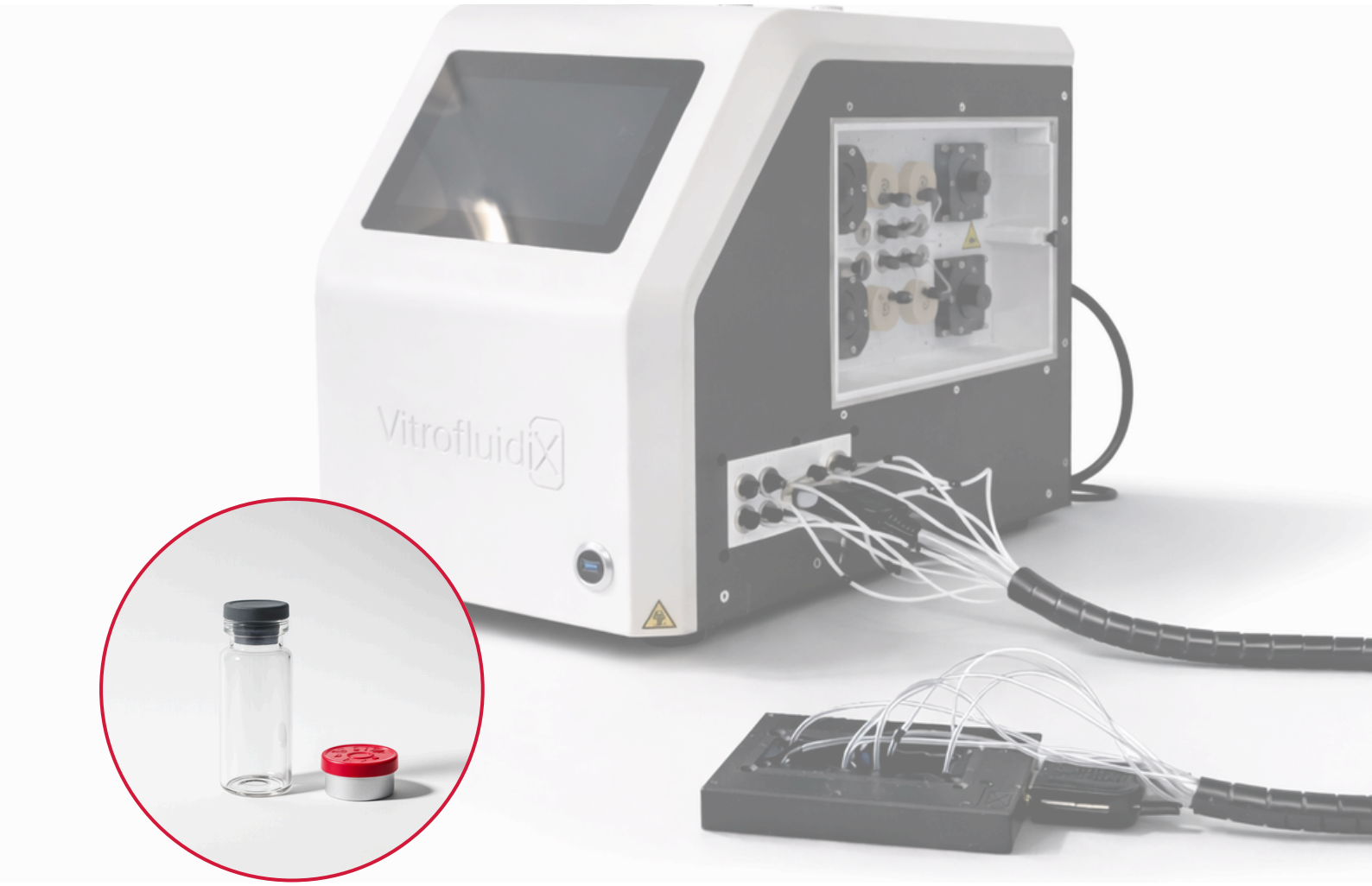
Vitrofluidix

USER MANUAL

Vial Preparation, Sterilization and Handling

For VitroFlow.Bio V2.3.



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1 General Information

The vials used in the VitroFlow.Bio system serve as sterile reservoirs for media and reagents and are an essential component for safe and reliable operation. Proper preparation, sterilization, and handling of the vials are therefore critical to prevent contamination, leakage, or damage to the device.

All steps described in this section must be carried out by trained personnel under appropriate laboratory conditions and in accordance with local safety and hygiene regulations.

2 Safety Instructions for Media Units

Warning - Risk of Injury from Needles

- The media units located in the lid of the device contain integrated needles which penetrate the rubber stoppers of the inserted vials. These needles pose a risk of injury.
- The needles inside the media units are not freely accessible during normal operation. However, they may be reached with fingers if the media units are handled improperly.
- The media units must therefore only be used exactly as described in this user manual.
- Under no circumstances should hands or fingers be placed inside the media units.
- Improper handling may result in puncture injuries.

3 Preparation of Vials

Before use, all vials, rubber stoppers, and aluminum caps must be carefully inspected.

Ensure that:

- no visible damage (e.g. cracks, deformation) is present
- all components are clean and free of particles or residues

Damaged or contaminated components must not be used, as they may compromise sterility and lead to leakage or system failure.

4 Sterilization of Vials

To ensure sterile operation, all vial components must be sterilized prior to use.

Common laboratory sterilization methods such as:

- steam sterilization
- dry heat sterilization
- UV sterilization
- plasma sterilization

...**may be used.**

➡ However, steam sterilization using an autoclave is strongly recommended to ensure reliable and reproducible sterilization.

Autoclave Sterilization Procedure

For optimal results, use a solid goods autoclave program with the following parameters:

- Temperature: 120 °C
- Duration: 90 minutes
- Pressure: overpressure (standard autoclave conditions)

Proceed as follows:

1. Place vials, rubber stoppers, and aluminum caps separately into autoclavable containers (e.g. a beaker covered with aluminum foil or an autoclave bag)
2. Mark each container with autoclave indicator tape to verify successful sterilization
3. Load the autoclave and run the program described above
4. After completion, verify successful sterilization using the autoclave tape
5. Inspect all components for condensation
6. (Optional) If condensation is present: Place the components in a drying oven until all moisture has completely evaporated

After completion of this process, all components are sterile and ready to be filled under sterile conditions.

5 Closing (Crimping) the Vials

After sterilization, the vials must be sealed using rubber stoppers and aluminum caps.

Proceed as follows:

1. First, place the rubber stopper onto the vial opening and press it gently to ensure proper seating.
2. Next, position the aluminum cap centrally on top of the stopper. Ensure that both stopper and cap are aligned horizontally and sit evenly on the vial.
3. Using a crimping tool, carefully compress the aluminum cap until it is securely fixed to the vial. Excessive force must be avoided to prevent damage.

After crimping, verify that the vial is properly sealed:

- visually inspect for gaps or misalignment
- attempt to rotate the cap by hand

➡ If the cap can be moved, the crimping process must be repeated.

Prepare the vial

Close the vial with a crimp tool

6 Filling and Handling Under Sterile Conditions

Filling of the vials must be carried out in a sterile working environment, such as a laminar flow hood.

Ensure that:

- only sterile media or reagents are used
- contamination from the environment is avoided
- appropriate personal protective equipment is worn

After filling, vials must be labeled according to laboratory requirements and stored under suitable conditions depending on the contents.

7 Insertion of Vials into the Device

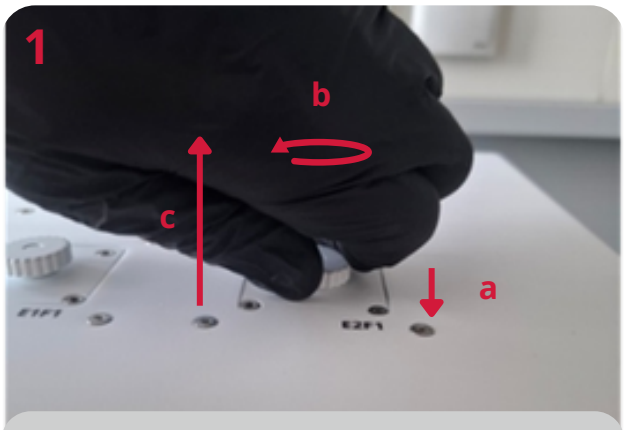
Before inserting a vial into the media unit, ensure that the vial has been properly prepared and sealed.

To insert a vial:

1. First, open the media insert by pressing the knob downward (a) and slightly rotating it (b) counterclockwise. The spring mechanism will move the holder into the loading position (upwoards, c).
2. Remove the flip-off cap from the vial.
3. Failure to remove the flip-off cap before insertion may damage the internal needles of the device.
4. Insert the vial upside down, with the stopper facing downward into the media unit.

   Important

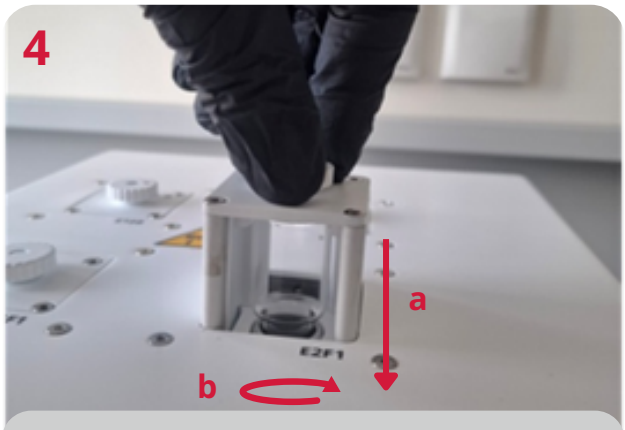
   Inserting the vial in an upright position or with the cap still attached may cause severe damage to the device.
5. After insertion, press the holder back into the device until a resistance (a) and lock it by turning the knob clockwise (b).



Open the media insert.

Remove flip-off cap.

Insert vial.



Close the media insert.

8 Notes for Safe Operation & Disposal

The use of improperly sealed, previously used, or non-sterile vials may result in:

- leakage
- contamination
- damage to the device

Always ensure that:

- only sterile and intact vials are used
- vials are correctly sealed and inserted
- all handling steps are performed according to this manual

Used vials must be disposed of in accordance with:

- the type of contained substances (biological, chemical, etc.)
- applicable national regulations
- The vials consist of:
- borosilicate glass
- rubber
- aluminum

Ensure proper separation and disposal according to local waste management guidelines.

Support

For any questions, feedback or technical support, please contact:

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For application-specific or detailed technical questions:

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