

EXTRACORPOREAL LIFE SUPPORT ORGANIZATION



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ELSO Registry Change Document

Updated April 3, 2022

April 2022 Summary:

2022 brings a few important upgrades to the main ELSO Registry and the addition of one voluntary Addenda. These upgrades are:

1. Updates to the addition of new equipment, device replacement reasons and associated mechanical complications to resolve and prevent entry of discordant device replacement reasons with run complications along with the interface for adding new equipment
2. Updated workflow surrounding patients transferred on ECLS between centers to more succinctly match patients and minimize the potential for confusion at the point of data entry
3. Introduction of a voluntary Trauma Addenda to more completely characterize this sub-set of ECLS supported patient
4. All complications will now have a date/time
5. COVID Validation regarding pregnancy, age, and sex

XML Changes – There are new tags for Trauma and transfers which can be used immediately. See documentation currently posted.

COMING JULY 2022 – XML Equipment tags are simplified. See XML documentation for information on that.

These upgrades have been motivated by the goals of increasing ELSO Registry data integrity and value while decreasing confusion at the point of data entry.

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Registry Change Document
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We welcome any questions or feedback you may have at registrysupport@elso.org

Thank you for your continued partnership.

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2022 Addition of Voluntary Trauma Addenda

April 3, 2022

The ELSO Registry Trauma Addenda has been created by an invested group of participating centers seeking a more granular dataset with respect to patients receiving ECLS as a consequence of trauma. Each participating center has agreed to contribute respective center data to the Trauma Addenda. If you would like to enter case data or have questions about the ELSO Registry Trauma Addenda, please reach out to Justyna Swol, MD PhD at jswol@icloud.com

2022 ELSO Registry Update to Data Entry Workflow Related to Patients Transferred on ECLS

April 3, 2022

Lack of clarity related to proper data entry surrounding patients transferred from one center to another on ECLS necessitates a clarifying process to more fully and accurately capture this important patient population and support centers in the Registry data entry process.

Updated Workflow for the Transferring Center:

- 1) *Discontinuation Reason*: Leave blank
- 2) *Discharged Alive*: Discharged on ECMO
 - a. When “Discharged on ECMO” is selected, the user will be allowed to select a receiving center by keyword search (including ELSO ID number). The ELSO center list will be available by hyperlink. If the transferring center cannot identify the receiving center utilizing these resources, they will be allowed to select “Other” and free text the name of the receiving center.
 - b. When “Discharged on ECMO” is selected, a message prompt will appear that clarifies the ECLS Stop Time will be considered the time your center discharged the patient.
- 3) *Date/Time of ICU Discharge / Hospital Discharge / ECLS Stop Date/Time*: Each of these times should align and be defined as the time care the patient is discharged from their center.

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- 4) *Hospital Discharge Location*: Transferred to another hospital
- 5) *When the user selects Discharged "ON ECMO", the system will not allow them to enter a Discharge Date/Time*. The Discharge Date and Time will auto-populate from what is entered as the ECLS Stop Date/Time. Respective notes will appear which direct the data enterer:
 - a. "Because this run is a transfer, please enter ECLS Stop Date as the Discharge Date/Time".
 - b. "Because this is a transfer, please enter ECLS Stop Time as the Discharge Time".

Updated Workflow for the Receiving Center:

- 1) *ECLS Start Time*: Time your center assumes care from the referring center or from the transporting team.
- 2) *Pre-ECLS Support Tab*: Select "Transported on ECMO"
 - a. This prompts a drop-down menu to appear that mandates the receiving center to identify the transferring center
 - b. When checkbox is selected, Pre-ECLS Assessment and Pre-ECLS Support fields will be hidden for that run.
 - c. When the user selects "Transferred on ECMO", the user will have to select one of two radio button options:
 - I. "From an ELSO Center": allows the user to enter a center name, after which text matches will allow the user to receiving center to identify the appropriate transferring ELSO center
 - II. "From a non-ELSO Center": allows the receiving to free text the name of the transferring center
- 3) Once the user selected transferred in ON ECMO, a note will guide the data enterer: "Because this is a transfer, the ECLS Start Date/Time should be entered as the time your center assumed care for this patient".

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2022 Other ELSO Registry Updates

April 3, 2022

- 1) All ELSO Registry complications now have an associated date/time
- 2) Additional COVID validations have been added regarding pregnancy, age and sex
- 3) The following organisms have been added:
 - a. Rhizopus species
 - b. Bacteroides fragilis
 - c. Klebsiella aerogenes
 - d. Alcaligenes xylosoxidans

2021 ELSO Registry Updates to Device Replacement Reason

December 1, 2021

On January 13, 2020, the ELSO Registry introduced a new field “Device Replacement Reason.” This reason applies to three devices: cannula, membrane lung and blood pump. Upon interrogating this data, we have noted that there was discrepancy between the data entered in the Device Replacement Reason and Complication data of Membrane Lung Failure and Blood Pump Failure. ELSO defines the Complication Membrane lung failure as a “Change indicated due to clot formation, gas exchange failure or blood leak.”

ELSO defines the Membrane lung device replacement reason as “This field collects the primary reason for membrane lung replacement, if applicable.” Data managers are instructed to “select from the drop-down box the primary reason for membrane lung replacement (removal of old membrane lung and addition of new membrane lung).” Please see Table 1 for a list of possible responses.

Table 1: Membrane lung replacement reasons

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Membrane lung device replacement reason	Description	Qualifies as membrane lung failure complication?
Structural integrity:	Membrane lung exchanged for suspected impaired structural integrity.	Always
Decreased efficiency of gas exchange:	Membrane lung exchanged for the primary reason of compromised oxygenation and/or ventilation.	Always
Acute obstruction to blood flow:	Membrane lung exchanged in response to a sudden loss or significant decrease in blood flow or acute spike in transmembrane pressure within the circuit.	Always
Increasing resistance to blood flow:	Membrane lung exchanged in response to increasing trans-membrane pressures.	Always
Coagulopathy with membrane lung as known source:	Device exchange primarily indicated by clot burden or coagulation derangement within the membrane lung.	Context-dependent
Hemolysis with membrane lung as known source:	Device exchange primarily indicated by center-specific markers of hemolysis (for example, plasma free hemoglobin, lactate dehydrogenase, haptoglobin or bilirubin) believed to be related to the membrane lung.	Context-dependent

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Entire circuit replaced due to coagulopathy of unknown source:	The entire circuit was exchanged due to clot burden or coagulation derangement of unspecified source.	Never
Entire circuit replaced due to hemolysis of unknown source:	The entire circuit was exchanged due to center-specific markers of hemolysis (for example, plasma free hemoglobin, lactate dehydrogenase, haptoglobin or bilirubin) of unspecified source.	Never
Equipment longevity / center protocol:	Device exchange indicated by center-specific protocol regarding longevity of use without evidence of other derangement. May be due to transition to or from a transport ECLS circuit.	Never
Entire circuit replaced due to indicated component(s) change:	Device was exchanged as part of whole circuit exchange primarily for an indication specific to a circuit component other than the membrane lung.	Never
Entire circuit replaced following temporary transition to bypass:	Device exchanged during whole circuit exchange following temporary transition of patient mechanical support or cardiopulmonary bypass within a continuous ECLS run.	Never
Other		Context-dependent

We identified the following three scenarios relating a lung failure complication and a lung exchange.

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Scenario 1: If a membrane lung exchange was listed for reasons of 'Structural integrity', 'Decreased efficiency of gas exchange,' 'Acute obstruction to blood flow,' or 'Increasing resistance to blood flow,' this fits our definition of a membrane lung failure complication, and a lung failure complication should always be entered (indicated by rows with 'Always' in last column of Table 1).

Scenario 2: If a membrane lung exchange was listed for reasons of 'Coagulopathy with membrane lung as known source,' 'Hemolysis with membrane lung as known source,' or 'Other,' this may or may not fit our definition of a membrane lung failure complication, and a lung failure complication could possibly be entered depending on the clinical context of the exchange (indicated by rows with 'Context dependent' in last column of Table 1).

Scenario 3: If a membrane lung exchange was listed for reasons of 'Entire circuit replaced due to coagulopathy of unknown source,' 'Entire circuit replaced due to hemolysis of unknown source,' 'Equipment longevity/center protocol,' 'Entire circuit replaced due to indicated component(s) change,' or 'Entire circuit replaced following temporary transition to bypass,' this does not fit our definition of a membrane lung failure complication, and a lung failure complication should never be entered (indicated by rows with 'Never' in last column of Table 1).

Define a discrepancy as any of the following: (i) an instance of Scenario 1 above in which no lung failure complication was reported anytime within +/- 4 hours of the equipment exchange; (ii) an instance of Scenario 3 above in which a lung failure complication was reported within +/- 4 hours of the equipment exchange, and there was not another equipment exchange that occurred closer to the lung failure complication; or (iii) an instance of a lung failure complication reported with no reported equipment exchange within +/- 4 hours of the equipment exchange. In this report, we tabulate the number of discrepancies in the ELSO registry as of December 1, 2021, at which time the registry was corrected at the point of entry to prevent future discrepancies of this nature.

As of December 1, 2021 new discrepancies cannot be added to the ELSO Registry. At the point of entry, the ELSO Data Manager is notified the data being entered is discrepant and cannot be entered. Each warning message is specific to the given discrepancy. If an ELSO center entered an ECMO run with a discrepancy between January 1, 2020 and December 1, 2021, then ELSO emailed the center to notify

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them which runs have discrepancy and requested they revise the discrepancy. If centers did not fix the discrepancy, then they were notified as of December 17th those runs were changed to unsubmitted. All of the data remains in the Registry, but the run will not contribute to center statistics regarding survival or complication reports until the discrepancy is resolved.

Analogous considerations apply for pump exchanges.

Table 2: Blood pump replacement reasons

Membrane lung device replacement reason	Description	Qualifies as membrane lung failure complication?
Mechanical replacement:	Blood pump replaced for failure or presumed failure of normal mechanical operation	Always
Obstruction to blood flow:	Device exchange primarily indicated by clot burden within the blood pump resulting in clinically significant decrease in blood flow.	Context dependent
Hemolysis with blood pump as known source:	Device exchange primarily indicated by center-specific markers of hemolysis (for example, plasma free hemoglobin, lactate dehydrogenase haptoglobin or bilirubin) believed to be related to the blood pump.	Context dependent
Entire circuit replaced due to hemolysis of unknown source:	The entire circuit was exchanged due to center-specific markers of hemolysis (for example, plasma free hemoglobin, lactate dehydrogenase, haptoglobin or bilirubin) of unspecified source.	Context dependent

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Entire circuit replaced due to coagulopathy of unknown source:	The entire circuit was exchanged due to clot burden or coagulation derangement of unspecified source.	Context dependent
Equipment longevity / center protocol:	Device exchange indicated by center-specific protocol regarding longevity of use without evidence of other derangement. May be due to transition to or from a transport ECLS circuit.	Never
Entire circuit replaced due to indicated component(s) change:	Device was exchanged as part of whole circuit exchange primarily for an indication specific to a circuit component other than the blood pump.	Never
Entire circuit replaced following temporary transition to bypass:	Device exchanged during whole circuit exchange following temporary transition of patient mechanical support or cardiopulmonary bypass within a continuous ECLS run.	Never
Other		Context-dependent

2020 ELSO Registry ECPR Addenda

January 21, 2020

PROPOSED vs ORIGINAL ECPR ADDENDA

Peta Alexander, Ryan Barbaro, Ravi Thiagarajan

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Development Process for Revised ECPR Addenda

As the Database Definitions project was approaching finalization, it was clear that the ECPR Addenda required updating and defining in an equivalent way. Representatives of the ELSO Registry Committees and experts in the field were convened to an *ECPR Addenda Working Group*. The new addenda were developed iteratively by small group teleconferences and wider group survey at multiple stages between February 2018 and January 2019. The process included audit of the existing ECPR Addenda for relevance, and rebuilding in line with current clinical practice and best available evidence. As the document was being finalized, targeted expert opinion was sought to optimize elements (with thanks to Dr Frank Moler, Professor of Pediatrics, Michigan Medicine, University of Michigan and Dr Monika Kleinman, Associate Professor of Anesthesia, Harvard Medical School). The current document (Proposed ECPR Addenda 7 January 2019.xls) is the result of the consultative process and is our recommendation for inclusion into the ELSO Registry to replace the current ECPR Addenda.

Data elements were grouped by Pre-Cardiac Arrest, Cardiac Arrest, Management of the Cardiac Arrest ('Code'), Circulation, Cannulation and Circuit Details and Post ECPR Management. Elements were classified as Mandatory or Non-Mandatory in keeping with the style of the revised ELSO Registry Database Definitions, but it should be noted that the entire ECPR Addenda represents a non-core dataset within the Registry (ie the addenda itself is non-mandatory, but *if it is to be completed*, there are fields within it which are core/mandatory elements). In addition, some elements of the ELSO Registry with particular relevance to ECPR are included in the document *for illustration only*. These will not be recollected in the ECPR Addenda.

In addition to a more global focus including adult ECPR care, one of the important changes to the ECPR Addenda is determining whether a cardiac or non-cardiac pathology precipitated the cardiac arrest.

There are a couple of outstanding issues:

1. We have included some *Process Quality Metrics* in the ECPR Addenda (+/- for migration to ELSO main Registry)

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2. This development process identified at least 1 additional cluster of data points which are relevant to the entire ELSO Registry, rather than just the ECPR Addenda – we suggest that these should be considered for inclusion in the main Registry.
3. If elements of the ECPR Addenda can be meaningfully incorporated into a predictive model for outcome of in-hospital mortality, then we propose that these elements should be migrated into the ELSO (main) Registry as MANDATORY fields. The rest of the ECPR Addenda should remain as an optional form for completion for relevant patients.

Process Metrics for Consideration

We propose inclusion of some features related to Quality of CPR – for example, end-tidal CO₂, the use of CPR feedback device and collection of NIRS if it is utilized during CPR.

The working group suggested collecting data on the neurological investigations used by centers in the first 24-hours after ECPR. These would serve to identify a ‘denominator’ for analyses of neurological injury. An example of potential process is included in Figure 1. Further discussion re: location of these fields in ECPR Addenda alone, or more relevant to the ELSO Registry may be warranted.

FIGURE 1

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EARLY POST-ECPR Procedures	Any procedure initiated within the first 24 hours post-ECPR	YES - MANDATORY Check All that Apply
NEUROLOGY EEG Monitoring <i>Standard</i> <i>Continuous</i> Intracranial Imaging <i>Cranial ultrasound</i> <i>CT Brain</i>	Post-ECPR electroencephalogram within the first 24 hours According to local protocols, regular duration of EEG EEG applied within the first 24 hours for a period of >12 hours of continuous monitoring	

In addition, it is established that team dynamics are an important component of ECPR success. We have included a field requesting information about inter-disciplinary team debriefing associated with the ECPR events reported to the registry (Figure 2).

FIGURE 2

DEBRIEF POST ECPR	<i>Monthly review of CPR cases has been associated with improved survival post CPR. Choose YES for this field if your inter-disciplinary team discussed the resuscitation event and ECPR process in the period following ECPR (Chan PS, JAMA Cardiology 2016). IF YES - did this occur within 24 hours? If >24 hours, did this occur within 1 month; if >1 month, did this occur within 3 months.</i>	NOT MANDATORY
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Data Points for Main Registry Consideration

There was meaningful interest from the working group to include medications which impact bleeding and clotting. Our suggested strategy for inclusion is shown in Figure 3. We would advocate that if these datapoints are included, it should be as additional ELSO Registry elements, rather than as part of the ECPR Addenda.

FIGURE 3

MEDICATIONS predisposing to bleeding at time of event.	The following medications were administered with the intention of therapeutically affecting the coagulation pathways within 12 hours of ECPR	MANDATORY
<ul style="list-style-type: none"> <i>Anti-platelet medication</i> <i>Heparin-based anti-thrombin mediated inhibition of anti-Xa anticoagulants</i> <i>Non-heparin based anti-thrombin mediated anticoagulants</i> <i>Direct thrombin inhibitors</i> <i>Vitamin K based inhibitors of coagulation</i> <i>Novel oral anti-coagulants (NOAC)</i> <i>Fibrinolytic therapy</i> 	<p>Any medication administered for the purposes of recuding platelet activity, examples include but are not limited to aspirin (acetylsalicylic acid, ASA), clopidogrel, tirofiban, dipyridamole, ticagrelor etc.</p> <p>Unfractionated heparin, or low molecular weight heparin For example danaparoid, fondaparinux</p> <p>For example bivalirudin, desirudin, lepirudin, argatroban</p> <p>For example warfarin</p> <p>For example apixaban, dabigatran, rivaroxaban, edoxaban</p> <p>For example tissue plasminogen activator (TPA), or streptokinase</p>	
MEDICATIONS predisposing to bleeding at time of event in deliberately sub-therapeutic dosing	The following medications were administered at prophylactic dosages	NON-MANDATORY
<ul style="list-style-type: none"> <i>Anti-platelet medication</i> <i>Heparin-based anti-thrombin mediated inhibition of anti-Xa anticoagulants</i> <i>Non-heparin based anti-thrombin mediated anticoagulants</i> <i>Direct thrombin inhibitors</i> <i>Vitamin K based inhibitors of coagulation</i> <i>Novel oral anti-coagulants (NOAC)</i> <i>Fibrinolytic therapy</i> 	<p>Any medication administered for the purposes of recuding platelet activity, examples include but are not limited to aspirin (acetylsalicylic acid, ASA), clopidogrel, tirofiban, dipyridamole, ticagrelor etc.</p> <p>Unfractionated heparin, or low molecular weight heparin For example danaparoid, fondaparinux</p> <p>For example bivalirudin, desirudin, lepirudin, argatroban</p> <p>For example warfarin</p> <p>For example apixaban, dabigatran, rivaroxaban, edoxaban</p> <p>For example tissue plasminogen activator (TPA), or streptokinase</p>	

In addition, the working group noted that some estimate of neurological outcome has increasingly been incorporated into reported clinical outcomes of studies. While especially relevant for patients undergoing ECPR, some assessment of neurological outcome could be incorporated into the ELSO Registry (Figure 4).

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FIGURE 4

NEUROLOGICAL ASSESSMENT AT DISCHARGE	<i>At hospital discharge - exact details to be determined</i>	NOT MANDATORY
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E-CPR Prediction Modelling

This project out of the ECPR Addenda working group, has been approved to proceed and we will anticipate sharing results in 2019.

DIRECT COMPARISON PROPOSED vs PRIOR ECPR ADDENDA

ELEMENT	PRIOR	PROPOSED
<i>PRE-ECPR</i>		
Precipitating Event	Not an element of the Addenda	Cardiac vs Non-cardiac
Antecedent Event		Choose from menu of conditions in the 4 hours prior to ECPR
Comorbid Conditions		Choose from menu of conditions present in the 24 hours before
Pre-existing Interventions	Collected as part of ELSO Registry	ECPR No change
<i>CARDIAC ARREST</i>		
Witnessed event and time		Question in CARDIAC ARREST

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	Question in Preliminary Information	With follow-on question for time etc
Location of arrest	Separate request for time of CODE Options included only inpatient, mainly pediatric settings	Choose from locations which also include outpatient and adult alternatives Triggered if outpatient setting listed
Outpatient specific questions	Not previously an element	
<i>CODE</i>		
Time CPR commenced	Collected in CODE table	Question in CODE
Total CPR time to ECMO flow	Collected in CODE table Not previously an element	Question in CODE Question in CODE
Multiple CPR in 24 hours?	Collected in CIRCULATION	Question in CODE
Pulse at time of cannulation	Collected in CODE table	Question in CODE
Compression method	In PRELIMINARY INFORMATION	Question in CODE
Initial documented rhythm	In PRELIMINARY INFORMATION	Question in CODE
Cardioversion or defibrillation	Not previously an element Collected in MEDICATIONS	Question in CODE Question in CODE
Rhythm at cannulation	Not previously an element	Question in CODE targeting pacing
Medications administered		
Other interventions during CPR		

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CIRCULATION

CPR quality – ETCO2

Not previously an element

Question in CIRCULATION

CPR quality – Arterial BP

Collected Best/Worse + SBP/MBP

DBP prior to ECMO only

Removed Best/Worst + SBP/MBP

CPR quality – feedback

Not previously an element

Question in CIRCULATION

device

Not previously an element

Question in CIRCULATION

CPR quality – NIRS

Not previously an element

Question in CIRCULATION

CPR quality – signs of life

CANNULATION AND CIRCUIT

Cannulation location

In PRELIMINARY INFORMATION

In CANNULATION AND CIRCUIT

Circuit pre-primed

In PRELIMINARY INFORMATION

In CANNULATION AND CIRCUIT

Priming solution

In PRIME

In CANNULATION AND CIRCUIT

POST-ECPR CARE

Cardiac

Not previously an element

LV decompression question

Neurology

Not previously an element

EEG and Imaging questions

Temperature management

Extensive questions about exact temperature management

Question re: intent of therapeutic strategy

Temperature achieved

Extensive questions about exact temperature management

Question re: max temp

Blood gas – first within 4 hours

Previously an element of the main registry

Question in POST-ECPR CARE

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REMOVED ELEMENTS

- Exact code times and timing of
- CPR during a multi-rhythm code
- Exact time of ROSC – we just ask
- for total CPR
- Best/worst pH and BPs during
- CPR
- Volume management
- First temperature
- Hours <32 degrees
- Hours 32-34 degrees
- Hours 34-35 degrees
- Hours 35-36 degrees
- Hours over 36 degrees
- Type of cooling system used
- Heparin Bolus

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With thanks to the ECPR Addenda Working Group

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Ryan Barbaro (Ann Arbor)
Joseph Tonna (Utah)
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Equipment and Cannula Data Entry Upgrade

January 21, 2020

Background:

Continued evolution in ECLS support necessitates upgrades to the ELSO Registry involving the ability to report equipment and cannula usage. Currently, the Registry asks for starting equipment and cannulas at the onset of an ECLS run and allows for the reporting of equipment exchanges or changes to cannulation strategies only with subsequent ECLS runs or modes. To date, reporting changes in cannulation strategy within the same ECLS mode (for example, change from thoracic to neck cannulation during the same V-A run) or equipment exchanges during a single ECLS run and mode has been limited by these restrictions.

When implementing any upgrade to Registry data entry, ELSO prioritizes improved flexibility in reporting options while not increasing the burden of data entry for the majority of unaffected ECLS runs. Upgrades to the *Mode and Equipment* tab (now *Modes and Cannulations*) and the addition of an *Equipment* tab adds functionality in the following ways:

- Allows for the removal or addition of cannulas with date stamps in event of a change in cannulation strategy
- Allows for the exchange or addition of blood pumps or oxygenators within a single ECLS run and mode
- Allows for the entry of simultaneous use of more than one piece of equipment within a single category (i.e. simultaneous utilization of more than one blood pump or oxygenator)
- Identifies reasons for changes in equipment or cannulation strategy

Additional information and guidance can be found below or on pages 80-94 of the ELSO Registry Database Definitions document, pages 3 and 4 of the ELSO ECLS Registry Form or the ELSO Registry 2020 Instructions document.

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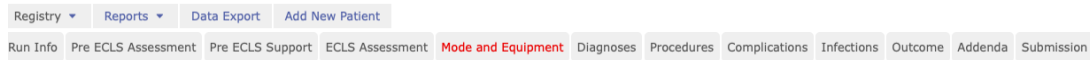
FAX: (734) 998-6602

EQUIPMENT AND CANNULA DATA ENTRY UPGRADE DIRECT COMPARISON PRIOR VS. FOLLOWING UPGRADE

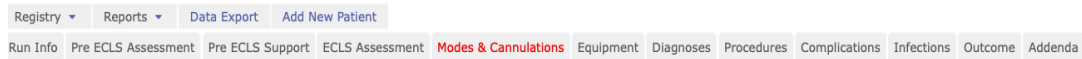
Modes & Cannulations:

ECLS Mode:

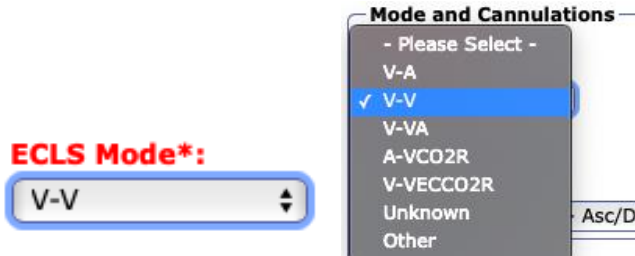
ECLS Mode Data Entry Location Prior to Upgrade: Mode and Equipment tab



ECLS Mode Data Entry Location After Upgrade: Modes & Cannulations tab



ECLS Mode Data Entry: No change to ECLS Mode data entry within appropriate tab



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ECLS Cannulations:

New Cannula Addition Location Prior to Upgrade: Mode and Equipment tab (see above)

New Cannula Addition Location After Upgrade: Modes & Cannulations tab (see above)

New Cannula Data Entry Comparison of Prior vs. After Upgrade:

- Add a new cannula in same way as prior:

ECLS Mode: V-V

Add New Cannula

- *Prior to upgrade*, no opportunity existed to clarify a start or end time for specific cannula use. Prior to upgrade, within a single mode of ECLS, data was not collected regarding time of cannula addition nor identification of cannula exchange or removal:

Cannulations

Percutaneous*: - Please Select -
Percutaneous is required

Preexisting*: - Please Select -
Preexisting is required

Manufacturer: - Please Select -

Cannula*: - Please Select -
Cannula is required

Center Specific Device*: - Please Select -
Cannula is required

Site: - Please Select -

Press the Save button below to save this cannulation.

- *Following upgrade*, if cannula(s) are in place for the entire ECLS mode, check the box confirming that the start and end times for that cannula are the same as the time on and time off ECLS:

Cannulations

Percutaneous*: - Please Select -
Percutaneous is required

Preexisting*: - Please Select -
Preexisting is required

Manufacturer: - Please Select -

Cannula*: - Please Select -
Cannula is required

Center Specific Device*: - Please Select -
Cannula is required

Site: - Please Select -

The start time and end time of the new device is the same as the time on and time off of the run:

Press the Save button below to save this cannulation.

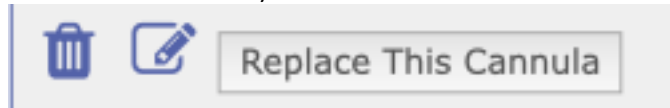
EXTRACORPOREAL LIFE SUPPORT ORGANIZATION



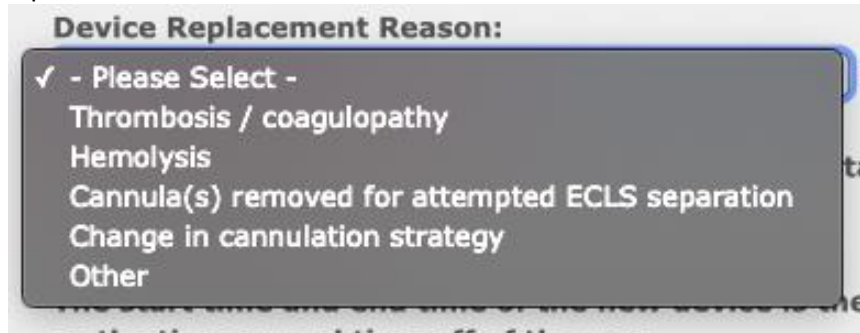
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FAX: (734) 998-6602

- *Following upgrade*, once a cannula has been entered, your center will have the opportunity to replace the cannula (for example with a change in cannulation strategy from thoracic cannulation to neck cannulation).



- *Following upgrade*, if you choose to replace a cannula, you will be required to supply a reason for replacement:



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- *Following upgrade*, if you add or remove a cannula, you will be given the opportunity to enter start and end times for cannula use if different from start and end times for ECLS support for that run:

The end time of the old device is the same as the start time for the new device:

The start time and end time of the new device is the same as the time on and time off of the run:

New Device Start Time:

Month / Day / Year

Hour : Minute

New Device Start Time is required

New Device End

Time:

Month / Day / Year

Hour : Minute

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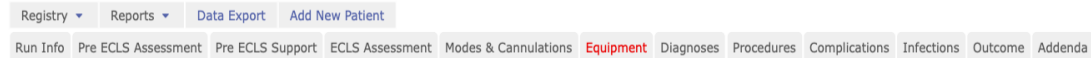
Equipment:

Equipment Data Entry Location:

Equipment Data Entry Location Prior to Upgrade: Mode and Equipment tab



Equipment Data Entry Location After Upgrade: Equipment tab



Equipment Replacements or Additions:

- *Prior to upgrade*, your center only had opportunity to enter a single equipment option for each type of equipment (i.e. membrane lung, blood pump, heat exchanger, hemofilter or temperature regulation) per ECLS mode:

Starting Equipment

Membrane Lung

Manufacturer:

Device:

Center Specific Device:

- *Following upgrade*, your center will have opportunity to either replace or add an additional membrane lung or blood pump:

Membrane Lung

Manufacturer:

Device:

This Membrane Lung was replaced during this Run

Another Membrane Lung was added during this Run

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- *Following upgrade*, if you **replace** a **membrane lung**, your center will have opportunity to identify replacement with the same device or a new device, and enter appropriate start and end times of use for that device:

Please add the new equipment below that replaced the Membrane Lung

Center Specific Device:
- Please Select -

Manufacturer:
- Please Select -

Device:
- Please Select -

Device Replacement Reason:
- Please Select - Device Replacement Reason is required

When did this Membrane Lung replace previous Membrane Lung

New Device Start Time:
Month / Day / Year Hour : Minute
New Device Start Time is required

New Device End Time:

- *Following upgrade*, if you identify **replacement** of a **membrane lung**, you will be required to identify a *primary* reason for device replacement from a list of reasons specific to membrane lung replacement:

Device Replacement Reason:

✓ - Please Select - Device Replacement Reason is required

- Structural integrity
- Decreased efficiency of gas exchange
- Acute obstruction to blood flow
- Increasing resistance to blood flow
- Thrombosis / coagulopathy
- Hemolysis
- Equipment longevity / center protocol
- Entire circuit replaced due to indicated component(s) change
- Entire circuit replaced following temporary transition to bypass
- Other

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- *Following upgrade*, if you identify **replacement** of a **blood pump**, you will be required to identify a *primary* reason for device replacement from a list of reasons specific to blood pump replacement:

Device Replacement Reason:

✓ - Please Select -
Mechanical replacement
Thrombosis / coagulopathy
Hemolysis
Equipment longevity / center protocol
Entire circuit replaced due to indicated component(s) change
Entire circuit replaced following temporary transition to bypass
Other

Device Replacement Reason is required

- *Following upgrade*, if you identify **addition** of a **membrane lung or blood pump** your center will have opportunity to identify replacement with the same device or a new device, and enter appropriate start and end times of use for that device:

Please select the additional device below that was added as an additional Membrane Lung in his Run

Center Specific Device:

- Please Select -

Manufacturer:

- Please Select -

Device:

- Please Select -

Device is required

New Device Start Time:

Month / Day / Year Hour : Minute

New Device Start Time is required

New Device End Time:

Month / Day / Year Hour : Minute

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With thanks for input from the following ELSO Technologies Committee members:

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Miscellaneous January 2020 Registry Updates

January 21, 2020

Infectious Organisms Added:

1. Herpes Virus 6, Organism ID: 224, Viruses and prions
2. Parvo Virus B19, Organism ID: 225, Viruses and prions
3. Mycobacterium chimera, Organism ID: 226, Mycobacterium