectrum
- ☐ Stop Heparin timer in Spectrum
- ☐ Restart Bivalirudin infusion to ECMO circuit
- ☐ Stop infusion to patient
- ☐ Remove alternative heat source
- ☐ Decrease/stop vasoactive infusions as ordered
- ☐ Return CRRT flows to ordered rates
- ☐ **Send Coagulation labs within 4 hours following last heparin bolus**
- ☐ Document Clamp Trial in EMR
- ☐ Wean Ventilator settings as ordered