Standards of Safety Management during
Extracorporeal Membrane Oxygenation (ECMO)
(2nd Edition)

September 24, 2024

[Standards of the equipment]

① A battery-drive system should be equipped.
② A manual operation system with a hand crank should be available
③ An oxygen (gas) blender should be equipped.
④ Alarm system for low and high blood flow for the centrifugal pump should be available.
⑤ An oxygen tank carrier for transportation is recommended.
⑥ Installation of a bubble detector is recommended.[1)]
⑦ Ability to measure the circuit pressures is recommended.
⑧ Use of a specially-made carrier for ECMO machine is recommended.
⑨ Monitoring of venous blood oxygen saturation (SvO_2) is recommended.[2)]

[Standards of the operation]

① Prepare a manual of ECMO operation (for each facility) and follow the manual when ECMO is used.
② Prepare safety checklists for the induction and operation of ECMO, separately.
③ Perform a periodic inspection (visual, operational, functional, and performance inspections) based on the instructions for use and keep inspection records.[3)]

[Standards during standby mode]

① Check the residual quantity of oxygen tank regularly, if an oxygen tank is equipped.
② Check the expiration dates of disposables to be used during ECMO.
③ It is recommended to prepare spare disposables in the hospital.
④ Check the built-in battery regularly, and always keep the battery fully charged.

[Standards during the induction of ECMO]

① Check that there is no damage to the exterior, knobs, or display.
② Confirm no residual air in the circuit and clamp the priming lines.
③ Ensure to carry out the flow of sweep gas.[4)]
④ Check the blood flow.
⑤ Check the oxygenation by the color of the arterial blood.

[Standards during transportation]

① Set the alarms adequately before transportation.
② Check the residual quantity of battery.
③ Check the residual quantity of oxygen tank, taking the duration of transportation

into account.

④ Bring a hand crank for a possible manual operation.

⑤ Check the flow of sweep gas and color of arterial blood during the exchange of gas sources.

⑥ Pay attention to the kink, accidental extraction of the cannulaes an the falling down of the machine.

[Standards during the operation]

① Confirm the power supply.

② Check the setting of alarms.

③ Check that the volume of the alarm sound is loud enough.[5)]

④ A hand crank for the manual operation should be always available at the treatment room.

⑤ Monitor the circuit, the machine and condition of the patient continuously.

⑥ Check the oxygenation and coagulation function periodically.

⑦ Check for complications like bleeding around the cannulation site and limb ischemia.

⑧ Connecting fluid lines or renal replacement circuit to the ECMO circuit is not recommended.

⑨ Daily check of the cannulae position is recommended.[6)]

⑩ It is recommended to check for damage to various connections such as the cannulae and the oxygenator.[7)]

[Standards during the weaning]

① Adjust the ventilator setting, hemodynamic support and the dose of oxygen according to ECMO flow.

② It is recommended to evaluate the coagulation function at the time of weaning.

③ Confirm the clamping of the circuit when ECMO support was stopped.

④ Prepare to re-start ECMO support even after weaning.

[Standards after the weaning][8)]

① Check that there is no damage to the exterior or knobs.

② Check that there is no damage or cracks to the power cord and various cables.

③ Check the residual quantity of oxygen tank, if an oxygen tank is equipped.

④ Connect to the power outlet and make sure the battery is charging.

Commentary of the Revised and Additional Items in the Standards of Safety Management during Extracorporeal Membrane Oxygenation (2nd Edition)

January 30, 2025

1) [Standards of the equipment] "Installation of a bubble detector is recommended" has been added. By installing a bubble detector, it is possible to detect air bubbles if there is a mishandling of the three-way stopcock or in the unavoidable event that air gets mixed when adding fluid from the venous line. Air contamination can lead to serious accidents.
2) [Standards of the equipment] "Monitoring of venous blood oxygen saturation (SvO_2) is recommended" has been added. In V-V ECMO, some of the arterial blood is recirculated, so when SvO_2 is high, recirculation has increased. It is also important to keep in mind that the metabolic rate does not accurately reflect the metabolic rate due to recirculation.
3) [Standards of the operation] stated to perform a periodic inspection based on the instruction manual (instructions for use), but we have added a more detailed statement that periodic inspections must also include "visual, operational, functional, and performance inspections". Periodic inspections are necessary to maintain the performance of the equipment, so please be sure to carry them out.
4) Regarding the sweep gas in [Standards during the induction of ECMO], it has been stated that the flow should be checked, but there have been reports of incidents of gas flow at the time of induction, so the wording has been changed to "ensure to be carried out". Missing to induce the sweep gas can lead to a serious accident, so please be sure to carry out the procedure.
5) [Standards during the operation] "The volume of the alarm sound should be loud enough" has been added. There are various alarms, some of which require action and some of which pose a danger, but if the alarm cannot be heard, it will not be able to take action, so it is necessary to adjust the alarm volume to a sufficiently loud level.
6) [Standards during the operation] "Daily check of the cannulae position is recommended" has been added. The position of the cannulae is important for maintaining circulatory support. If the arterial cannulae becomes dislodged, it could lead to a serious accident. In addition, depending on the position of the venous cannulae, it may be difficult to maintain the flow rate, so daily checks are required.
7) [Standards during the operation] "It is recommended to check for damage to various connections such as the cannulae and the oxygenator" has been added. Be sure to implement safer circulatory support management by preventing air contamination and blood loss caused by damage to various components during circulatory support operations.
8) All items in [Standards after the weaning] have been added. There may be cases where circulatory support is required again after weaning, so we have provided

information on how to prepare the circulatory support and to prepare in consideration of the fact that it involves transportation. Circulation and respiratory status may be unstable after weaning, and prompt preparation will ensure smooth recirculation.