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Minicon® Concentrators

Introduction

Minicon® concentrators are non-sterile, disposable, multi-well ultrafiltration devices designed for concentrating macromolecules in clinical specimens such as urine, cerebrospinal fluid (CSF), or other biological solutions. The concentrators, which require no additional equipment and can be operated unattended, are used by researchers and clinical laboratories worldwide as a preparatory step to increase the sensitivity of subsequent tests.

Intended Use

Minicon® clinical concentrators are non-sterile disposable, multi-well ultrafiltration devices for in vitro diagnostic use and are intended for concentrating macromolecules in small volumes (2.5mL (CS15) and 5mL (B15)) of biological samples e.g. serum, urine, cerebrospinal fluid (CSF) or other biological fluids prior to in vitro diagnostic analysis. Device intended to be single-use and used by a laboratory professional.

Typical uses for Minicon® concentrators include:

- Enrichment of urine specimens before electrophoresis for detecting proteins
- Concentration of clinical samples (e.g., serum, urine) prior to electrophoresis or immunoelectrophoresis
- Simple concentration of research samples
- Increasing antibody and antigen titers
- Concentration of spinal and other dilute body fluids
- Concentration of enzymes or isoenzymes
- Removal or exchange of salts and other microsolutes by repetitive dilution and concentration
- Purification of membrane-retained macrosolute

Limitations

Minicon® concentrators are intended for qualitative evaluation. Because there is always some nonspecific binding of solute onto the membrane surface, as well as non-recoverable film loss due to wetting of the sample chamber, Minicon® concentrators are not recommended for applications where quantitative analysis of results is required. Note also that the amount of recoverable solute decreases with concentration. In most instances, slight
over-con centration will produce the required degree of enrichment.

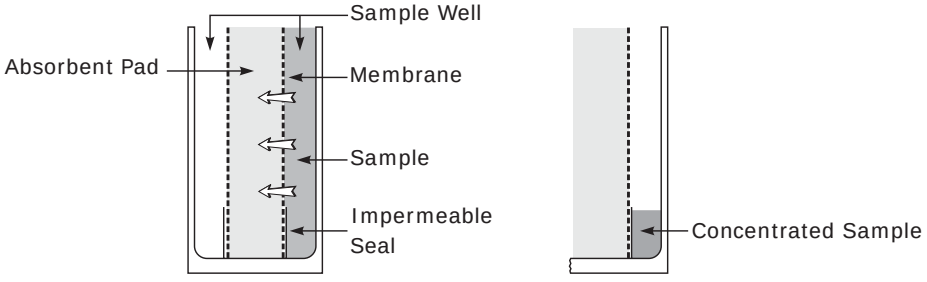
Storage and Stability

Refer to product label for storage conditions and shelf life. Store unused concentrators in a dry environment at 15–25 °C. Refrigerate all used concentrators after first use. To retard microbial growth, a preservative may be added to previously used chambers. Discard unit if microbial growth is observed.

Concentration Process

1. The user pipettes solution into one or more of the fixed-volume sample chambers that are bounded by a semi-permeable membrane.
2. An absorbent backing material immediately begins to wick away water and permeating species, gradually reducing sample volume.
3. After several hours, the starting volume is significantly reduced, thereby increasing the concentration of the retained solutes inside the sample chamber.
4. Filtration ceases in the Minicon® concentrator when the liquid level falls to the maximum concentration line.
5. User removes concentrated sample from device and, if desired, adds more solution to sample chamber to begin a second concentration cycle. This step may be repeated twice.

Cut-away View of Minicon® Concentrator



Concentration Factors

The graduation lines on the sample chamber sides indicate the achievable concentration factors. The concentrator has an impermeable seal at the bottom of each sample chamber (positioned at maximum concentration line) to prevent further liquid contact with the membrane. This seal provides a deadstop to prevent accidental reduction to dryness. Once the liquid level reaches the device's maximum concentration line, filtration ceases. The concentration factor can be estimated using the tables in the Operating Procedure section.

Minicon® Concentrators Sample Chamber Refill

Because the capacity of the absorbent pad in the Minicon® concentrator is two to three times chamber volume, the individual sample chambers may be refilled with additional sample to process volumes that exceed chamber capacity, or to achieve higher concentrations than those listed in the concentration factor charts. Another way to achieve high concentrations is by filling several Minicon® wells with sample solution. Add combined concentrates to a fresh well and process again; continue filtering to desired concentration level.

The samples can also be rediluted one or more times to perform a wash-out of permeating species (e.g., salts and other species only partially retained). The ratio of permeating solute removed with the wash depends on solute retention by the membrane. Species below 1,000 in molecular weight (MW), for example, are not retained by Minicon® concentrators and wash out according to the amount of solvent removed. It is possible to lower the salt content of a sample by concentrating the sample volume 10 to 15-fold, then rediluting the sample back to the original volume, using a diluent with a lower salt content. The salt content of the final sample will depend on the salt concentration of the diluent and how many concentration/redilution cycles are performed.

Minicon® Concentrators Operating Procedure

This section outlines the general operating procedure for the Minicon® B15 and CS15 concentrators.

Materials Required

- Filter paper
- 9-inch (228 mm) Pasteur pipette or syringe

Concentrating Samples

1. Prefilter samples through the filter paper.
2. Determine approximate sample macrosolute content desired (for electrophoresis or immunoelectrophoresis, protein concentration should be approximately 25 mg/mL).
3. Use the following tables to estimate maximum concentration factor from the initial protein concentration. In the shaded boxes, locate the initial sample volume and the graduation mark for the final liquid level, then read the concentration factor in the unshaded box at the row and column intersection. To calculate final volume, divide the initial volume by the concentration factor.

Minicon® B15 Concentration Factor

Initial Volume	Graduation Mark				
	5X	**10X**	**25X**	**50X**	**100X**
5 mL	5X	10X	25X	50X	100X
4 mL	4X	8X	20X	40X	80X
3 mL	3X	6X	15X	30X	60X
2.5 mL	2.5X	5X	12.5X	25X	50X
2 mL	2X	4X	10X	20X	40X
1.5 mL	1.5X	3X	7.5X	15X	30X
1 mL	—	2X	5X	10X	20X

Minicon® CS15 Concentration Factor

Initial Volume	Graduation Mark			
	5X	**10X**	**20X**	**80X**
2.5 mL	5X	10X	20X	80X
2 mL	4X	8X	16X	64X
1.5 mL	3X	6X	12X	48X
1 mL	2X	4X	8X	32X
0.5 mL	—	2X	4X	16X

CAUTION: Very dilute specimens (e.g., spinal fluid) may occasionally concentrate beyond the maximum rated concentration factor. To assure complete recovery of valuable samples, check the concentration level periodically during operation. Remove concentrate when the sample level reaches the maximum concentration ratio.

4. Use a 9-inch Pasteur pipette or syringe to introduce sample through opening at top of well.

   CAUTION: Avoid scratching the membrane or exceeding the well fill line.

5. Allow sample to filter through membrane and into the absorbent pad. Sample volume will steadily decrease as macrosolute concentration progresses. The volume at the graduation lines is shown in the concentration factor tables above. For samples below 5 mL, graduations are determined proportionally.

   CAUTION: Specimens that are normally very dilute, such as spinal fluid, can concentrate beyond the maximum concentration factor, thereby losing their usefulness. If this happens, introduce approximately 50 µL of normal saline or buffer, mix by drawing in and out several times with a pipette, and then remove the sample. Most of the concentration volume can be recovered using this technique.

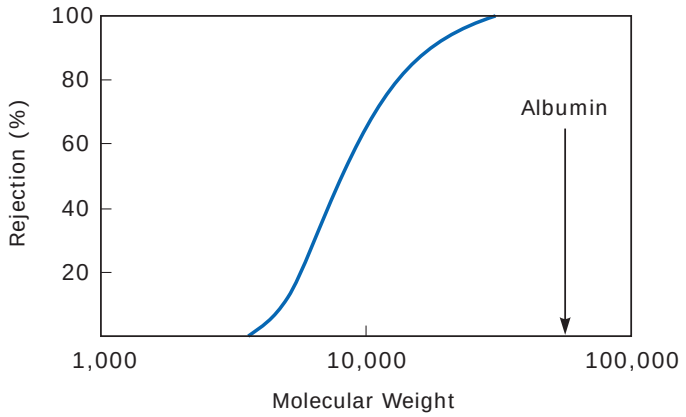
6. After you have achieved the desired concentration, carefully insert a pipette or syringe into the cell bottom and gently draw the sample in and out several times before removing. This ensures adequate mixing and improves sample recovery.

   NOTE: If sample concentrates to dryness, pipette buffer or saline (up to 0.5 mL) into sample chamber, then mix the solution by drawing it in and out of the pipette several times. Remove sample after mixing thoroughly.

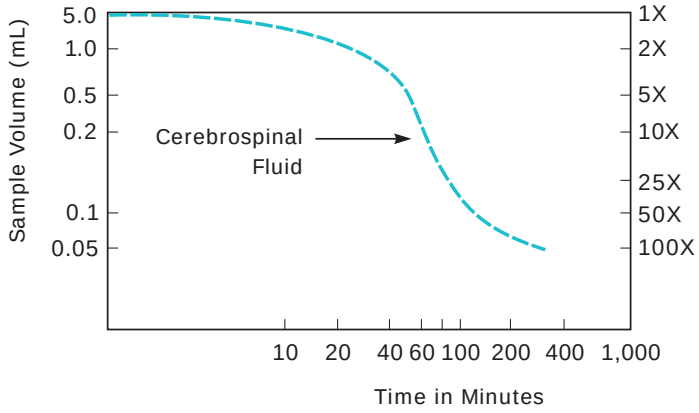
Performance Characteristics

- Minicon® membranes are rated at a specific MW cut-off (MWCO), based on performance with well-characterized proteins.
- Although solute rejection is determined by a molecule's physical size and shape, molecular weight has proven to be a more convenient working parameter to use for most purposes.
- The specified membrane cut-off may not hold true for all materials and should not be taken as absolute.
- Species whose MW is close to the membrane cut-off may be partially retained.
- Solute rejection and filtration rate have been characterized with several common materials. These results can be used to estimate performance with other solutes. Experimentation and analyses are required to obtain more accurate performance characteristics.
- Because filtration is viscosity-limited, concentration times may increase slightly at low temperatures.
- Concentration time varies by sample due to different sample characteristics such as temperature and viscosity.

Minicon® B15 Concentrator Typical Solute Rejection



Minicon® B15 Concentrator Typical Concentration Rate



Chemical Compatibility

Minicon® Ultra centrifugal devices are intended for use with biological fluids and aqueous solutions.

Specifications

	Minicon® B15 Concentrator	Minicon® CS15 Concentrator
Membrane	Polyethersulfone	Polyethersulfone
Number of chambers	8	10
Chamber capacity, mL	5.0	2.5
Membrane area, cm²	22	9.9
Membrane cut-off (MWCO)	15,000	15,000
Length	14.7 cm (5.8 in.)	14.2 cm (5.6 in.)
Width	4.5 cm (1.8 in.)	2.9 cm (1.1 in.)
Height	10.2 cm (4.0 in.)	7.0 cm (2.8 in.)

Product Ordering

Description	Qty/Pk	Catalogue Number
Minicon® B15 Concentrator	40	9031
Minicon® CS15 Concentrator	50	9051

Symbol Definitions

Symbol	Definition	Symbol	Definition
IVD	In vitro diagnostic medical device		Date of manufacture
REF	Catalogue number		Manufacturer
	Do not reuse		Non-sterile product
	Use-by date	CE	CE conformity marking
LOT	Batch code		Temperature limit
eIFU	Instructions for use available online		Do not use if package is damaged
	Download product documentation online	UKCA	United Kingdom mark of conformity

Notice

We provide information and advice to our customers on application technologies and regulatory matters to the best of our knowledge and ability, but without obligation or liability. Existing laws and regulations are to be observed in all cases by our customers. This also applies in respect to any rights of third parties. Our information and advice do not relieve our customers of their own responsibility for checking the suitability of our products for the envisaged purpose.

Collection and Disposal

All samples must be clearly labelled. Suitable instruments must be used for obtaining and preparing samples.

NOTE: Follow precautions for disposal of items contaminated with potentially infectious or hazardous biological material according to all applicable international, federal, state, and local regulations.

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