

SPECIAL SUPPLEMENT TO DIRECTIONS FOR USE: Centrifugal Pump CP5
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
Centrifugal Pump CP5	60-00-60

INDICATIONS FOR USE

FDA-Cleared Indications for Use

Centrifugal Pump (CP5) is a cardiopulmonary bypass speed control device indicated for use exclusively with the Sorin Revolution for speed-controlled pumping through the cardiopulmonary bypass circuit for typical durations of six hours or less.

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 Risk

All known risks and warnings for CP5 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)

The following phenomena should be monitored:

- Connection to heart lung machine power supply
- Battery Levels of the connect heart lung machine
- Availability and function of the manual hand cranking system

For correct device installation and connection to heart lung machine refer to the DFU.

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

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.

Due to the device intended use (not in body contact body fluid or expired gases) and operating principle (medical electrical equipment containing several electro-mechanical function groups), the device is not sterile (sterility is defined as free from all viable microorganisms). Instead, the device requires regular cleaning (defined as removal of contamination from an item to the extent necessary for further processing or for intended use) and disinfection of high contact surfaces.

The CP5 must only be operated with a flow sensor connected. If a flow sensor becomes defective during perfusion, replace it without delay. If this is not possible, complete the perfusion with increased care and attention to overall device and clinical status assessed by other measured values. Have the defective flow sensor checked by a qualified service technician immediately after completing perfusion. The CP5 must be monitored at all times during operation (as is the case for the overall system). If the device is not properly monitored, the patient may be at additional risk. The safety features of the overall system (alarm signals etc.) are intended to support the user as part of a standard protocol for continuous monitoring.

Sensors and monitoring features of the heart lung machine employed in cardiopulmonary bypass may be used in the conduct of extracorporeal membrane oxygenation (ECMO).

The CP5 system shall be operated only by an authorized medical professional and shall be operated and maintained as required by the Instructions for Use of the device.

The CP5 system can generate notifications in form of alarms, warnings & error messages according to relevant conditions, all such notifications shall be handled appropriately as indicated in the Instructions for Use.

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

See Instructions for Use at section “**2.2 REGULATIONS AND SAFETY INSTRUCTIONS**”.

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

