

SPECIAL SUPPLEMENT TO DIRECTIONS FOR USE: S5 SYSTEM
TEMPORARY MODIFICATION TO INDICATIONS FOR USE TO ADDRESS COVID-19

BACKGROUND

The United States Food and Drug Administration issued a guidance document ***Enforcement Policy for Extracorporeal Membrane Oxygenation and Cardiopulmonary Bypass Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency*** (Monday, April 6, 2020) to expand the availability of devices used in extracorporeal membrane oxygenation (ECMO) therapy to address the Coronavirus Disease 2019 (COVID-19) Pandemic. This policy is intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by the Department of Health and Human Services (HHS), including any renewals made by the HHS Secretary.

COVID-19 can trigger acute respiratory failure and/or acute cardiopulmonary failure. Under such conditions, long-term extracorporeal oxygenation (i.e., extracorporeal oxygenation for greater than 6 hours) can be an important tool for treating patients and FDA recognizes the importance and utility of increased availability of extracorporeal oxygenation devices for patients during the COVID-19 public health emergency. Cardiopulmonary bypass devices, cleared or approved by FDA, are technologically capable of being used for ECMO therapy, providing extracorporeal oxygenation for longer than 6 hours. Therefore, to facilitate expanded availability of devices to perform ECMO therapy to treat COVID-19 patients, FDA is permitting manufacturers of cardiopulmonary bypass devices to modify the indications for use of their devices to include ECMO greater than 6 hours, without prior submission of a premarket notification to FDA (i.e. FDA clearance).

Device description	Part Number
S5 Modular Perfusion System	45-95-02
S5 Console 3-Position	48-30-00
S5 Console 4-Position	48-40-00
S5 Console 5-Position	48-50-00

S5 is a modular heart lung machine system that may include several optional components, for the full list of part numbers and compatible accessories refer to the S5 System Directions For Use (DFU).

INDICATIONS FOR USE

FDA-Cleared Indications for Use

The S5 System is indicated for speed-controlled pumping of blood through the cardiopulmonary bypass circuit for durations of six hours or less, left ventricular venting, cardiotomy suction, administration of cardioplegia solution, when used by a qualified perfusionist who is experienced in the operation of the S5 System.

Special Indications for Use permitted by FDA on a temporary basis to address the COVID-19 pandemic

The device can be used in an ECMO circuit to treat patients who are experiencing acute respiratory failure and/or acute cardiopulmonary failure. The device can be used in an ECMO circuit greater than 6 hours.

ADDITIONAL INFORMATION RELATED TO SPECIAL INDICATIONS FOR USE

The following information provides an addendum to the existing FDA-Cleared Directions for Use (DFU) about the device related to the Special Indications for Use.

Device Performance

Device performance is the same as that established in the DFU.

Summary of Durability Testing

The summary of durability testing is the same as that established in the DFU. According to IEC 60601-1 conformance test report the mode of operation is continuous.

CONTINUOUS OPERATION is defined as operation in normal use for an unlimited period of time without the specified limits of temperature being exceeded.

Summary of Animal Testing

There is no additional animal testing related to use for ECMO greater than 6 hours.

Summary of Clinical Performance

Summary of device performances is established in the DFU.

Potential Risks

Some of the following hazardous situations may arise during the use of the device in an ECMO circuit greater than 6 hours:

- Interruption in flow
- Interruption in sensor derived parameters or readings (e.g. flow, pressure, time)

In addition, all known risks and warnings for S5 use are applicable and no additional information regarding potential risks is available.

Clinical Signs and Observations that suggest device change-out is required

- Per the Extracorporeal Life Support Organization (ELSO) Guidelines for Adult Respiratory Failure, a pump or pumping system should have a battery backup system in the event of electrical power failure. ((ELSO), 2017, p. 18) The circuit should be designed to automatically switch to battery operation if the main source of electricity is lost. An alarm should sound when the circuit switches to battery operation. The battery will operate the circuit for 30-60 minutes while the cause of the problem is being identified. If the electrical circuit and the battery fails, the alarm will be a low flow alarm or alarms attached to the patient (saturation or blood pressure). In that case it will be necessary to crank the pump by hand.
- Battery power can be leveraged when transporting a patient within the hospital or between hospitals, if necessary. Per guidelines, it may be necessary to travel to radiology, the operating room, or the cath lab as follows. Be sure that the battery is fully charged and the hand crank is available for the pump. ((ELSO), 2017, p. 19)

In addition, the following phenomena should be monitored:

- Connection to AC Power
- Battery Levels
- Availability and function of the manual hand cranking system

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In case any that power is disrupted, and battery backup is insufficient for the conditions required, maintain goal pumping with manual hand cranking and replace the pump system with a backup system.

Use Conditions

Intended use relevant to the current FDA guidance are identical to those in the product DFU with the exception of duration of use which is anticipated to exceed the existing labeled indications of six hours.

The extracorporeal circulation is intended to temporarily bypass the heart and lungs function by an external circuit, where single components work independently but in synergy with each other.

Sensors and monitoring features of the Heart Lung machine employed in cardiopulmonary bypass may be used in the conduct of ECMO.

The S5 System shall be operated only by an authorized medical professional and shall be operated and maintained as required by the DFU of the device.

The S5 System can generate notifications in form of alarms, warnings and error messages according to relevant conditions, all such notifications shall be handled appropriately as indicated in the DFU.

There are no additional contraindications for use relevant to the current FDA guidance beyond those provided in the product DFU.

See DFU at sections **“2.2.1 INTENDED USE”**, **“2.2.2 CONTRAINDICATIONS”** and **“2.2.3 GENERAL INSTRUCTIONS”**.

ELSO, E. L. (2017). *Adult Respiratory Failure Guidelines, Ven 1.4*. Extracorporeal Life Support Organization.