Additional Sheet to the multiFiltratePRO Instructions for Use regarding the use of the multiECCO2R to remove CO_2 together with the multiFiltratePRO device

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**This Additional Sheet expands on the multiFiltratePRO Instructions for Use with information on the procedure for partial CO_2 removal.
It includes instructions regarding the use of the Eurosets multiECCO2R blood gas exchanger together with the multiFiltratePRO device.**

Irrespective of this supplement, the Instructions for Use and, in particular, the warnings and precautions stipulated therein must be observed for the multiFiltratePRO device, for the multi**ECCO2R** blood gas exchanger, and for the other products used in the therapy.

Consumables and accessories required in addition to those for continuous renal replacement therapy:

Part	Part number	Description
multi**ECCO2R** holder	F00014754	Holder for blood gas exchanger
multi**ECCO2R**	EU5060	Blood gas exchanger
2 x NaCl solution		1000 ml 0.9 % NaCl solution

Note

Consumables for continuous renal replacement therapy are shown on the multiFiltratePRO display.

1 Intended use

1.1 Purpose

The multiFiltratePRO device is intended for partial extracorporeal CO_2 removal combined with continuous renal replacement therapy (CRRT) in clinics and, in particular, in intensive-care units.

1.2 Application specification

Treatment consisting of continuous renal replacement therapy (CRRT) combined with extracorporeal CO_2 removal is intended for adult patients with a body weight of over 40 kg.

1.3 Treatment procedure and application areas

For patients who need continuous renal replacement therapy as well as partial extracorporeal CO_2 removal in order to treat a combination of kidney failure and lung failure.

The following multiFiltratePRO treatment options can be combined with the multi**ECCO2R** blood gas exchanger:

– CVVHD, recommended for combination with multi**ECCO2R**
– CVVH
– CVVHDF

Note

In the case of treatments with citrate anticoagulation, a maximum blood flow of 200 ml/min is possible. This restriction limits the CO_2 removal by the multi**ECCO2R** blood gas exchanger. This must be taken into account when determining indications.

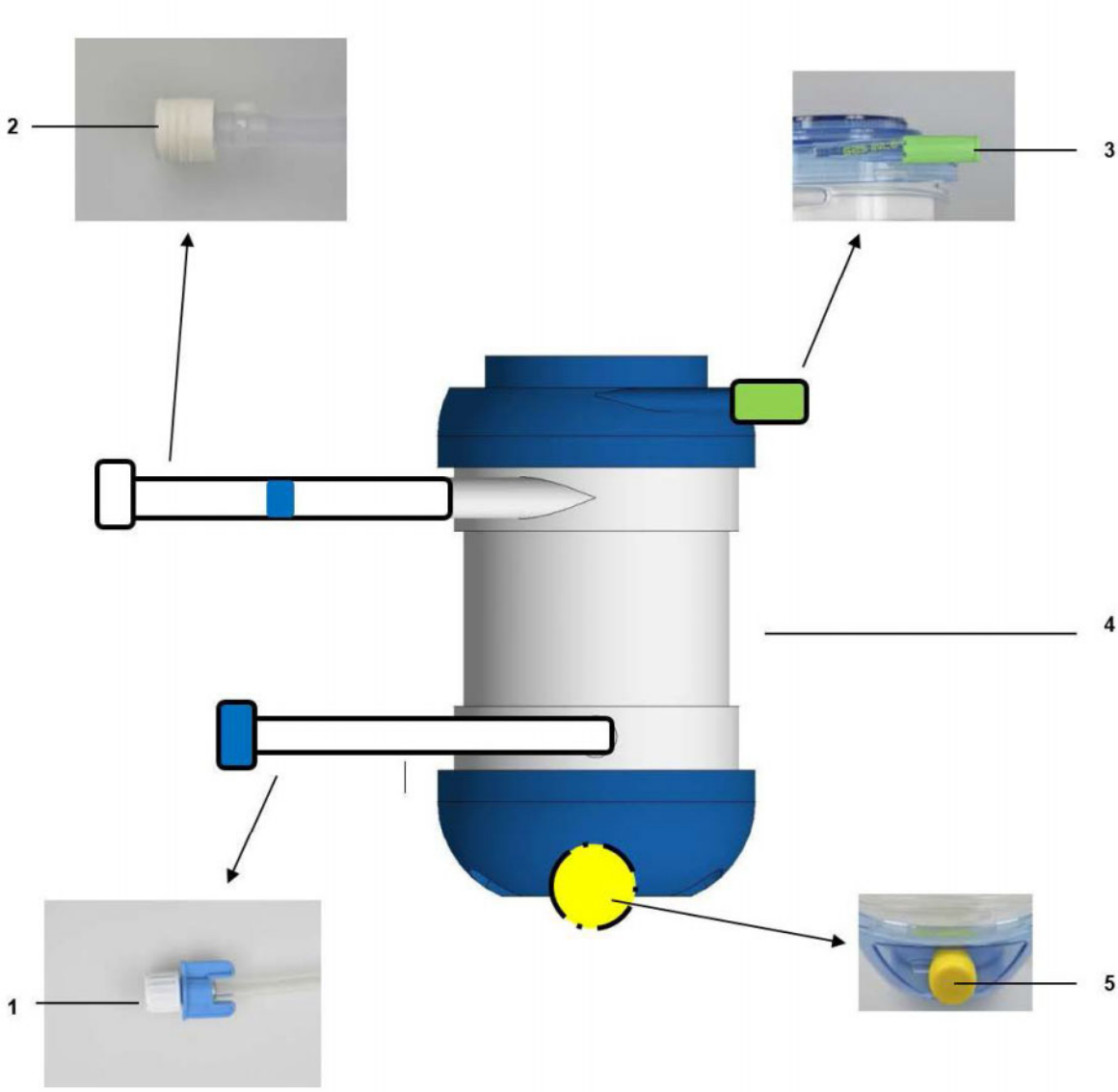
1.4 Contraindications

Indication for extracorporeal oxygenation medically necessary.

2 multiECCO2R

Schematic layout of the blood gas exchanger and the gas line:

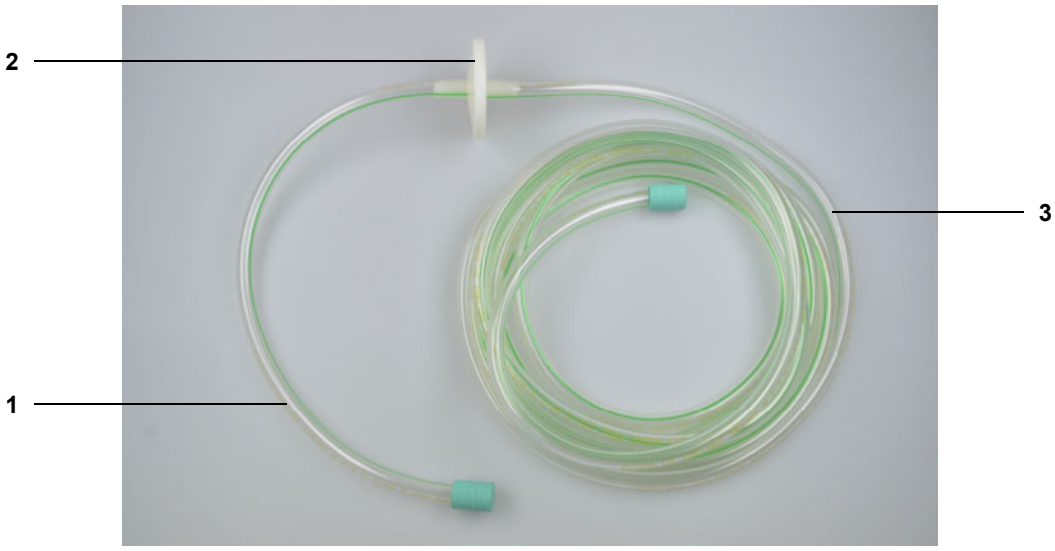
Fig.: Schematic layout of the blood gas exchanger



Legend

1 Blood inlet
2 Blood outlet
3 Gas inlet
4 Blood gas exchanger
5 Gas outlet

Fig.: Schematic layout of the gas line



Legend

1 Short connection end of the gas line
2 Particle filter
3 Long connection end of the gas line

3 Preparation

To ensure safe operation, the instructions listed here must be followed.

3.1 Preparing ready for operation/selecting starting conditions

When preparing ready for operation and selecting the starting conditions, the following settings in particular must be observed:

– Select and confirm the prescribed CRRT treatment mode.
– Complete the starting conditions for the selected treatment and confirm.

Warning

Danger to patients due to excessive heat loss

Adding the multi**ECCO2R** to the extracorporeal blood circuit increases the operational heat loss for the patient.

➢ Carry out treatment at a room temperature of at least 21 °C.

➢ Prevent draughts during treatment.

➢ Set the temperature for the dialysate/substituate to 39 °C.

➢ Regular monitoring of patient temperature.

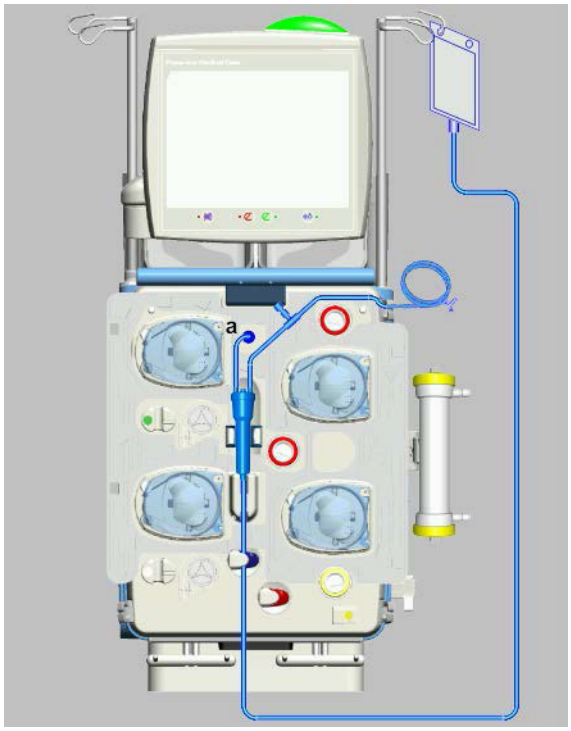
➢ If necessary, introduce heating measures such as electric blankets.

3.2 Setting up the tubing system

3.2.1 Inserting the cassette

Insert cassette according to the on-screen instructions.

3.2.2 Return system



1. Insert bubble catcher in level detector.
2. Insert return line in optical detector / air bubble detector and in occlusion clamp (blue).
3. Hang empty bag on IV pole (right).
4. Connect return pressure line (a).
5. Do **not** connect the filter connector to the filter.

3.2.3 Access system

Insert access system according to the on-screen instructions.

3.2.4 Filtrate system

Insert filtrate system according to the on-screen instructions.

3.2.5 Dialysate / substituate bag

Load solution bags onto scales according to the on-screen instructions.

3.2.6 Dialysate / substituate system

Insert dialysate / substituate system according to the on-screen instructions.

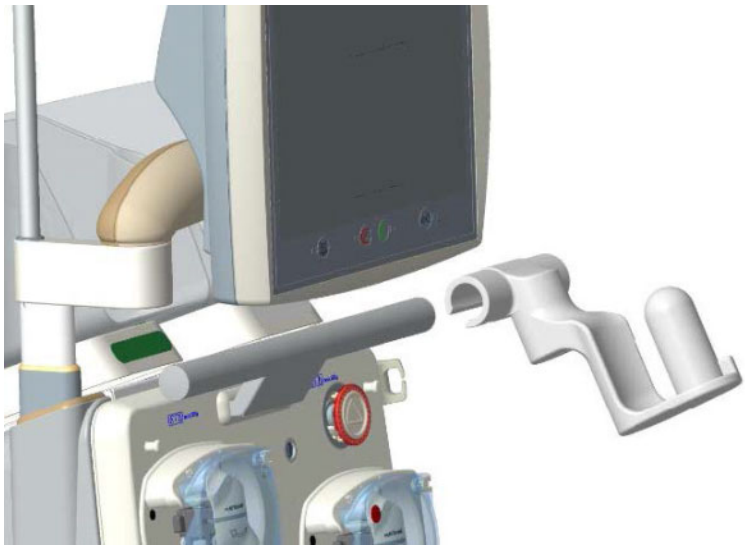
3.2.7 Ci-Ca system

Insert Ci-Ca system according to the on-screen instructions.

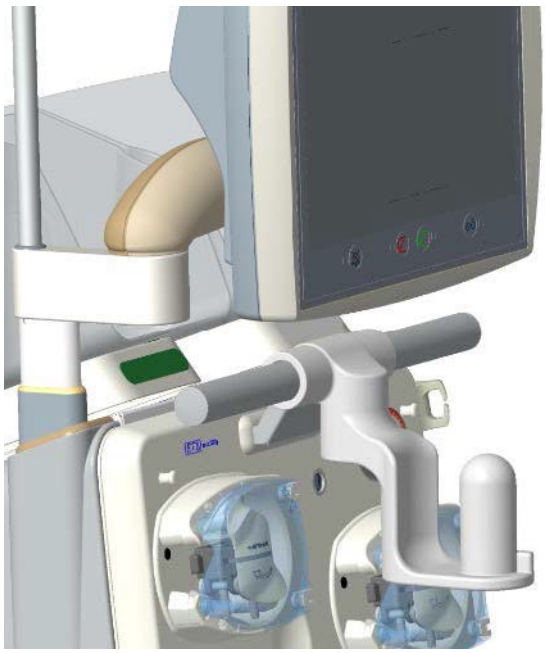
3.2.8 Heparin syringe

Insert heparin syringe according to the on-screen instructions.

3.2.9 Mounting the multiECCO2R holder



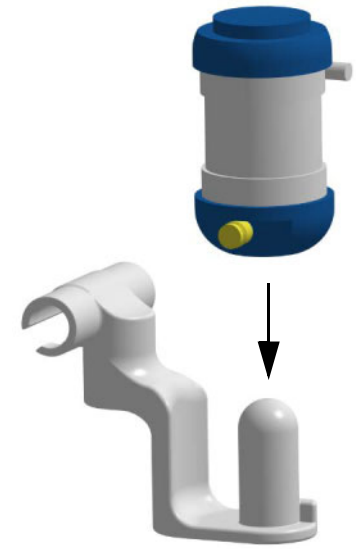
➢ Slide the holder to the centre of the front handle from the right-hand side.



➢ Lock the holder in place.

➢ Check the holder for proper fit.

3.2.10 Mounting the multiECCO2R

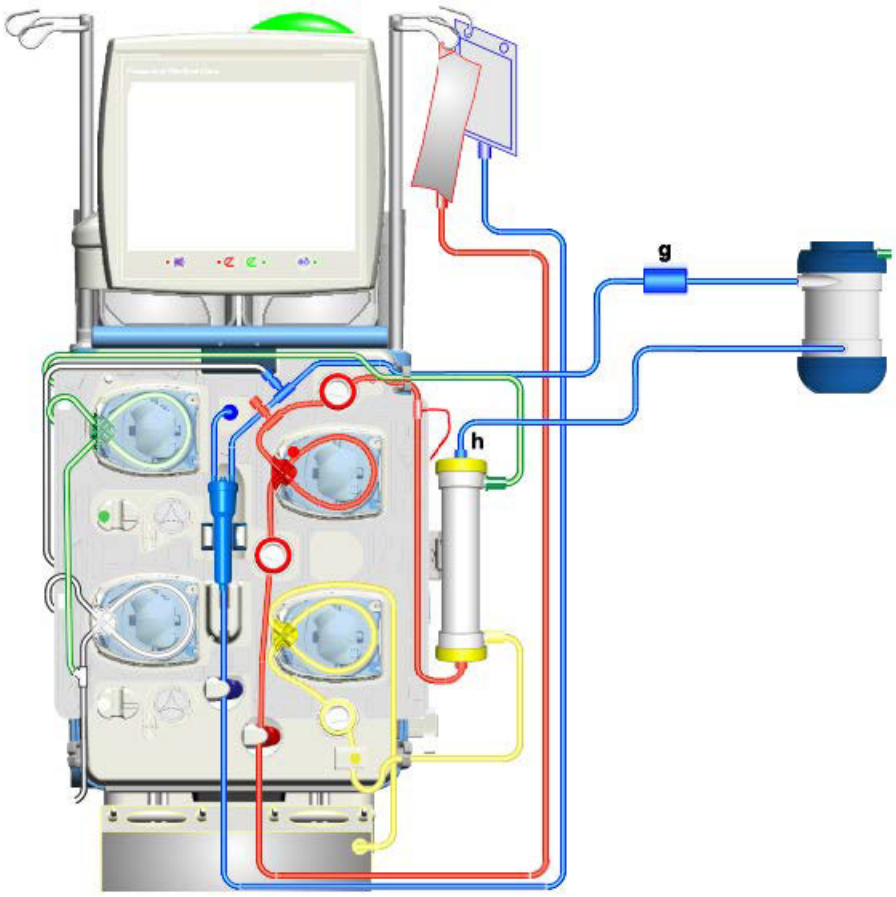


➢ Lower the multi**ECCO2R** onto the mount and lock it in place (it must no longer be possible to turn the multi**ECCO2R**).

➢ Remove the yellow cap from the gas outlet of the multi**ECCO2R**.

3.2.11 Connecting the multiECCO2R

*Fig.: Schematic tubing arrangement for a CVVHDF treatment in combination with multi**ECCO2R***



➢ Connect the venous filter connection (blue) of the cassette system with the blood outlet line (transparent screw cap with white sealing cap) of the blood gas exchanger.

➢ Connect the blood-side inlet of the blood gas exchanger (blue) with the venous outlet of the filter.

3.3 Filling the tubing system

➢ Fill the system according to the instructions on the screen.

Tip

Due to the system conditions, there will be air bubbles in the lower part of the blood gas exchanger after filling. These will be eliminated once treatment starts.

Note

Due to the increased volume of the extracorporeal blood circuit caused by the multi**ECCO2R**, it is no longer possible to detect the dilution method. In the event of the error message 5304, check whether the selected dilution method matches the dilution method actually set up and confirm the message.

3.4 UF rinsing

Use a new, full 1000 ml NaCl bag before switching to UF rinsing. When using an NaCl bag with a connection or an NaCl bottle, use a Y adapter.

➢ Rinse the system according to the instructions on the screen.

3.5 Connecting the gas line

➢ Remove the green cap from the gas inlet of the blood gas exchanger.

➢ Remove the green cap from the short gas line end.

➢ Slide the short end of the gas line onto the gas inlet until it forms a seal (slide on approx. 1 cm).

➢ Connect the long end of the gas line to the connection of the medical compressed air of a suitable flow regulator.

If not done yet, remove the yellow cap from the gas outlet of the multi**ECCO2R**. Do not start the gas flow until the treatment has begun.

Note

Refer to the multi**ECCO2R** Instructions for Use for information on how to properly connect the gas line.

3.6 Connecting the patient

➢ Follow the on-screen instructions to connect the patient.

4 Treatment

The following information must be observed when starting the treatment:

– After starting the treatment, set the blood flow as high as possible (recommendation: at least 100 ml/min, ideally 500 ml/min).

– Set the gas flow in accordance with the multi**ECCO2R** Instructions for Use.

The table below specifies the maximum permissible gas flows for selected blood flows when using the blood gas exchanger. Alternatively, this formula can be used:

Maximum permissible gas flow [l/min] = 0.015 x blood flow [ml/min]

Blood flow [ml/min]	Maximum permissible gas flow [l/min]
100	1.5
200	3.0
300	4.5
400	6.0
500	7.5

Note

Check the maximum permissible gas flow in the event of changes to the blood flow. Adjust the gas flow as needed.

4.1 Blood gas analysis

Perform blood gas analyses in accordance with the multi**ECCO2R** Instructions for Use.

The sampling points for this purpose are located on the blood-side inlet of the blood gas exchanger (transparent sampling point on the blood gas exchanger) and on the blood-side outlet of the blood gas exchanger (blue sampling point on the CRRT cassette).

4.2 Anticoagulation

A sufficient dose of systemic anticoagulation must be ensured.

Refer to the multi**ECCO2R** Instructions for Use for information on anticoagulation.

4.3 Ending the treatment

➢ Turn off the gas flow before ending the treatment!

➢ End the treatment according to the on-screen instructions with or without blood return.