

Instructions for Use CombiSet True Flow Series, 2008K@home blood lines

Setting up the Arterial Lines

- Insert dialyzer into holder
- Open CombiSet True Flow Series, remove arterial line and place packaged venous line on top of the machine. A bracket above the drain bag posts is provided to help you organize the bloodlines during setup.
- Hang Drain Bag on posts on left side of the machine, lines should hang below the bag.
- Snap arterial chamber into holder.
- Remove **Tap 1** to uncoil the bloodlines from the blood pump segment. Place the bloodlines on the bracket.
- Open blood pump door, verify the blood pump is set for an 8mm diameter pump segment.
- Press and hold blood pump 'Start/Stop' key to align rotor. Use thumb pressure to push the left retractor clamp panel back.
- Feed the beginning of pump segment into the blood pump rotor track. Release clamp panel to hold tubing.
- Press and hold 'Start/Stop' key, release after blood pump segment has been pulled along the track all the way.
- Using thumb pressure press clamp panel on right and insert blood pump segment and close door.
- Remove **Tap 2** and connect arterial line to bottom of dialyzer. Insert line into tubing guides. Press Done.
- Connect patient end of arterial line to the Drain Bag.
- Connect transducer protector to arterial pressure port.
- Tighten both sides of the red and blue recirculation connector.
- Close saline clamp (S) and hang saline bag.
- Remove **Tap 3** and connect saline bag. (clamp below saline spike to remain open) Press Done.

Setting up the Venous Lines

- Roll venous chamber into holder.
- Insert line into venous clamp and optical detector. The mark on the chamber must line up with the top of the holder.
- Close and latch the level detector door.
- Rotate the Optical Detector door clockwise and flip the Venous Clamp open.
- Make certain that you place the bloodline completely into the Venous Clamp.
- Rotate the Optical Detector door back over the bloodline.
- Connect patient end of the venous line to the drain bag.
- Remove **Tap 4** and connect venous line to top of dialyzer.
- Insert line into tubing guides, connect transducer protector to venous pressure port and close both medication clamps (M). Press Done.
- If the Heparin pump is used: Insert the Heparin syringe, prime the line and close heparin clamp (H) if the Heparin pump is not used, do not close the heparin line clamp yet.
- Open saline clamp (S).
- Gravity prime arterial line to drain bag. Close arterial patient clamp (A).
- Turn on the blood pump.
- Set the arterial chamber level.

- Press Prime and press CONFIRM twice. Intermittently pinch the blood line between the blood pump and the dialyzer. Gently tap the dialyzer. If Heparin pump is not used, close the (H) clamp after the heparin line is primed. When the priming bar graph shows 100% and the Done button changes from gray to blue.
 - Press Done.
- Testing the Dialysate
- Colled a sample of dialysate.
 - Test the dialysate conductivity with an independent device and press the dialysate conductivity button to highlight it and enter the value.
 - Test the dialysate pH press the dialysate pH button and enter the value, press CONFIRM.
 - Press Done

Priming the Dialysate Side

- Rotate dialyzer so the venous line is on the bottom.
- Connect blue dialysate line to blue side of the dialyzer.
- Connect red dialysate line to red side of the dialyzer.
- Close clamp (D) at drain bag.
- Open arterial patient clamp (A).
- Press Recirc Saline and CONFIRM. When your machine passes the bloodline test, a blue x will appear in the ? in the "OK" column. When recirculation is complete press Done.
- Set UF goal and press Done.

Flushing the lines

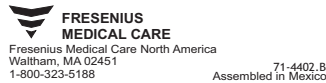
- Press TX Connect button. Stop blood pump and change to a fresh saline bag. Open clamp (D) and gravity flush arterial line to drain bag. Close arterial clamp (A). Start the blood pump and run 300 ml into drain bag (watch saline bag level drop by 300 ml) Stop blood pump and close clamps (S, D) and (V). Touch Is Line Flushed button and CONFIRM lines were flushed. Press Done.

Connecting the Bloodlines

- Remove **Tap 5** to uncoil patient arterial line.
- Disconnect arterial line from Drain Bag and connect to arterial access.
- Remove **Tap 6** to uncoil patient venous line.
- Disconnect venous line from Drain Bag and connect to venous access.
- Open clamps (A), (V), (a) and (v).
- If prescribed heparin, open heparin clamp (H).

Starting the Blood Pump

- Set blood pump speed, turn blood pump on and monitor arterial and venous pressures and drip chamber levels.
- Press TX Paused button to change to TX running and CONFIRM.
- Press Done to continue to monitor pressures.



HEMODIALYSIS BLOOD TUBING SET WITH PRIMING SET AND TRANSDUCER PROTECTORS

INSTRUCTIONS FOR USE

CAUTION:

Federal (USA) law restricts this device to sale by or on the order of a physician.

WARNINGS:

- Do not reuse or alter this set.
- Do not use if protective caps are not in place.
- Non-pyrogenic fluid pathway. Sterile if package is not damaged and protective sterility caps are in place.
- Always use aseptic technique when making or breaking any fluid path connection.
- Product sterilized by ethylene oxide gas (ETO).
- Be careful not to kink the bloodline tubing during set-up and patient use. Do not use severely kinked tubing as hemolysis may result.
- Ensure all connections are secure before use, and monitor for leaks regularly during patient use. Blood leaks can result if connections are not secure.
- Ensure visibility of bloodline connection to fistula needle or catheter at all times during the treatment. Do not cover the access or bloodlines with a blanket or clothing prior to or during the treatment.
- Bloodline clamps are used to completely occlude the tubing and should be disengaged when not in use. These clamps are not intended as flow regulating devices for the extracorporeal circuit.
- Hemolysis may occur at elevated negative or positive pressures. Excessive negative pressure may cause partial collapse of the pump segment resulting in an actual blood flow substantially less than indicated on the hemodialysis machine. Continuous monitoring of pre-pump arterial pressure is recommended. Check bloodline and patient access when excessive pressures are noted. Deficiencies in access flow, and/or improper position of the fistula needle, bloodline, or catheter may cause reduced blood flow that can result in increased negative pressures.
- The use of a properly calibrated venous air bubble/foam detector is required. Continuously monitor the venous return line or chamber with an air detector. Air entering the extracorporeal circuit during dialysis may result in serious patient injury or death.
- Clotting may result from inadequate anticoagulation, excessive ultrafiltration, and/or stagnant blood flows.
- Protect from moisture, freezing, and excessive heat.

INDICATIONS FOR USE:

The blood tubing is indicated for use with a prescribed hemodialyzer. The suitability of a particular configuration is the responsibility of the physician.

FEATURES:

Standard blood path tubing is 4.57 mm I.D. and 6.73 mm O.D. Standard blood pump segment is 8.0 mm I.D. and 12.0 mm O.D. as indicated on the label.

This product does not contain latex.

INSTRUCTIONS FOR USE:

For 2008K@home users, refer to step-by-step instructions on the last page of this Instructions For Use document.

Refer to instructions provided by the dialyzer and hemodialysis machine manufacturers for bloodline setup, detailed priming, anticoagulation, dialysis, and rinsing procedures. The following precautions are emphasized to ensure patient safety.

Blood Pump Adjustments - Ensure the blood pump is calibrated for the appropriate pump segment diameter according to machine manufacturer's instructions. If the pump is not recalibrated for the pump segment used, significant under-dialysis or over-dialysis may result.

Setup Precautions

- Follow the machine manufacturer's instructions for installation of the pump segment. The inlet pump segment adaptor must be flush with the inlet-side pump housing.
- Ensure that the pump segment is not kinked, stretched, or twisted. Failure to properly install the pump segment may kink the tubing, which may result in hemolysis, undetected by machine pressure monitors, or can rupture the tubing resulting in blood loss.
- Ensure the machine's venous occlusion clamp is functioning properly and will effectively occlude the tubing.
- Ensure the connection of the transducer protector to the bloodline monitor line is tight before connecting to the machine pressure port. Twist the female luer clockwise while twisting the transducer protector in the opposite direction.



- Attach the arterial and venous transducer protectors to the machine pressure ports by inserting the transducer protector into the port and twisting the female luer clockwise to tighten. Ensure both the transducer protector and female luer connections are tight to maintain a closed system.



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Setting up the Arterial Lines

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- Open CombiSet True Flow Series, remove arterial line and place packaged venous line on top of the machine. A bracket above the drain bag posts is provided to help you organize the bloodlines during setup.
- Hang Drain Bag on posts on left side of the machine, lines should hang below the bag.
- Snap arterial chamber into holder.
- Remove **Tap 1** to uncoil the bloodlines from the blood pump segment. Place the bloodlines on the bracket.
- Open blood pump door, verify the blood pump is set for an 8mm diameter pump segment.
- Press and hold blood pump 'Start/Stop' key to align rotor. Use thumb pressure to push the left retractor clamp panel back.
- Feed the beginning of pump segment into the blood pump rotor track. Release clamp panel to hold tubing.
- Press and hold 'Start/Stop' key, release after blood pump segment has been pulled along the track all the way.
- Using thumb pressure press clamp panel on right and insert blood pump segment and close door.
- Remove **Tap 2** and connect arterial line to bottom of dialyzer. Insert line into tubing guides. Press Done.
- Connect patient end of arterial line to the Drain Bag.
- Connect transducer protector to arterial pressure port.
- Tighten both sides of the red and blue recirculation connector.
- Close saline clamp (S) and hang saline bag.
- Remove **Tap 3** and connect saline bag. (clamp below saline spike to remain open) Press Done.

Setting up the Venous Lines

- Roll venous chamber into holder.
- Insert line into venous clamp and optical detector. The mark on the chamber must line up with the top of the holder.
- Close and latch the level detector door.
- Rotate the Optical Detector door clockwise and flip the Venous Clamp open.
- Make certain that you place the bloodline completely into the Venous Clamp.
- Rotate the Optical Detector door back over the bloodline.
- Connect patient end of the venous line to the drain bag.
- Remove **Tap 4** and connect venous line to top of dialyzer.
- Insert line into tubing guides, connect transducer protector to venous pressure port and close both medication clamps (M). Press Done.
- If the Heparin pump is used: Insert the Heparin syringe, prime the line and close heparin clamp (H) if the Heparin pump is not used, do not close the heparin line clamp yet.
- Open saline clamp (S).
- Gravity prime arterial line to drain bag. Close arterial patient clamp (A).
- Turn on the blood pump.
- Set the arterial chamber level.

- Press Prime and press CONFIRM twice. Intermittently pinch the blood line between the blood pump and the dialyzer. Gently tap the dialyzer. If Heparin pump is not used, close the (H) clamp after the heparin line is primed. When the priming bar graph shows 100% and the Done button changes from gray to blue.
 - Press Done.
- Testing the Dialysate
- Colled a sample of dialysate.
 - Test the dialysate conductivity with an independent device and press the dialysate conductivity button to highlight it and enter the value.
 - Test the dialysate pH press the dialysate pH button and enter the value, press CONFIRM.
 - Press Done

Priming the Dialysate Side

- Rotate dialyzer so the venous line is on the bottom.
- Connect blue dialysate line to blue side of the dialyzer.
- Connect red dialysate line to red side of the dialyzer.
- Close clamp (D) at drain bag.
- Open arterial patient clamp (A).
- Press Recirc Saline and CONFIRM. When your machine passes the bloodline test, a blue x will appear in the ? in the "OK" column. When recirculation is complete press Done.
- Set UF goal and press Done.

Flushing the lines

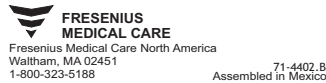
- Press TX Connect button. Stop blood pump and change to a fresh saline bag. Open clamp (D) and gravity flush arterial line to drain bag. Close arterial clamp (A). Start the blood pump and run 300 ml into drain bag (watch saline bag level drop by 300 ml) Stop blood pump and close clamps (S, D) and (V). Touch Is Line Flushed button and CONFIRM lines were flushed. Press Done.

Connecting the Bloodlines

- Remove **Tap 5** to uncoil patient arterial line.
- Disconnect arterial line from Drain Bag and connect to arterial access.
- Remove **Tap 6** to uncoil patient venous line.
- Disconnect venous line from Drain Bag and connect to venous access.
- Open clamps (A), (V), (a) and (v).
- If prescribed heparin, open heparin clamp (H).

Starting the Blood Pump

- Set blood pump speed, turn blood pump on and monitor arterial and venous pressures and drip chamber levels.
- Press TX Paused button to change to TX running and CONFIRM.
- Press Done to continue to monitor pressures.



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- Always use aseptic technique when making or breaking any fluid path connection.
- Product sterilized by ethylene oxide gas (ETO).
- Be careful not to kink the bloodline tubing during set-up and patient use. Do not use severely kinked tubing as hemolysis may result.
- Ensure all connections are secure before use, and monitor for leaks regularly during patient use. Blood leaks can result if connections are not secure.
- Ensure visibility of bloodline connection to fistula needle or catheter at all times during the treatment. Do not cover the access or bloodlines with a blanket or clothing prior to or during the treatment.
- Bloodline clamps are used to completely occlude the tubing and should be disengaged when not in use. These clamps are not intended as flow regulating devices for the extracorporeal circuit.
- Hemolysis may occur at elevated negative or positive pressures. Excessive negative pressure may cause partial collapse of the pump segment resulting in an actual blood flow substantially less than indicated on the hemodialysis machine. Continuous monitoring of pre-pump arterial pressure is recommended. Check bloodline and patient access when excessive pressures are noted. Deficiencies in access flow, and/or improper position of the fistula needle, bloodline, or catheter may cause reduced blood flow that can result in increased negative pressures.
- The use of a properly calibrated venous air bubble/foam detector is required. Continuously monitor the venous return line or chamber with an air detector. Air entering the extracorporeal circuit during dialysis may result in serious patient injury or death.
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Blood Pump Adjustments - Ensure the blood pump is calibrated for the appropriate pump segment diameter according to machine manufacturer's instructions. If the pump is not recalibrated for the pump segment used, significant under-dialysis or over-dialysis may result.

Setup Precautions

- Follow the machine manufacturer's instructions for installation of the pump segment. The inlet pump segment adaptor must be flush with the inlet-side pump housing.
- Ensure that the pump segment is not kinked, stretched, or twisted. Failure to properly install the pump segment may kink the tubing, which may result in hemolysis, undetected by machine pressure monitors, or can rupture the tubing resulting in blood loss.
- Ensure the machine's venous occlusion clamp is functioning properly and will effectively occlude the tubing.
- Ensure the connection of the transducer protector to the bloodline monitor line is tight before connecting to the machine pressure port. Twist the female luer clockwise while twisting the transducer protector in the opposite direction.



- Attach the arterial and venous transducer protectors to the machine pressure ports by inserting the transducer protector into the port and twisting the female luer clockwise to tighten. Ensure both the transducer protector and female luer connections are tight to maintain a closed system.

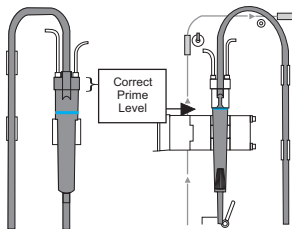


- Use a luer lock syringe on all heparin infusion and level adjustment lines.

- To spike saline bag, remove the spike protector without touching the spike, and insert the spike through the port on the saline bag.

Priming Precautions

- The vented arterial patient end protector cap may remain closed for gravity priming.
- During pump priming, ensure the clamp to the drain bag is open to reduce resistance to the exiting saline, which may result in excessive pressure in the extracorporeal circuit.
- Prime the dialyzer according to manufacturer's instructions.
- If instructions require clamping bloodlines, unclamp pressure-monitoring lines before occluding tubing to prevent excessive dialyzer pressures. Do not allow fluid to enter the monitoring line while clamping the bloodlines.
- Prime pre-pump arterial chamber 85 to 95% full, post pump arterial and venous chambers 65 to 75% full.



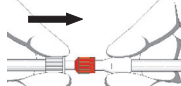
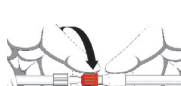
- If there will be a significant waiting period prior to the start of dialysis, the following steps should be taken:
 - Ensure that the extracorporeal circuit contains fresh saline immediately prior to initiation of treatment.

Dialysis Treatment Precautions

- Before Initiation verify:

- The air detector is engaged.
- The venous drip chamber is positioned and secured correctly in holder according to the hemodialysis machine manufacturer recommendations.
- The absence of any air bubbles in the extracorporeal circuit.
- Monitor lines are bloodline clamps are open.
- All connections are secure. For proper connection between fistula needle/catheter and bloodline:

NOTE: To maintain sterility of the blood path, do not allow the open ends of the bloodlines to come into contact with non-sterile solutions or surfaces which may contaminate the blood path.

- Firmly insert the male luer of the bloodline into the female luer of the fistula needle.
- 
- Then twist the colored-collar of the bloodline clockwise while twisting the female luer of the fistula needle in the opposite direction.
- 

NOTE: It is recommended to use a large gauge fistula needle for prescribed blood flow rates >350 Ml/min.

- During Treatment
 - Periodically check the extracorporeal circuit for any evidence of possible Separation or leaks.
 - Maintain fluid level in pre-pump arterial chamber at 85 to 95% full, post-pump arterial and venous chambers at 65 to 75% full. Levels may rise or drop during the treatment due to changes in pressure or flow rate. Readjust levels as needed. Air Leaks will also cause the chamber levels to fluctuate.
 - Periodically monitor rate of heparin delivery to ensure proper dosage.
- During Termination of the Treatment:
 - Maintain a proper fluid level in chambers to ensure that no air is returned to the patient.
 - To complete termination procedure, refer to machine, dialyzer and manufacturer instructions, physician prescription, and/or facility protocol.

NOTE: Air rinseback at termination of dialysis is not recommended.

- Properly dispose of the extracorporeal circuit after termination of dialysis.

NOTE: Discard the extracorporeal circuit in an appropriate biohazard waste receptacle. References: 29CFR 1910.145, 1910.1030 (Code of Federal Regulations) and appropriate state or local codes.

SPLIT SEPTUM INJECTION SITE

Split Septum Injection Sites - are used for intermittent sampling of blood or administering medication.

INSTRUCTIONS FOR USE:

- Use a 21 gauge or smaller conventional metal needle or an approved plastic anti-stick needle for intermittent sampling of blood or administering medication. See Figure A.

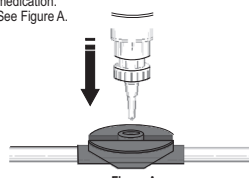


Figure A

- Disinfect injection site immediately prior to use with 70% isopropyl alcohol or 10% Povidone-iodine solution.

- Insert appropriate needle or plastic needle into the center of the injection site at a 90-degree angle as shown in Figure B.

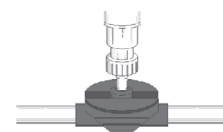


Figure B

VIRAL-RETENTIVE TRANSDUCER PROTECTOR (TP)

The set contains one or more pre-attached TP's on the pressure monitoring lines. It contains a 0.2-micron hydrophobic filter, which helps prevent the passage of bacteria, viruses, and particulate matter, as well as preventing the passage of fluid to the machine at pressures of 600 mmHg or less. In vitro testing was performed by an independent testing laboratory using a ϕ X174 bacteriophage with the size of 25nm to 27nm and a spherical morphology similar to HBV/HCV, and HIV.

INSTRUCTIONS FOR USE:

CAUTION: Ensure that the TP is tightly connected to the pressure monitoring line as well as the machine, or the following may result:

Pre-pump arterial - fluid level will drop.
Post-pump arterial and venous - fluid level will rise.

Do not over-tighten the TP to the machine as this may cause the female luer to crack, resulting in a leak.

In the event that fluid should completely fill the bloodline side of the TP, the transmission of pressure will be blocked. If this occurs, clamp the pressure monitoring line and remove the TP from the machine. Use a syringe to clear any fluid from the monitoring line and reset the proper blood level in the blood chamber. Then securely attach replacement TP, reattach to the machine, and unclamp monitoring line.

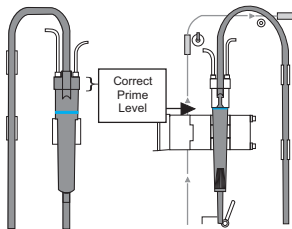
If fluid is visible on the side of the TP that faces the machine, have qualified personnel open the machine and check for contamination after the treatment is completed. If contamination has occurred, the machine must be taken out of service and disinfected before further use according to manufacturer recommendations.

- Use a luer lock syringe on all heparin infusion and level adjustment lines.

- To spike saline bag, remove the spike protector without touching the spike, and insert the spike through the port on the saline bag.

Priming Precautions

- The vented arterial patient end protector cap may remain closed for gravity priming.
- During pump priming, ensure the clamp to the drain bag is open to reduce resistance to the exiting saline, which may result in excessive pressure in the extracorporeal circuit.
- Prime the dialyzer according to manufacturer's instructions.
- If instructions require clamping bloodlines, unclamp pressure-monitoring lines before occluding tubing to prevent excessive dialyzer pressures. Do not allow fluid to enter the monitoring line while clamping the bloodlines.
- Prime pre-pump arterial chamber 85 to 95% full, post pump arterial and venous chambers 65 to 75% full.



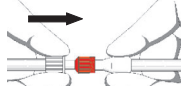
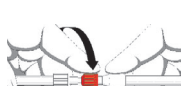
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- The air detector is engaged.
- The venous drip chamber is positioned and secured correctly in holder according to the hemodialysis machine manufacturer recommendations.
- The absence of any air bubbles in the extracorporeal circuit.
- Monitor lines are bloodline clamps are open.
- All connections are secure. For proper connection between fistula needle/catheter and bloodline:

NOTE: To maintain sterility of the blood path, do not allow the open ends of the bloodlines to come into contact with non-sterile solutions or surfaces which may contaminate the blood path.

- Firmly insert the male luer of the bloodline into the female luer of the fistula needle.
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- Then twist the colored-collar of the bloodline clockwise while twisting the female luer of the fistula needle in the opposite direction.
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NOTE: It is recommended to use a large gauge fistula needle for prescribed blood flow rates >350 Ml/min.

- During Treatment
 - Periodically check the extracorporeal circuit for any evidence of possible Separation or leaks.
 - Maintain fluid level in pre-pump arterial chamber at 85 to 95% full, post-pump arterial and venous chambers at 65 to 75% full. Levels may rise or drop during the treatment due to changes in pressure or flow rate. Readjust levels as needed. Air Leaks will also cause the chamber levels to fluctuate.
 - Periodically monitor rate of heparin delivery to ensure proper dosage.
- During Termination of the Treatment:
 - Maintain a proper fluid level in chambers to ensure that no air is returned to the patient.
 - To complete termination procedure, refer to machine, dialyzer and manufacturer instructions, physician prescription, and/or facility protocol.

NOTE: Air rinseback at termination of dialysis is not recommended.

- Properly dispose of the extracorporeal circuit after termination of dialysis.

NOTE: Discard the extracorporeal circuit in an appropriate biohazard waste receptacle. References: 29CFR 1910.145, 1910.1030 (Code of Federal Regulations) and appropriate state or local codes.

SPLIT SEPTUM INJECTION SITE

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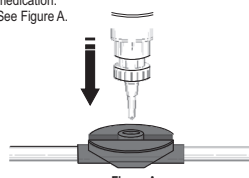


Figure A

- Disinfect injection site immediately prior to use with 70% isopropyl alcohol or 10% Povidone-iodine solution.

- Insert appropriate needle or plastic needle into the center of the injection site at a 90-degree angle as shown in Figure B.

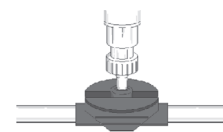


Figure B

VIRAL-RETENTIVE TRANSDUCER PROTECTOR (TP)

The set contains one or more pre-attached TP's on the pressure monitoring lines. It contains a 0.2-micron hydrophobic filter, which helps prevent the passage of bacteria, viruses, and particulate matter, as well as preventing the passage of fluid to the machine at pressures of 600 mmHg or less. In vitro testing was performed by an independent testing laboratory using a ϕ X174 bacteriophage with the size of 25nm to 27nm and a spherical morphology similar to HBV/HCV, and HIV.

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