

DESCRIPTION OF
106 MICRODIALYSIS PUMP

The 106 Microdialysis Pump is specially designed for use with 70 Microdialysis Catheter and Perfusion Fluid. The pump, syringe and catheter comprise an optimised system, where the microprocessor of the pump controls the high flush flow and the lower normal flow. Intended use: The 106 Microdialysis Pump is a portable syringe pump intended to pump perfusion fluid and dialysate through a microdialysis catheter, enabling microdialysis sampling. Indications and contraindications are according to information in the Instructions for use of the microdialysis catheter in use. The pump is intended to be operated by medically trained staff.

Caution! The 106 Microdialysis Pump must only be used for microdialysis, together with microdialysis catheters and accessories from M Dialysis AB.

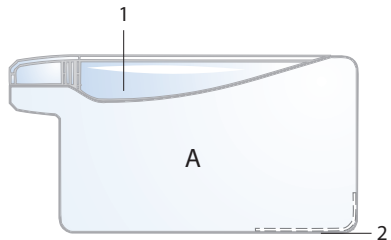
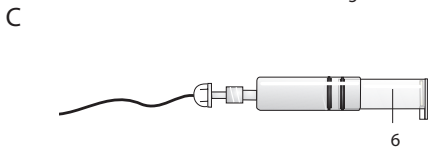
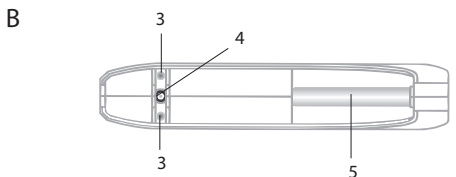


Fig. 1A
Pump:
(1) Cover
(2) Battery Cover.

DESCRIPTION OF
106 MICRODIALYSIS PUMP

Fig. 1B
Pump from above:
(3) Light-emitting diodes,
(4) Power switch,
(5) Drive screw.

Fig. 1C
Syringe:
(6) Piston with thread.



BATTERY CHANGE

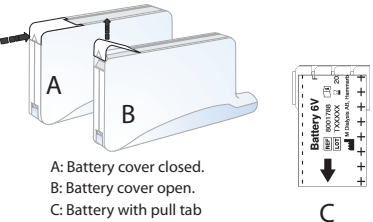


Fig. 2
A: Battery cover closed.
B: Battery cover open.
C: Battery with pull tab

1. Open the battery cover by pressing with your thumb in the direction of the arrow (see Fig. 2 A,B).
2. Remove the old battery by pulling the label tab.
3. Attention: Be sure to insert the battery properly. Insert the positive end (+) of the battery to the positive end of plate first, followed by the negative (-) side to avoid a short circuit.
4. Fold the label down.
5. Replace the battery cover.

Low battery is indicated by two red light signals every ten seconds. Battery replacement can be made during a microdialysis investigation which is underway provided that the syringe remains in the pump and that the syringe cover is not opened. Used batteries should be disposed of according to local environmental regulations or contact M Dialysis for more information.

Caution! If the pump is not in use, the battery should be removed.

CONNECTION OF SYRINGE

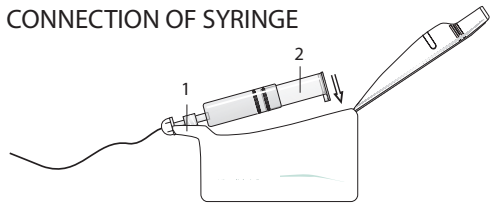


Fig. 3. Positioning of syringe in pump.

1. Fill the syringe with a maximum of 2.5 mL Perfusion Fluid at room temperature
2. Remove any air bubbles. Remove the filling needle from the syringe.
3. Connect the luer connector of the syringe to the inlet tubing of the microdialysis catheter. Before flushing, fit a microvial into the microvial holder.
4. Fit the syringe into the pump by inserting the front section first (1). Allow the syringe to drop into position so that the threaded piston (2) lines up with the drive screw (see Fig 3).
5. To avoid wear of the cover, close the cover by pressing on the sides of the cover so there is no "click". The pump will start automatically and the green light will flash every other second during the flush sequence (5 min). Note that each time the pump is opened and closed with a syringe in place, a new flush sequence will start.
6. Check that there is fluid in the microvial after the flush sequence and change to a new vial. If there is no fluid in the microvial, start a new flush sequence by opening and closing the pump cover.

PUMP FUNCTIONS

Standby: No syringe in pump.

Flush sequence: Syringe in pump. High flow for five minutes (15 µL/min).

Normal flow: Flow rate 0.3 µL/min.

To indicate the current function of the pump, there are two light emitting diodes (LEDs, see fig. 1) located under the transparent cover by the "nose" of the pump. The LEDs can illuminate red or green. When the syringe is inserted into the pump and the cover is closed, a switch underneath the front end of the syringe is activated (see Fig. 1) and the flush sequence starts. During the flush sequence, a green light will flash every other second (see Light signals). The flush sequence is programmed so that the complete microdialysis catheter is filled with fluid and all air bubbles are removed. When the flush is complete the pump changes to normal flow which is indicated with a green light flash every 10 seconds (see Light signals).

LIGHT SIGNALS

INFORMATION SIGNALS

System OK
After correct insertion of battery: Three green/red light signals ending in one green signal of about 3 seconds.

Flush sequence
Green light signal every other second.

Normal flow
Green light signal every 10 seconds.

ERROR SIGNALS

Pump error
Red light signal every 5 seconds if the problem is during flushing, every 10 seconds if the problem is during normal flow.

Low battery
Two red light signals every 10 seconds.

The error signal stops when the fault has been corrected (e.g. filling the syringe, removing the blockage in the syringe, changing the battery etc.)

CLEANING

Use a moist soft cloth to clean the casing of the pump.
Do not use abrasive cleaners.
Recommended cleaning substances:
- Soap solution
- 70 % ethanol

WATER RESISTANCE

The pump is splash proof and can tolerate short-duration splashing with water.
This means that the patient can shower with the pump functioning if the pump is protected with a plastic bag. If the pump is accidentally immersed in water, the syringe and battery compartments must be dried out.

WARRANTY

M Dialysis guarantees all components of the 106 Microdialysis Pump to be free from defects of material and workmanship for a period of 12 months after initial purchase. M Dialysis will repair or replace, at our discretion, the 106 Microdialysis Pump during the aforementioned warranty period.
M Dialysis reserves the right to waive all warranties in the case of problems due to improper handling, improper field of application or unauthorised modifications.
For warranty repair, the 106 Microdialysis Pump must be returned to M Dialysis or to an authorised representative. The Owner shall prepay shipping charges to M Dialysis, and M Dialysis shall pay shipping charges to return the product to the Owner.

WARNINGS

- No modification or repair of this equipment is allowed.
- Do not drop this equipment. If dropped, consult the Pump Safety Test Sheet (8050067).
- Only use battery from M Dialysis, ref no 8001788
- Connect only items that have been specified as part of the equipment (see Microdialysis Catheter Instruction for use).
- Remove battery from equipment when not in use
- Never submerge the equipment in water or other liquid
- Battery compartment shall be clean and dry.
- Read instruction for battery handling on battery package labeling
- For battery disposal follow hospital procedure for disposing of batteries.
- In order not to affect the function of the pump, ensure that radiotransmitters, mobile telephones and other wireless communication equipment is used at a safe distance from the 106 Microdialysis Pump.
- 106 Microdialysis Pump should not be exposed to disturbance levels exceeding those given in IEC 60601-1-2.
- If the 106 Microdialysis Pump is to be discarded, please contact M Dialysis AB or your local supplier for more information.
- Remove the pump before MRI scanning
- To avoid skin irritation, do not place the pump in direct contact with the skin.
- The pump must be cleaned after each use. See section Cleaning page 8.
- Any serious incident occuring in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.
- The device shall not be used as the sole basis for decisions as to diagnosis or therapy.
- 106 Syringe is for single use only. If the device is re-used there is a risk for cross-contamination and infection.

EXPLANATION OF SYMBOLS

- IPX4

Protected against splashing water.
- Follow instructions for use.
- Type CF applied part
- STERILE EO

Sterilized with ethylene oxide (106 Syringe)
- Separate collection for waste of electrical and electronic equipment.
- Conforms to UL 60601-1 Certified to CAN/CSA Standard CSA C22.2#601.1,
- MR Unsafe
- Manufacturer and date of manufacture
- REF

Catalogue number
- MD

Medical Device
- Operating temperature
Humidity limitation
- SN

Serial Number

TECHNICAL SPECIFICATION

- Dimension:

Weight:

Battery:

Battery lifetime:

Casing:

Flush flow:

Normal flow:

Operating temperature:

Error signals
- 90 x 50 x 20 mm

70 g (incl. battery)

6 V Silver oxide Ref 8001788

10 days

ABS plastic, splash-proof

15 µL/min

0.3 µL/min

+5 - +40 °C

Pump error
Low battery

The pump is not tested in an Oxygen Rich Environment.

ORDERING INFORMATION

- REF P000003

REF 8010191
- 106 Microdialysis Pump

106 Syringe, sterile

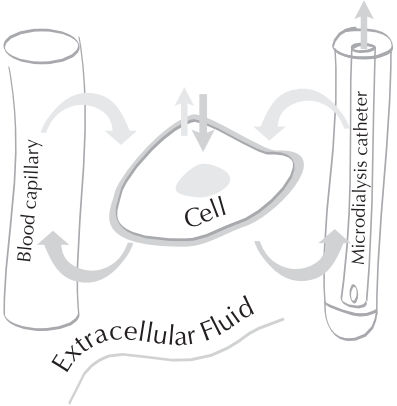
DISPOSAL OF 106 SYRINGE NEEDLE

106 Syringe Needle shall be disposed according to the hospital routines for biohazardous material.

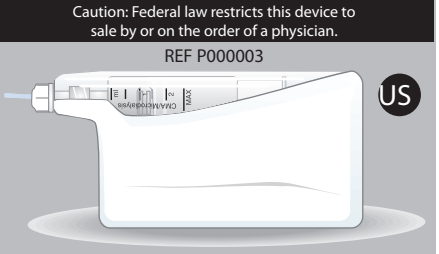
INTENDED USE ENVIRONMENT

The 106 Microdialysis Pump is intended to be used in intensive care, surgery, and general wards.

PRINCIPLE OF MICRODIALYSIS



106 MICRODIALYSIS PUMP



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