Exercise 4: PUPSIT live demo

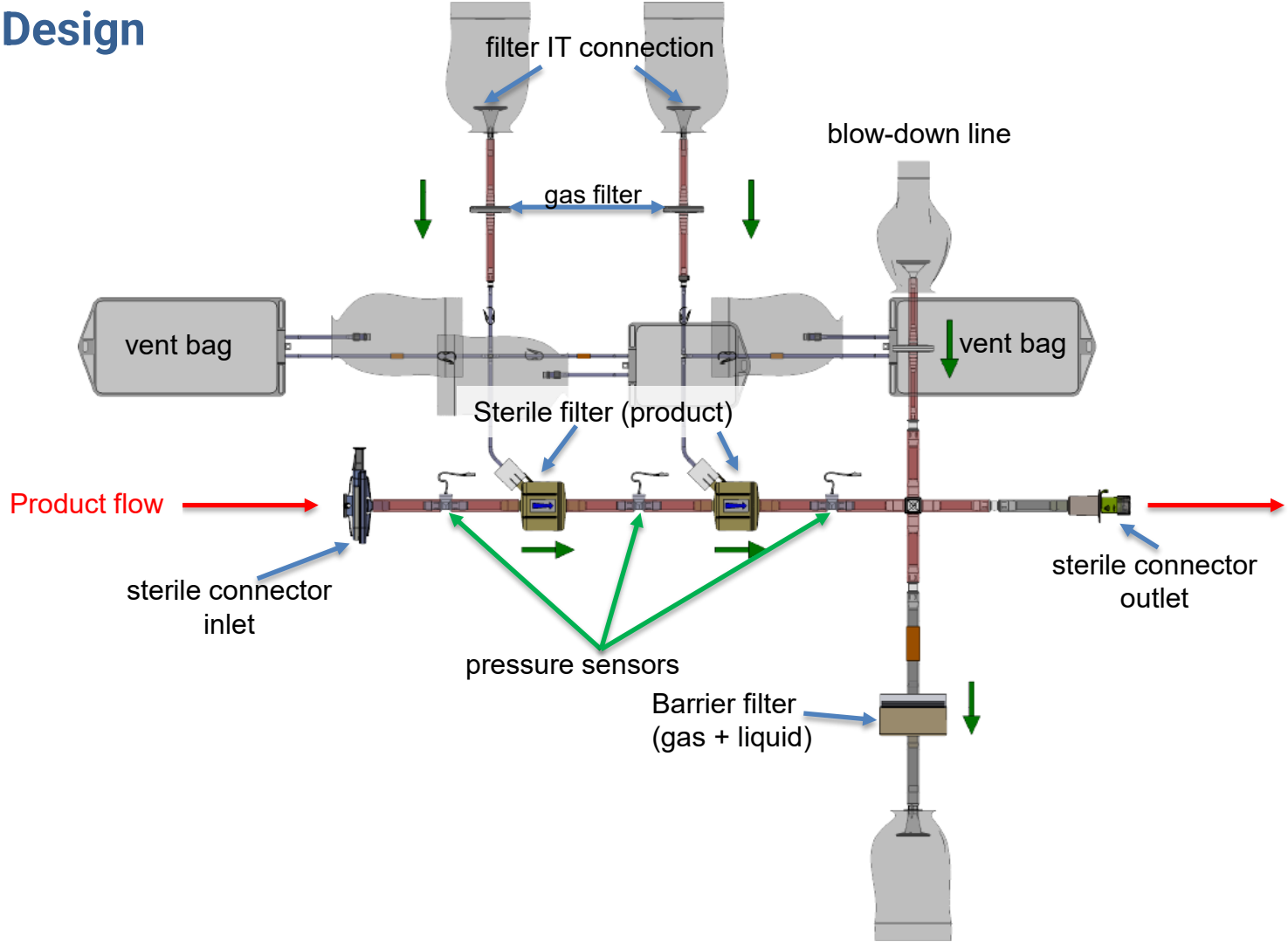
PDA Parenteral Drug Association

PDA TRAINING

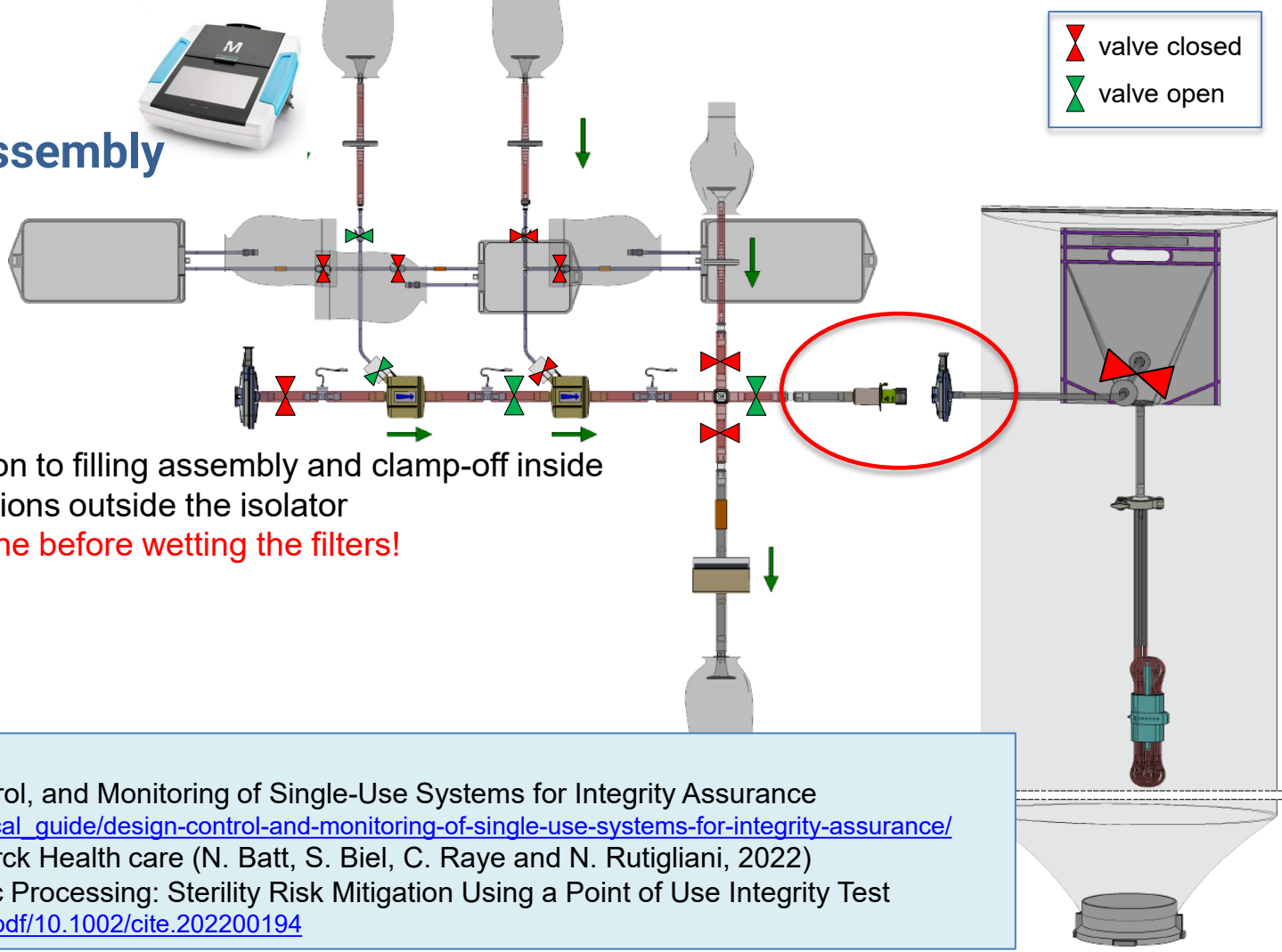
PUPSIT steps

Pos.	Step	description
01	Tara pressure sensors	All clamps open, press Tara on PMAT
02	POU Test	OPTIONAL POU integrity test of the single-use assembly (not done in training)
02	Start position	Close all clamps to have a defined start
03	Priming and venting of F1	Pump speed: 200mL / min slow filling and venting of the filter
04	Priming and venting of F2	Pump speed: 200mL / min slow filling and venting of the filter
05	Wetting of F1 and F2	Pump set at 1000mL / min for 5min Actuate vent valves to remove accumulating air
06	~200 mbar purge	Via lines IT1 + IT2 (optional)
07	Filter IT of F1	IT5 attached to line IT1, vent line of F2 open
08	Filter IT of F2	IT5 attached to line IT2, venting through Millibarrier

Assembly Design



Optional:
POU integrity test of the single-use assembly



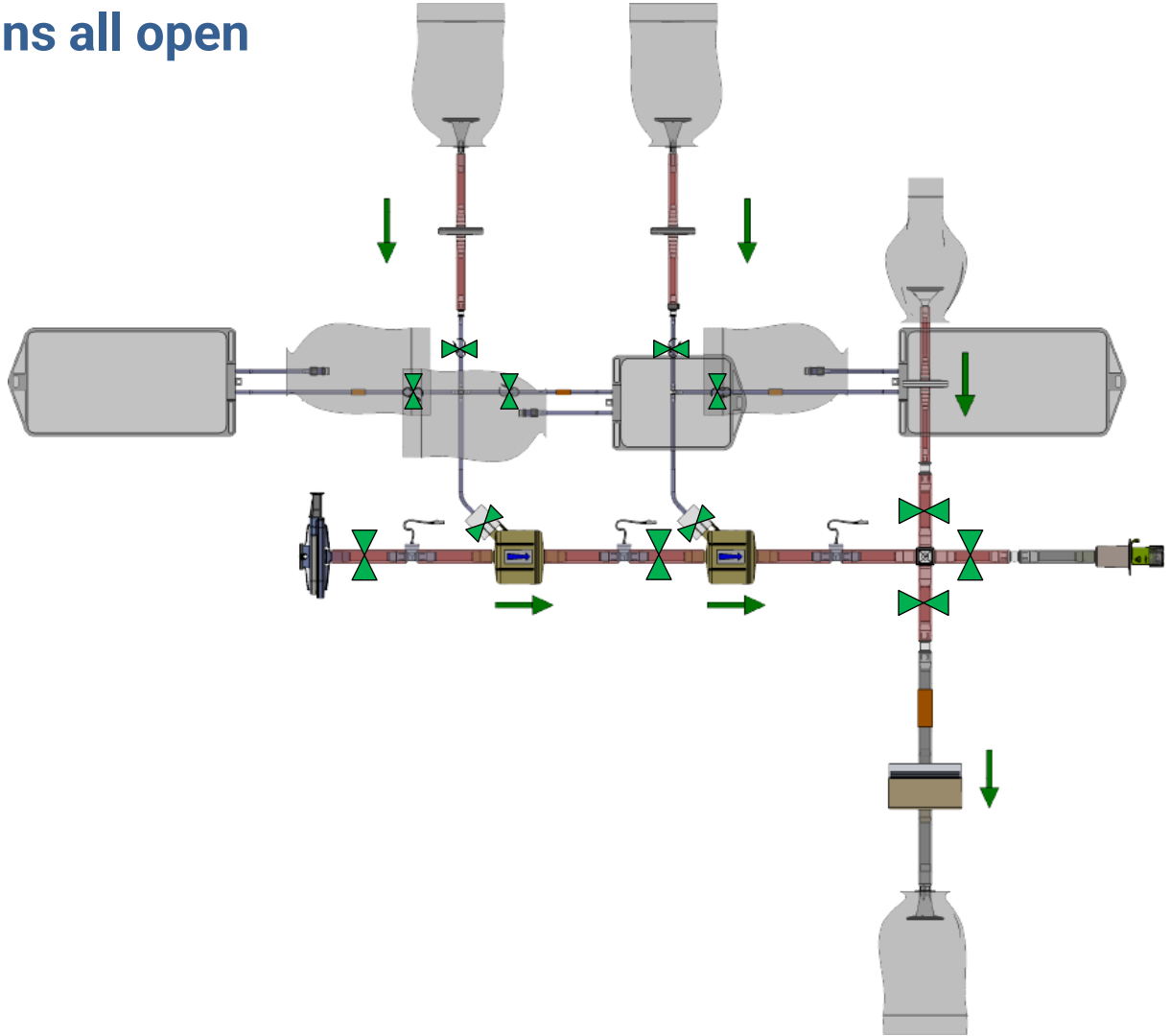
Establish sterile connection to filling assembly and clamp-off inside isolator to test all connections outside the isolator

=> If needed, must be done before wetting the filters!

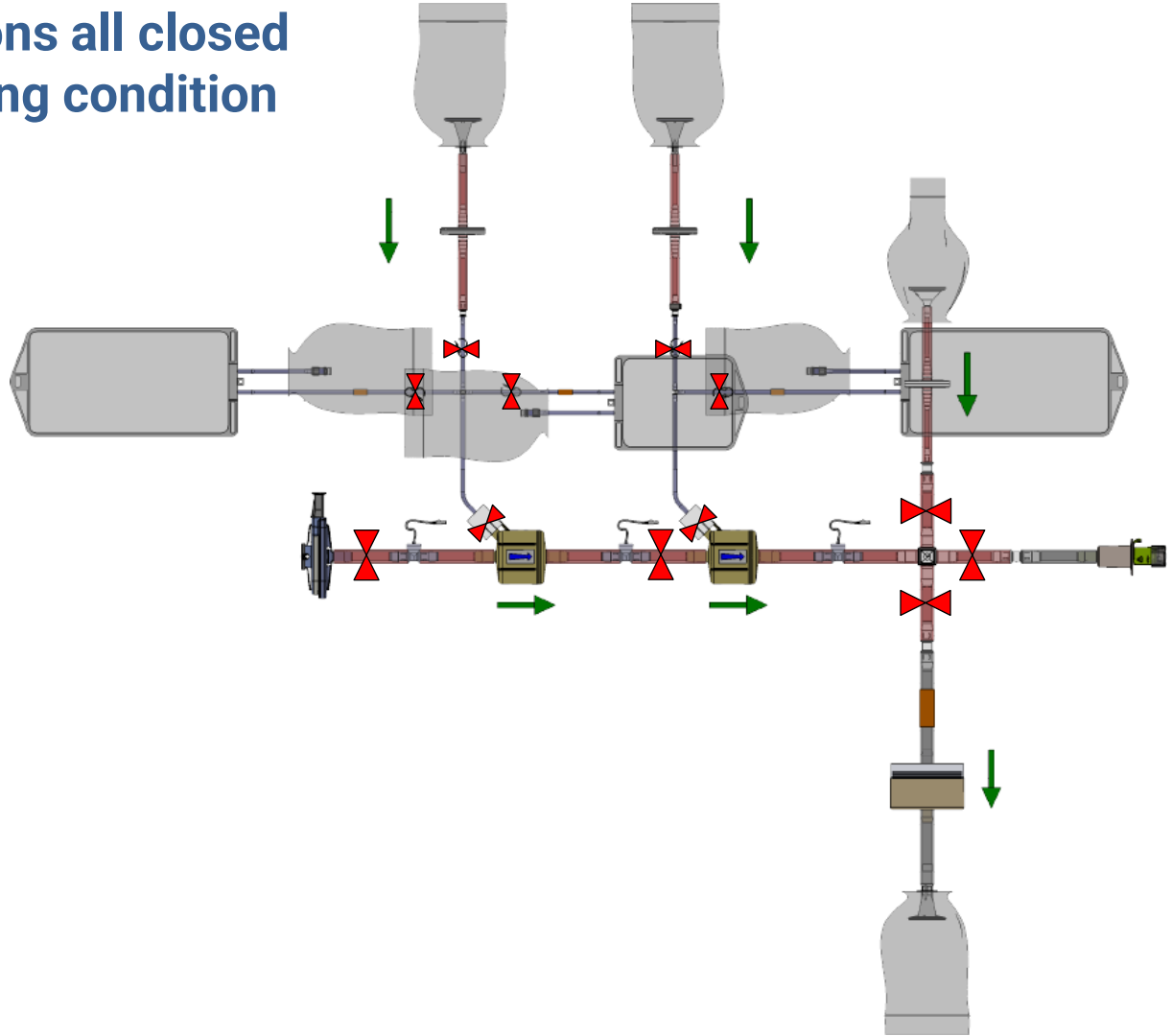
Discussed references:

- BPSA (2017): Design, Control, and Monitoring of Single-Use Systems for Integrity Assurance
https://bpsalliance.org/blog/technical_guide/design-control-and-monitoring-of-single-use-systems-for-integrity-assurance/
- Case Study Paper from Merck Health care (N. Batt, S. Biel, C. Raye and N. Rutigliani, 2022)
Single-Use Systems in Aseptic Processing: Sterility Risk Mitigation Using a Point of Use Integrity Test
https://onlinelibrary.wiley.com/doi/pdf/10.1002/cite.202200194

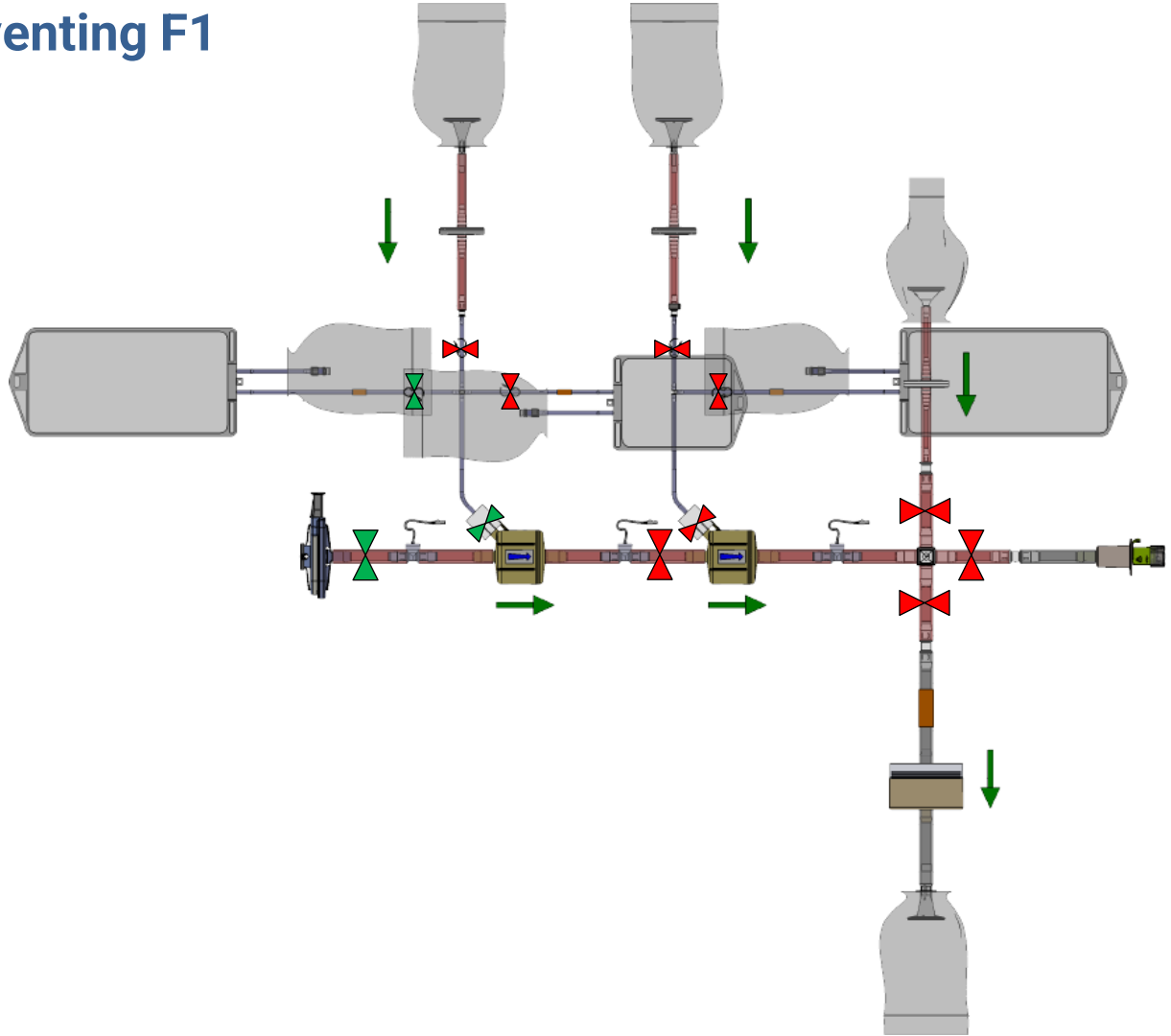
Clamp positions all open
- press Tara -



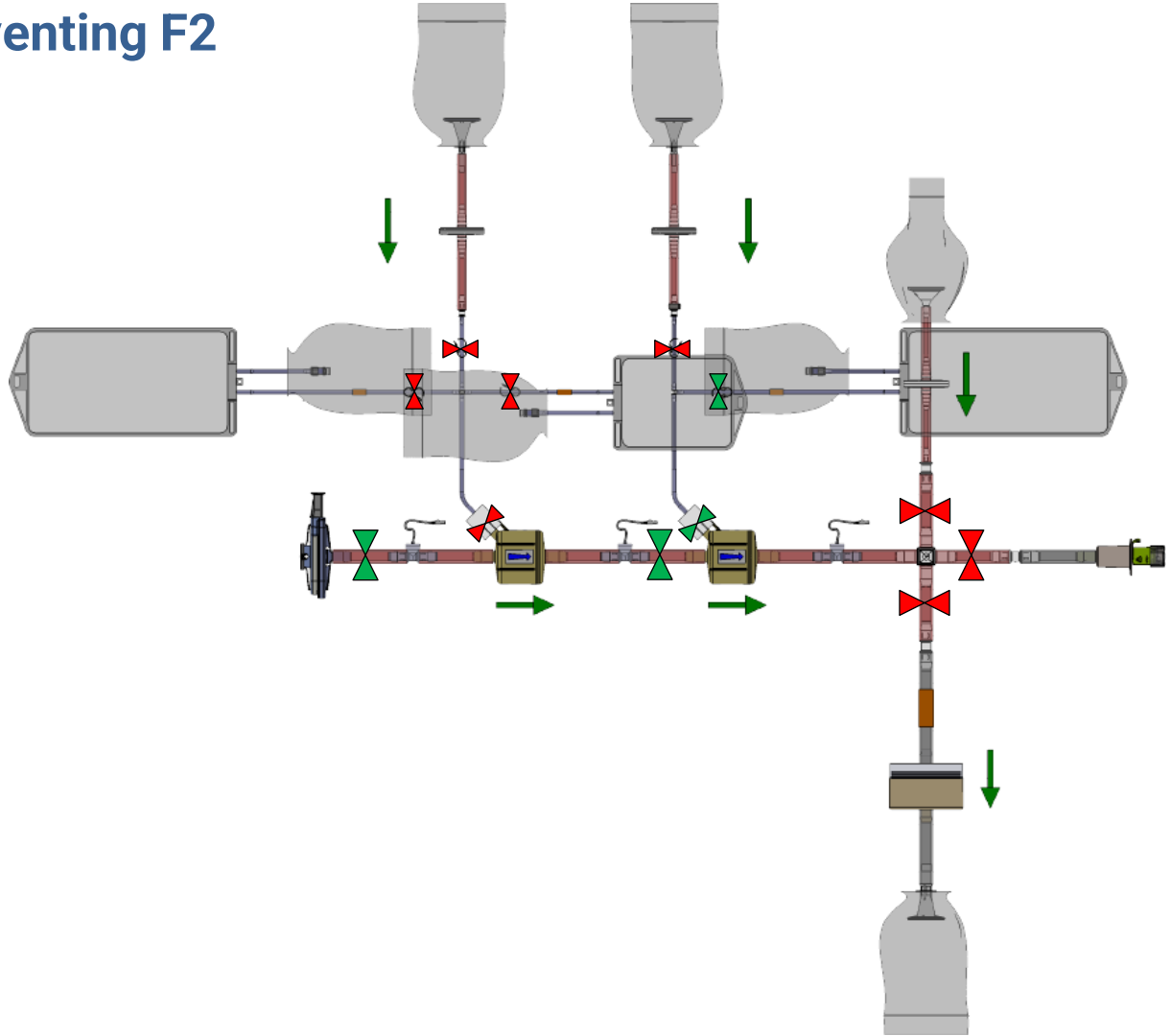
Clamp positions all closed
defined starting condition



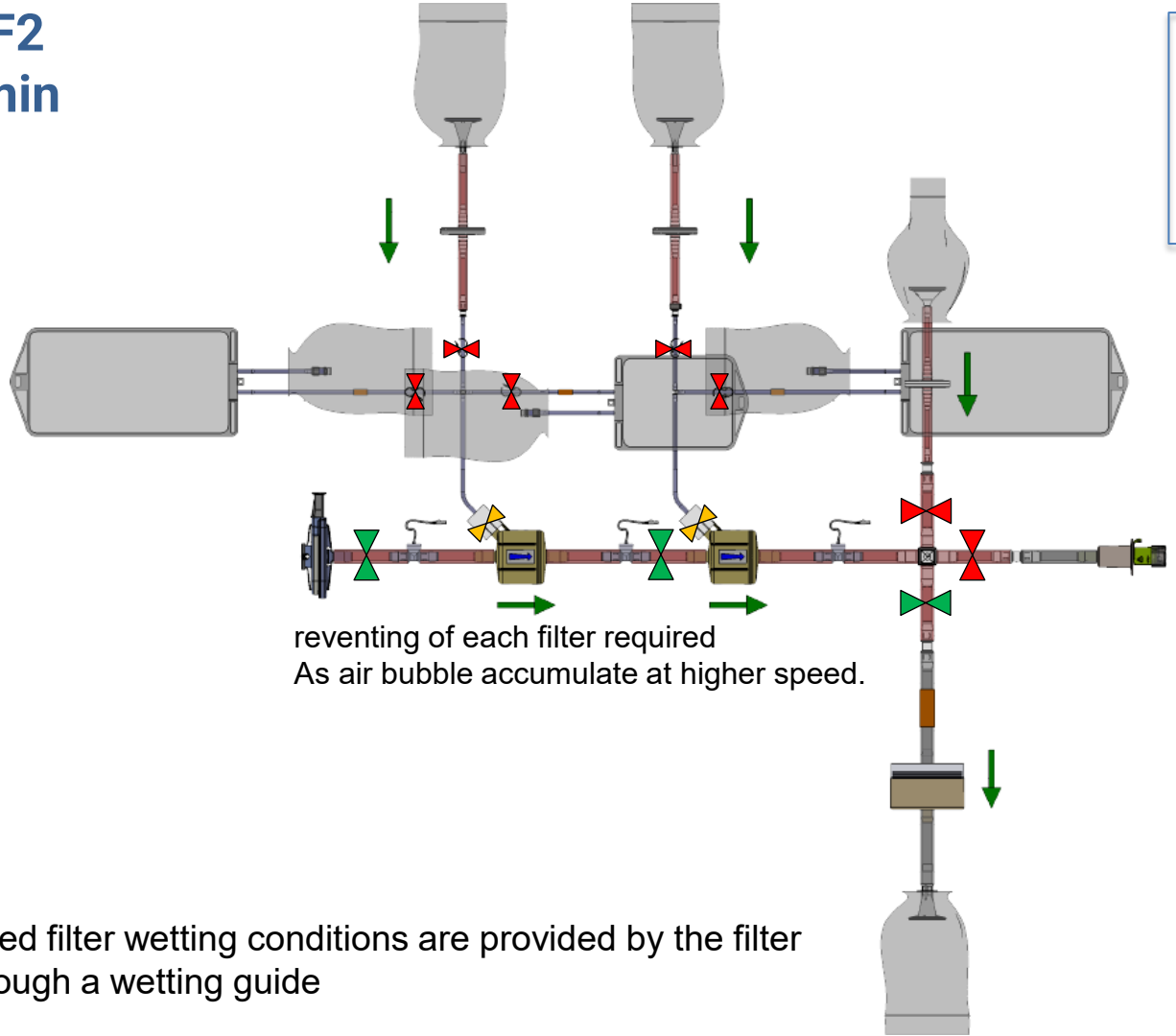
Priming and venting F1 at 0,2L/min



Priming and venting F2 at 0,2L/min



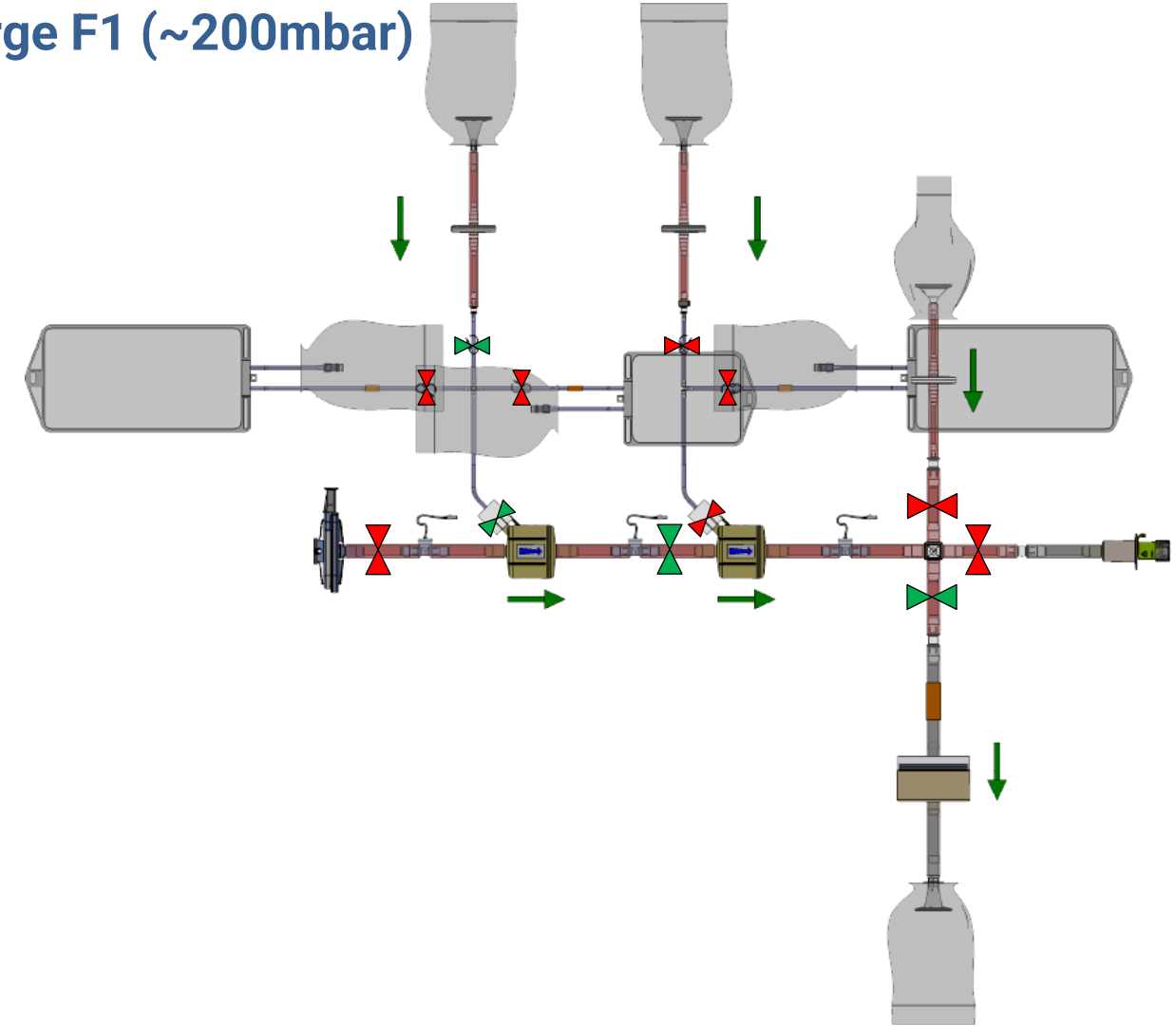
Wetting F1 + F2
5min at 1L / min



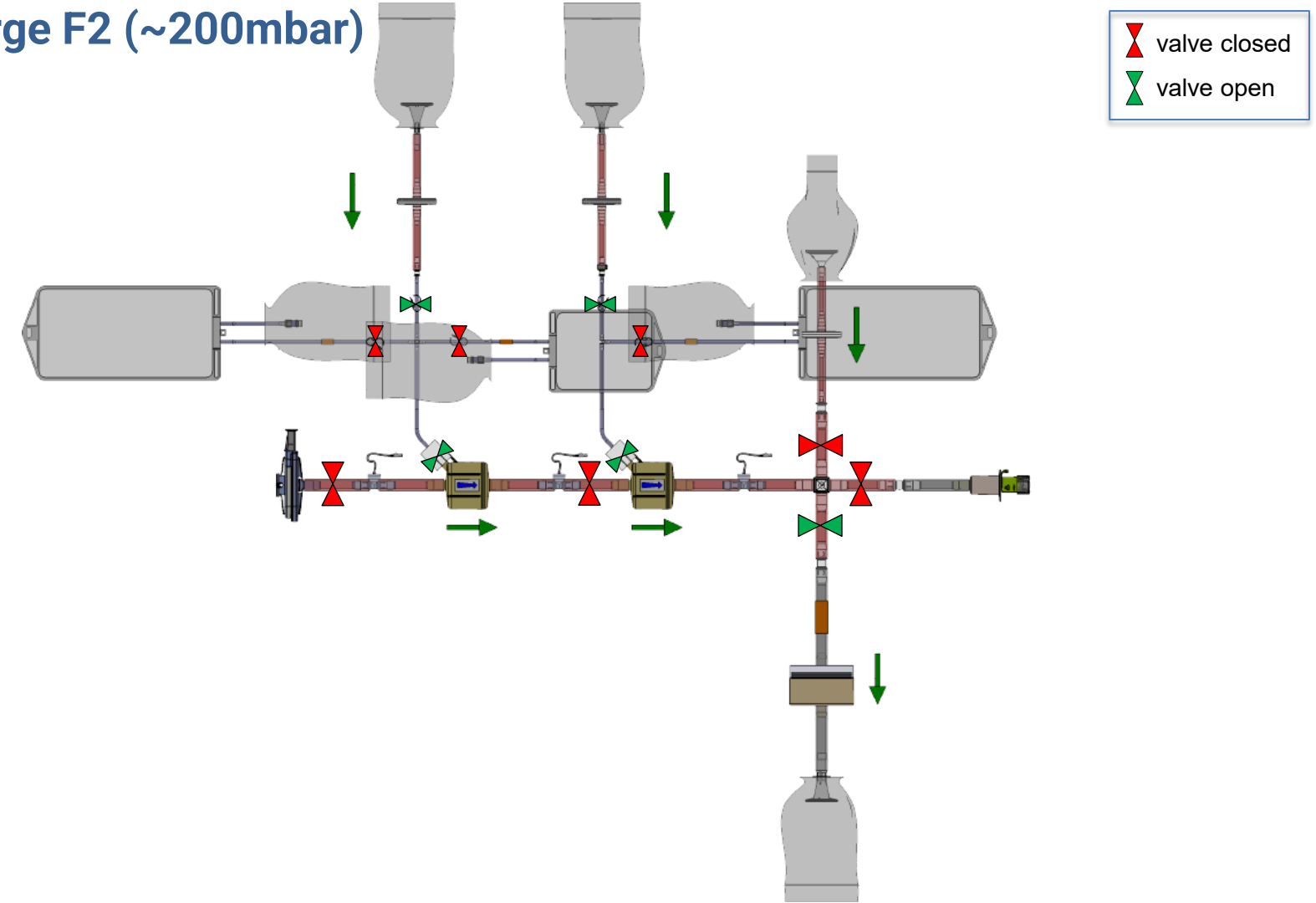
reventing of each filter required
As air bubble accumulate at higher speed.

The recommended filter wetting conditions are provided by the filter supplier, e.g. through a wetting guide

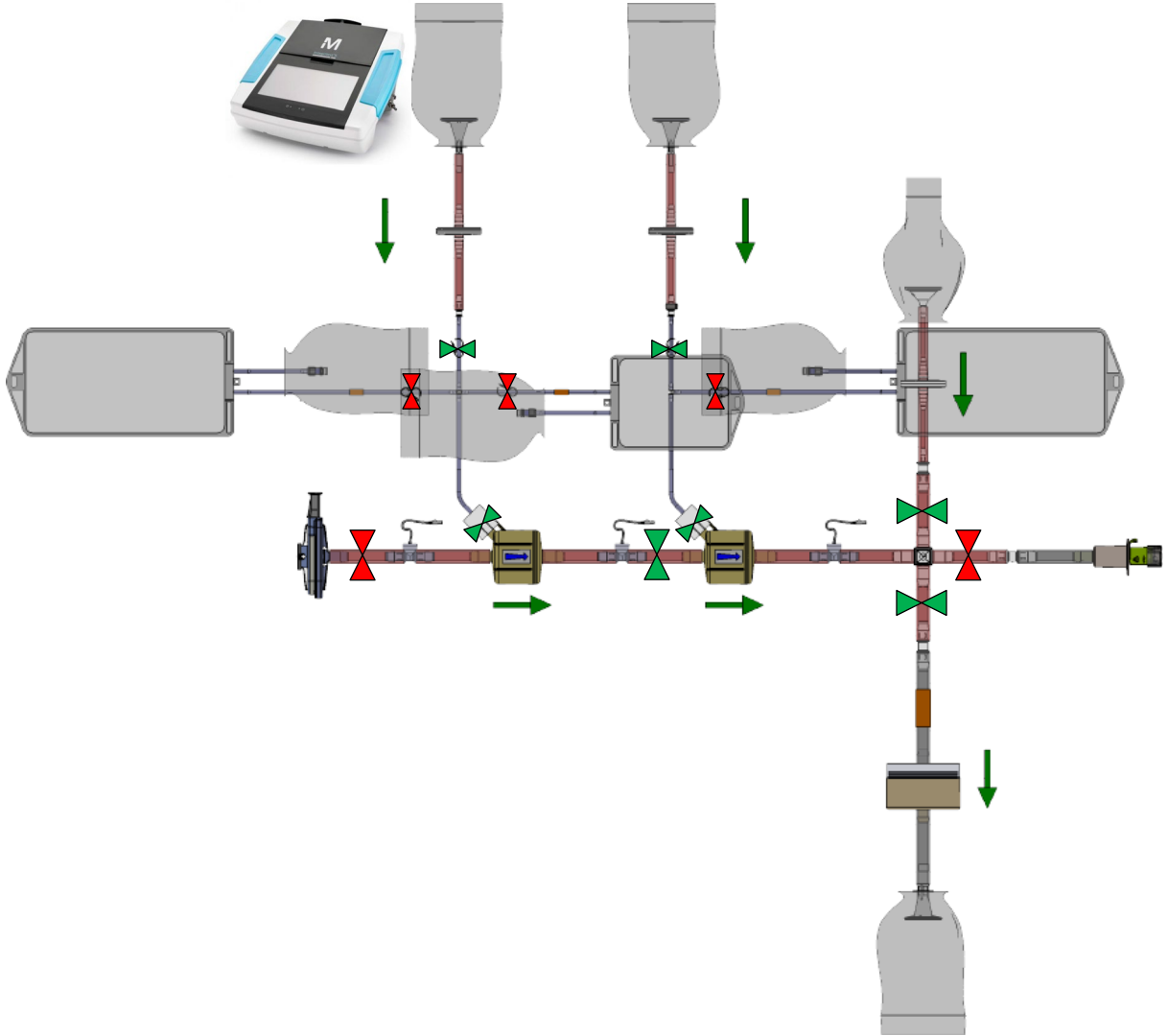
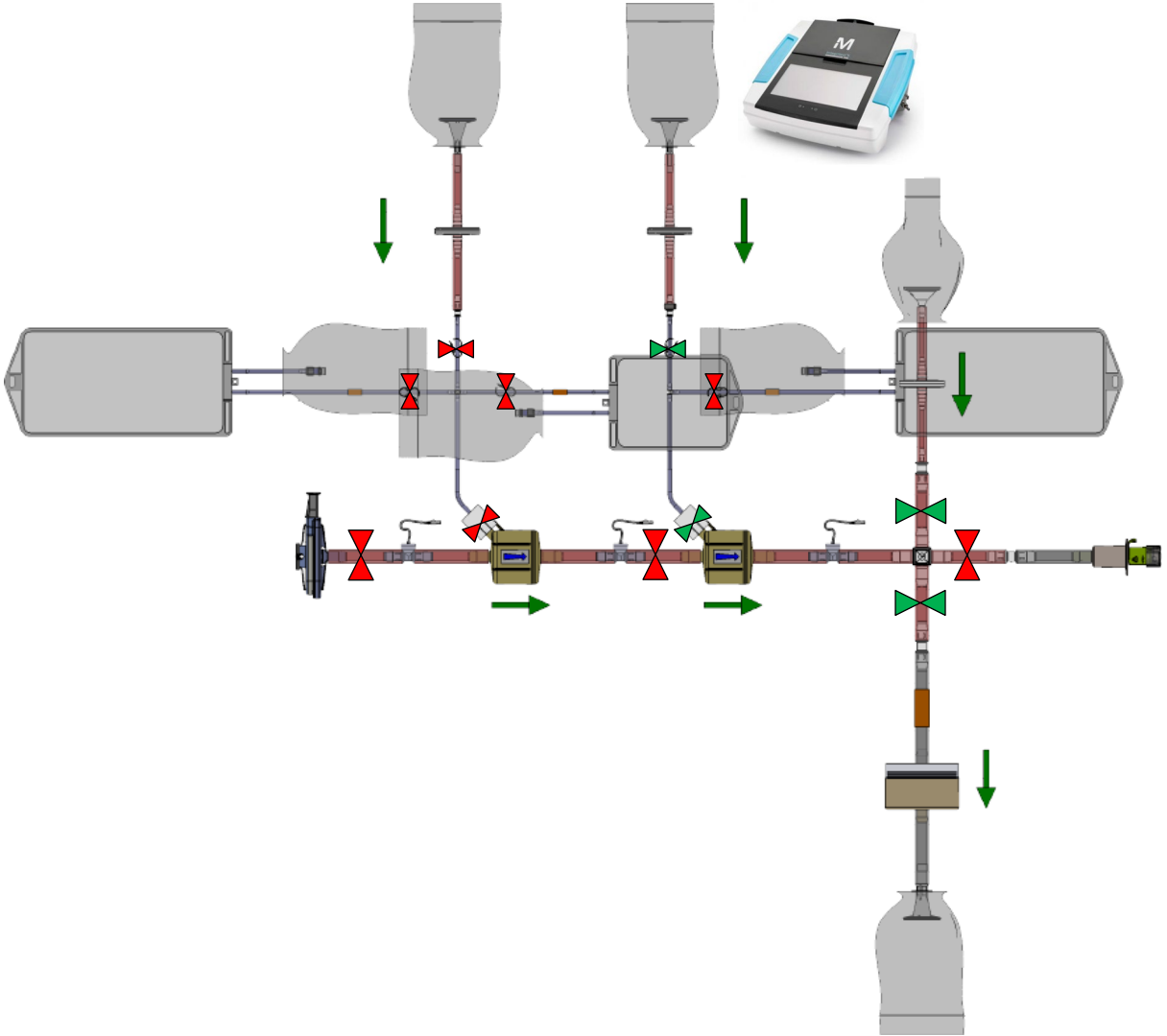
Optional: Purge F1 (~200mbar)



Optional: Purge F2 (~200mbar)



Filter IT F1



Filter IT F2