PuriFi Standalone with CytoSorb®

Quick Setup Guide



- CytoSorb® adsorber
- Access (arterial) inline pressure sensor
- Pre adsorber inline pressure sensor
- Return (venous) pressure sensor and auto-leveling bubble trap
- Air blood detector / Venous clamp
- Blood return line line is connected to either a waste bag, a saline bag or the patient as indicated in the setup instructions > Setup instructions on the inside
- Access blood line line is connected to saline bag or patient indicated in the setup instructions > Setup instructions on the inside
- Saline bag for priming 1x2 or 2x1 liter
- Blood pump
- Heparin line and heparin syringe pump

Setup modes

Back

Blood line setup vascular

Direct connection to vascular access (e.g. Shaldon line) with disconnect alarm on blood return line, if return pressure is <10 mmHg in case of a disconnect.

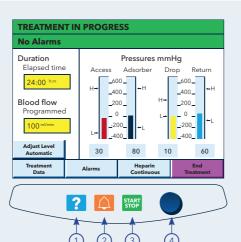
Blood line setup ECMO

Connection to an ECMO system. The system is optimized for ECMO pressure conditions. No disconnect alarm on the blood return line.

PRIMING PARAMETERS No Alarms Volume Priming Type of Treatment 24:00 h:m Treatment Time Select yellow Parameter Field Adjust and Confirm with Rotary Dial

Choose:

- 1. Volume for priming of the adsorber
- 2. Adult or Pediatric blood line set
- 3. Planned treatment time



- 1 Help function
- 2 Mute / Reset alarms
- (3) Start / Stop pump
- (4) Rotary dial to change and confirm selected parameter

PuriFi by CytoSorbents



PuriFi Standalone with CytoSorb®

Use of 2x plastic scissor clamps for 6.8 mm lines



Anticoagulation

· Anticoagulation must be effective at the start of treatment.

PuriFi

by CytoSorbents

- In general no special adjustments to anticoagulation protocols are required when using CytoSorb®.
- Specifications of the device manufacturer must be followed.
- Systemic heparinization:
- An aPTT of 60-80 s or an ACT of 160-210 s is usually sufficient for CytoSorb®. The aPTT or ACT should be checked frequently.
- Any decision on dosage and target values is the responsibility of the treating physician.

Materials required

for air within the circuit.

Quick Setup Guide

Notes prior to treatment start

adsorber and do not replace them.

Please read and follow them for the application of the products.

Normal saline NaCl 0.9%, 1x2 **or** 2x1 liter, sterile

• These instructions are a supplement to the operating instructions of the PuriFi System or the CytoSorb®

CytoSorb®, the supply tubing system must be airlessly primed with sterile isotonic saline solution.

Caution: Under no circumstances should air be allowed to enter the CytoSorb® adsorber.

The maximum run time of a CytoSorb® adsorber and tubing set should not exceed 24 hours.

When installing CytoSorb® always follow the flow direction indicated on the label.

The blood flow rate should be 150-450 mL/min, but at least 100 mL/min

• Preparation and use of CytoSorb® must always be carried out under hygienic conditions. Before connecting

· It may be advisable to replace the adsorber even earlier if there are indications of an exhausted elimination capacity.

· Check the extracorporeal circuit at regular intervals for signs of blood clots, secure fit of the connections and

• This document does not replace IFU's of products used. Please ensure reading of all involved product IFU's.



CytoSorb® and integration solution











CytoSorb® adsorber

Disposables and blood volume

- M90444 Adult Tubing 100mL
- + Kalos heating line 15mL
- M90461 Pediatric Tubing 75mL
- + Kalos heating line 15mL

CVtoSorbents Global Distribution

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Medolla (MO), ITALY

MEDICA Legal manufacturer

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Watch the complete set-up video: cyto.zone/setup-purifi-video/eng

The clinical and preclinical data and results obtained with the CytoSorb® adsorber are not transferable to other products. CytoSorb® should only be administered by personnel who have been properly trained in administration of extracorporeal therapies. CytoSorb® is not available for commercial sale in USA.

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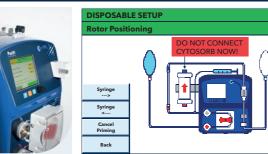


Switch on PuriFi and adjust treatment parameters. Choose setup mode: Connection to vascular access or ECMO. Details on page 4

Begin Setup



Mount the CytoSorb® adsorber.



Setup bloodlines as shown on screen. Start with the access blood line with the pump segment.



 Confirm pump segment and inline transducer placing



Connect heparin syringe to heparin line and place syringe in slider.

2. Confirm heparin syringe is connected and in place

Open clamp on heparin line. Press **Syringe <---** to prime line.

> . Confirm heparin line clamp is open and primed

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Connect **blood return line**, transparent bypass adapter and access blood line.

4. Confirm the connection to the CytoSorb bypass adapter



Mount chamber (bubble catcher) on blood return line.

Push down return chamber.

6. Confirm the return chamber placing clamp line placing



Insert **blood return line** in air sensor and automatic clamp.

6. Confirm air sensor and return



Insert hydrophobic filter to metal connector.

> Confirm return

Secure it with the blue luer cap. Check tightening!

7. Confirm connection of pressure line to return pressure transduce

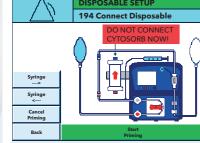


Connect blood return line to waste bag.

8. Confirm connection of the return line to the waste bag

Connect access blood line to saline bag.

9. Confirm connection of access line to saline bag



Start Priming

Don't touch system while

During priming remove adsorber from clamp and tap it to remove air bubbles.



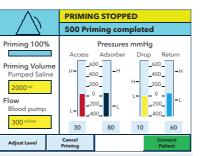
- Red connector on adsorber inlet Blue connector on adsorber outlet

Don't remove both adsorber port plugs caps at the same time. Save adapter caps.

10. Confirm lines connected to CytoSorb



11. Confirm return line connection to saline bag

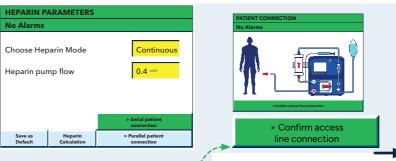


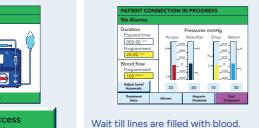
After priming is completed:

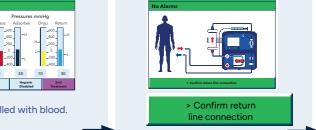
connection press the button below the display:

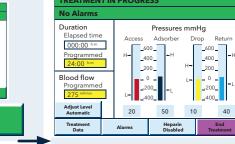


Connect Patient









Adjust treatment parameters and start CytoSorb® Therapy.

To start the blood pump press the button below the display:

Adjust alarms once the system has stabilized while running on the patient.

Plan adsorber exchange at least every 24h.



To initiate priming press:

<Test in Progress> is displayed.



Connect blood return line to saline bag to have both lines on the same bag.

