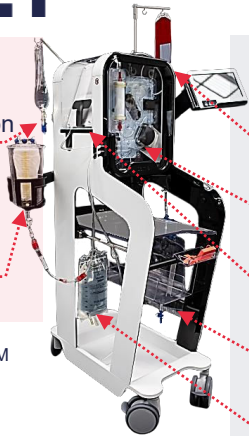


STAGE 1

Anticoagulant solution

Blood collection reservoir



STAGE 2

Reinfusion bag

Treatment set

Treatment bag

Waste bag

Washing bag

NECESSARY CONSUMABLES

Provided by i-SEP:

- 1 treatment set
- 1 blood collection reservoir
- 1 suction line
- 1 antibacterial filter
- 1 vacuum line

Not provided by i-SEP:

- 1 anticoagulant solution
- 1 washing bag

ADDITIONAL CONSUMABLES Provided by i-SEP

- Reinfusion bag: 1 per additional cycle
- Additional micro-aggregates chamber - Waste bag

ADDITIONAL CONSUMABLES Not provided by i-SEP

- Anticoagulant solution
- Washing bag

Stage 1: Starting the blood collection

1



Switch on the machine by pressing the Button .

2



Remove the blood collection holder from the back of the machine.

The holder is a weighing device to be handled with care.

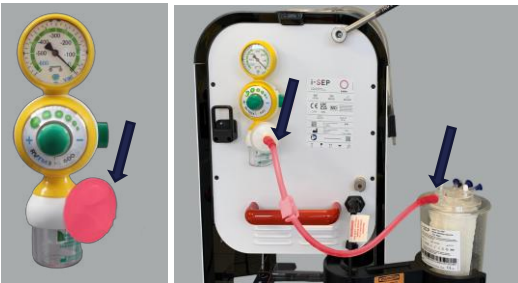
3



Install the blood collection reservoir in its holder.

Close the clamp on this connection.

4



Clip the antibacterial filter onto the vacuum regulator.

Connect the vacuum line to the filter and the other end to the blood collection reservoir (yellow cap).

5



Start the vacuum pump by pressing the button below the display.

Close the vacuum line clamp.

Set the vacuum to -150 mbar using the manometer and then unclamp.

Switch off the vacuum pump by pressing the button .

6



Remove the anticoagulant solution holder.

Place the bag on the holder.

Connect the bag and collection reservoir to the suction line.

Prime the drip chamber.

Restart the vacuum pump by pressing the button .

7



Prime the blood collection reservoir with 200mL of anticoagulant solution.

Blood aspiration can begin.

STAGE 2 →

Stage 2: Installing the set



CAUTION:
Do not install the set until you are invited to do so!

Follow the step-by-step process indicated on the screen.

Click on the icon ? if necessary.

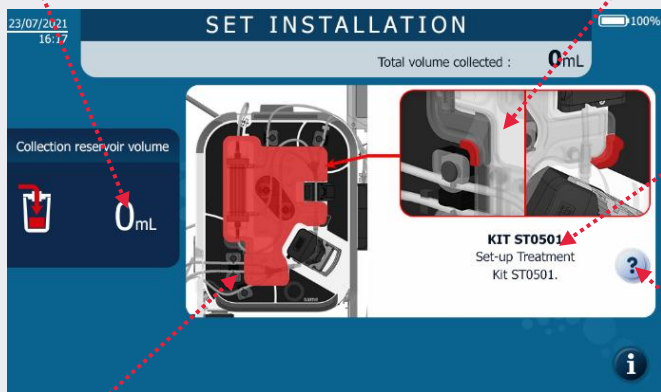
CAUTION:
- Place the double template at the bottom of the supports.
- Place the tubes in the claws.

Treatment Screens presentation

Volume of blood collected

The screen of the installation

Zoom on the concerned zone



Instructions

Help:
Additional instructions

Area of interest

Access to history, installation, help, parameters, maintenance

Presentation of the treatment screen

General information (set installation time, number of cycles and total volume collected)

Current step and progress bar

Volume of blood in the reservoir

Special Programs

To collect 300mL of diluted blood instead of 500 mL

To reduce washing and increased speed

To increase hematocrit level

Message (alarm, warning, error)



Button play / pause

Pause audible alarm
Cumulative volume of blood treated

To force the transfer of blood to the reinfusion bag

To access to history, installation, help, parameters, maintenance

End of procedure

To empty the blood collection reservoir and the reinfusion line

To stop processing to change the waste bag

Uninstallation

1. Press the button to initiate the end of procedure.
2. Follow the instructions on the screen to uninstall the treatment set.

Access to the IFUs



<https://www.i-sep.com/en/e-labeling/>

Treatment Information

Automatic start:

- Cycle 1 → Volume BCR = 830 mL
Cycle ≥ 2 → Volume BCR = 670 mL

At the end of surgery, use:

To process a **smaller volume**, use:

- Cycle 1 → Volume BCR = 630 mL
Cycle ≥ 2 → Volume BCR = 470 mL

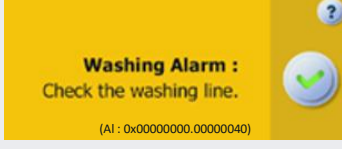
⚠ Don't forget to deactivate the function.

Hotline

Most frequent alarms

⚠ This guide only indicates the most frequent steps to follow when certain alarms appear. If the problem persists, follow the instructions on the or contact our hotline on +33228290262.

WASHING ALARM DURING AUTOTEST



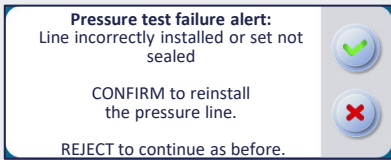
Difficulty to connect the washing solution bag
(i.e. Clearflex®, Baxter)



Install 2 washing solution bags AND check their well connection to the punchers.

⚠ At installation, the available volume of washing solution must be ≥ 2 liters.

PRESSURE TEST ALERT



Line detected incorrectly



Press then reinstall the line OR Press to continue despite the incorrect detection.

MICRO-AGGREGATES CHAMBER ALARM



Change the micro-aggregates chamber to preserve the fiber.

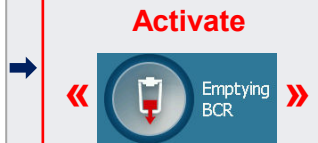
⚠ Ensure that the procedure in the instructions is followed and that **personal protective equipment** is used.

⚠ During **complex surgeries**, it is recommended to change the micro-aggregates chamber as a **preventive measure**.

BLOOD COLLECTION RESERVOIR ALARM

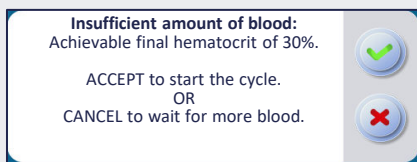


If no clamp is closed but blood is very diluted in the blood collection reservoir



⚠ Use « Emptying BCR » 3 times maximum. This function does not terminate the surgery.

LOW HAEMATOCRIT INFORMATION



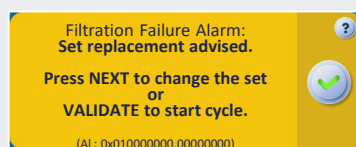
Diluted blood in the blood collection reservoir



If blood is expected to ARRIVE, press: OR If **SURGERY IS COMPLETE / BLOOD is needed URGENTLY, press:**

⚠ Cycle launch: the treated blood will have a haematocrit lower than 45 %. Additional volume transfer starts when there is at least 330 mL in the BCR.

CLOGGED FIBER ALARM



If waste manual clamps OPENED but long treatment time



Activate to Accelerate treatment OR Change set if remaining blood to be treated.

⚠ Cycle duration > 14min.

ANTICOAGULANT INFORMATION

Do not hesitate to INCREASE THE FLOW RATE of the anticoagulant, whenever a large amount of blood arrives or after protamine!



To avoid slowing down the treatment