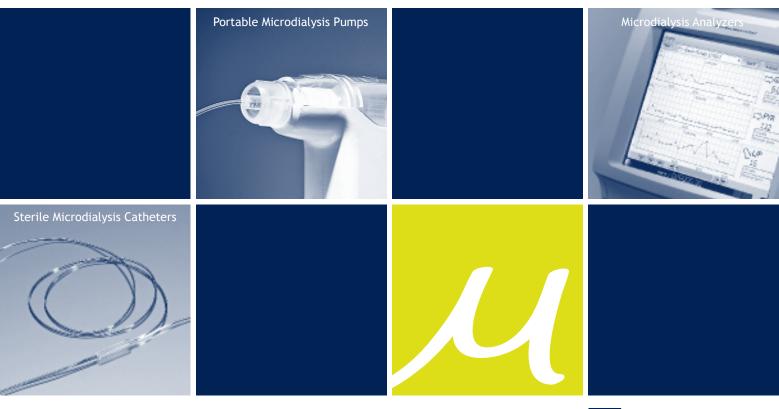
Microdialysis for Clinical Use







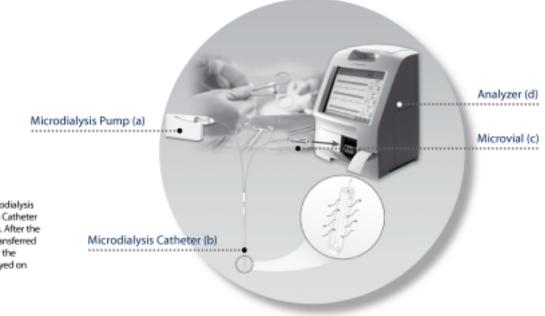
3 Introduction

The ability to diagnose a disease or condition prior to the onset of clinical signs would markedly change the way medicine is practiced today and ultimately drive the improvement of patient care. Monitoring tissue chemistry and diagnosis based on changes in the local metabolism offer windows of opportunities that may lead to improved quality of life.

The idea of Microdialysis is simple: a thin dialysis tube is introduced into the tissue and perfused with a physiological salt solution. Molecules diffuse over the membrane and the perfusate gradually equilibrates with the composition of the interstitial fluid – analogous to a capillary perfused with blood.

The technique of microdialysis has advanced well beyond its first application in the brain tissue of small rodents, and is continually finding new applications in larger animals and patients. Parts of the clinical microdialysis system include: small battery driven microdialysis pumps (a), sterile microdialysis catheters (b), specialized collection vials (c), and a chemical microdialysis analyzer (d) that can measure markers of cellular damage as well as substances related to energy metabolism. These analyte levels can then be displayed on a screen within minutes.

Today this system is being used throughout the world for clinical research as well as for routine monitoring of the human brain in neurointensive care and free flaps following reconstructive surgery. In Europe, microdialysis instruments are CE labeled according to the Medical Device Directive (MDD). Some of the catheters have been cleared by the US FDA for the Neuromonitoring application. Other catheters in this catalogue are in the US considered investigational devices, and therefore are limited by US law to investigational use, only in Institutional Review Board (RB) approved or, if applicable, FDA-approved studies.



The Microdialysis System

Perfusion Fluid flows from the Microdialysis Pump (a) through the Microdialysis Catheter (b) into a Microvial (c) for collection. After the sampling period, the microvial is transferred to the Microdialysis Analyzer (d) for the analysis. The results are then displayed on the screen.

4

61 Hepatic Microdialysis Catheter

8010226

for metabolic research in liver tissue

ORDERING INFORMATION

61 Hepatic Microdialysis Catheter 4/pkg Ref. No.

61 Hepatic Microdialysis Catheter includes Splitable Introducer SI-2 (4/pkg)

Accessories

For product information on Microvials, Microvial racks, Syringes, Perfusion Fluid and Tunnelating needle, see page 24-27.

Parts of the 61 Hepatic Microdialysis Catheter

 1. Dialysis membrane
 7. Inlet tube

 2. Shaft
 8. Luer-Lock

 3. Liquid cross
 9. Fixating dr

 4. Outlet tube
 10. Suture

 5. Vial holder
 11. Splitable

6. Microvial

8. Luer-Lock connection
 9. Fixating device (PEBAX")
 10. Suture
 11. Splitable Introducer

TECHNICAL INFORMATION

Membrane cut-off: 20 000 Daltons

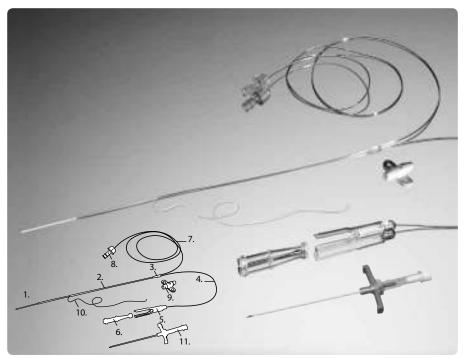
	Material	Length (mm)	Diameter (mm)
Inner Shaft	PUR**	310	0.9
Outer Shaft	PUR**	280	1.5
Membrane	PAES*	30	0.6
Inlet tubing	PUR**	400	1.0
Outlet tubing	PUR**	70	1.0

* polyarylethersulfone ** polyurethane

THE sterile, single use 61 HEPATIC MICRODIALYSIS CATHETER has a very long shaft to allow continuous collection of tissue metabolites in the liver for several days. The dialyzing membrane has excellent diffusion characteristics that allow a high recovery of substances from the extracellular fluid.

The 61 Hepatic Microdialysis Catheter has a shaft length of 310 mm with a 30 mm PAES membrane. It is introduced into the abdominal cavity via a tunnelating needle. Insertion into the liver is achieved with the help of a splitable introducer. After insertion, the catheter shall be fixed with the attached suture.

The inlet tubing of the catheter is connected to a Microdialysis Pump and the outlet ends in a microvial which collects the sample. The samples can be analyzed in the Microdialysis Analyzer for Glucose, Lactate, Pyruvate, Glycerol, Glutamate and Urea or sent to the laboratory for further analysis.



CAUTION: Investigational Device

Limited by United States Law to Investigational Use.

To be used only for Institutional Review Board (IRB) approved or, if applicable, FDA approved studies.

* For monitoring in hepatic tissue
 * Easy to insert into the tissue with the splitable introducer
 * Gold tip for location by CT Scan

62 Gastrointestinal Microdialysis Catheter

for Microdialysis in intraperitoneal cavity

THE sterile, single use 62 GASTROINTESTINAL MICRODIALYSIS CATHETER is a unique device. It allows monitoring and detection of local changes in metabolism in the gastrointestinal tract for several days.

The 62 Catheter has a shaft length of 180 mm with a 30 mm membrane. The catheter is introduced into the intraperitoneal cavity during open surgery.

The dialyzing membrane of this microdialysis catheter has excellent diffusion characteristics that allow a high recovery of substances from the intraperitoneal fluid. The catheter inlet tubing is connected to a Microdialysis Pump and the outlet ends in a microvial which collects the sample. The samples can be analyzed in the Microdialysis Analyzer for Glucose, Lactate, Pyruvate, Glycerol, Glutamate and Urea or sent to the laboratory for further analysis.

CAUTION: Investigational Device Limited by United States Law to Investigational Use. To be used only for Institutional Review Board (IRB) approved or, if applicable, FDA approved studies.

* High biocompatibility * Designed to monitor metabolic changes

* Gold tip for location by CT scan

ORDERING INFORMATION

62 Gastrointestinal Microdialysis Catheter 4/pkg

Ref. No.

Catheters

62 Gastrointestinal	
Nicrodialysis Catheter	8010292

Accessories

For product information on Microvials, Microvial racks, Syringes, Perfusion Fluid and Tunnelating needle, see page 24-27.

Parts of the 62 Gastrointestinal Microdialysis Catheter

 Dialysis membrane
2. Shaft
3. Liquid cross
4. Outlet tube
5 Vial holder

6. Microvial 7. Inlet tube

8. Luer-Lock connection

9. Fixating device (PEBAX")

TECHNICAL INFORMATION

Membrane cut-off: 20 000 Daltons

Material	Length (mm)	Diameter (mm)
PUR**	• •	0.9
PAES*	30	0.6
PUR**	600	1.0
PUR**	220	1.0
	PUR** PAES*	(mm) PUR** 180 PAES* 30 PUR** 600

* polyarylethersulfone ** polyurethane

6

63 Microdialysis Catheter

for Microdialysis in liver, resting skeletal muscle and adipose tissue

ORDERING INFORMATION

63 Microdialysis Catheter

	Ref. No.
63 Microdialysis Catheter 60/10, includes Splitable Introducers	8010509

63 Microdialysis Catheter 8010514 40/30, includes Splitable Introducers

Accessories

For product information on Microvials, Microvial racks, Syringes, Perfusion Fluid and Splitable Introducer, see page 24-27.

Parts of the 63 Microdialysis Catheter

1. Dialysis membrane	6. Microvial
2. Shaft	7. Inlet tube
3. Liquid cross	8. Luer-Lock connection
4. Outlet tube	9. Fixating device (PEBAX')
5. Vial holder	10. Splitable Introducer

TECHNICAL INFORMATION

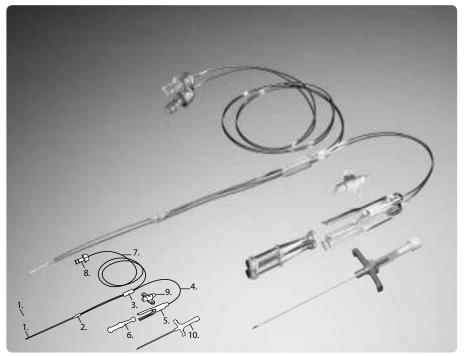
Membrane cut-off: 20 000 Daltons

	Material	Length		Diameter
		(mm) (mm)		(mm)
Shaft	PUR**	60	40	0.9
Membrane	PAES*	10	30	0.6
Inlet tubing	PUR**	600	600	1.0
Outlet tubing	PUR**	220	220	1.0

* polyarylethersulfone ** polyurethane

THE sterile, single use 63 MICRODIALYSIS CATHETER is used in deep buried flaps, subcutaneous adipose tissue, resting skeletal muscle, and for research in hepatic tissue during open surgery. It is available in two different membrane and shaft lengths for the different applications. The catheter is easily introduced into the tissue with a splitable introducer (included) and can be implanted for several days.

The catheter's inlet tubing is connected to a Microdialysis pump and the outlet tubing ends with a microvial holder where the sample is collected into microvials. The samples can be analyzed in the Microdialysis Analyzer for Glucose, Lactate, Pyruvate, Glycerol, Glutamate and Urea or sent to the laboratory for further analysis.



CAUTION: Investigational Device

Limited by United States Law to Investigational Use.

To be used only for Institutional Review Board (IRB) approved or, if applicable, FDA approved studies.

Suitable for many applications
 Splitable Introducers are included
 Gold tip for location by CT scan

7

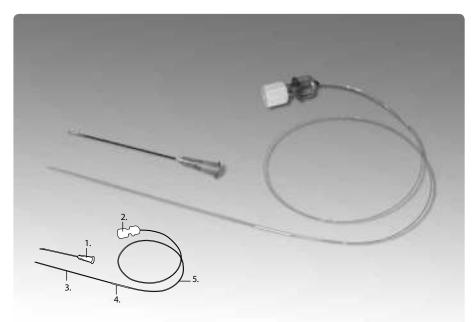
66 Linear Microdialysis Catheter

for use in skin, adipose, and resting skeletal muscle tissue

THE 66 LINEAR MICRODIALYSIS CATHETER is a minimally invasive sterile single use device intended for microdialysis monitoring in skin, adipose or resting skeletal muscle tissue. The catheter is available with either 20,000 or 100,000 Daltons cut off membrane. The 66 is suitable for many research applications: metabolic research, estimating the free concentration of a drug, pharmacokinetic and pharmacodynamic studies or monitoring inflammatory processes in vivo.

Insertion into the tissue is easily done with the help of a small needle introducer. The unique patented linear design makes the catheter robust and safe to use for several days. If ultrafiltration occurs when using the high cut off membrane, we recommend perfusing the catheter with a fluid containing high molecular weight substances to balance colloidal osmosis (e.g. 30g Dextran 60/1000mL).

The samples can be analyzed in the Microdialysis Analyzer for Glucose, Lactate, Pyruvate, Glutamate, Glycerol and Urea or sent to the clinical laboratory for various analyses by methods such as ELISA or HPLC.



CAUTION: Investigational Device Limited by United States Law to Investigational Use. To be used only for Institutional Review Board (IRB) approved or, if applicable, FDA approved studies.

* Available with 20 000 or 100 000 Daltons cut-off
 * Unique Linear Microdialysis Catheter for clinical use

ORDERING INFORMATION

66 Linear Microdialysis Catheter 4/pkg

Ref. No. 66 Linear Catheter 30 mm, 20kD includes Needle introducer 8010650 66 High Cut Off Linear Catheter 30 mm, 100kD includes Needle introducer 8010651 66 Linear Catheter 10 mm, 20kD Includes Needle introducer 8010670 66 High Cut Off Linear Catheter 10 mm, 100kD includes Needle introducer 8010671

Accessories

For product information on Perfusion Fluid and Syringes, see page 25-26 Parts of the 66 Linear Microdialysis Catheter

1. Introducer needle 21 G, 50mm 2. Luer-Lock connection 3. Outlet tube 4. Dialysis membrane 5. Inlet tube

TECHNICAL INFORMATION

Membrane cut-off: 20 000 Daltons or High Cut Off membrane: 100 000 Daltons

	Material	Length		Diamete
		(mm) 8010650/51	(mm) 8010670/71	(mm)
Membrane	PAES*	30	10	0.5
Inlet tubing	PUR**	400	400	0.38
Outlet tubing	PUR**	100	100	0.38

* polyarylethersulfone ** polyurethane

67 Intravenous Microdialysis Catheter

for peripheral blood monitoring

ORDERING INFORMATION

67 IV Microdialysis Catheter 4/pkg

8

	Ref. No.		
67 IV Microdialysis Catheter 46/10, includes Introducer	8050090		
67 IV Microdialysis Catheter 46/20, includes Introducer	8050091		
67 IV Microdialysis Catheter 46/30, includes Introducer	8050092		
67 IV Microdialysis Catheter 130/10, includes Introducer	8050093		

Accessories

For product information on Microvials, Microvial racks and Syringes see page 24-25.

Parts of the 67 IV Microdialysis Catheter

1. Dialysis membrane	6. Microvial
2. Shaft	7. Inlet tube
3. Liquid cross with	8. Luer-Lock connection
Luer-Lock connection	9. Peripheral Venous
4. Outlet tube	Catheter
5. Vial holder	

TECHNICAL INFORMATION

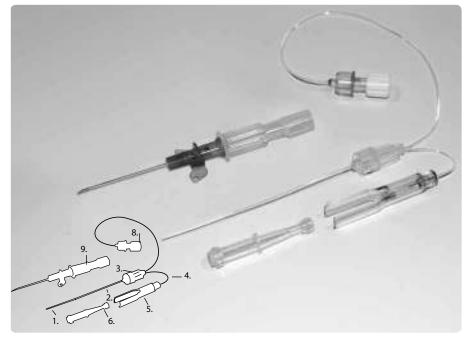
Membrane cut-off: 20 000 Daltons

	Material (mm)		Length (mm) (mm)		Diamete (mm)	
	8050090	8050091	8050092	805009	93	
Shaft	PUR** 46	46	46	130	0.9	
Membrane	PAES* 10	20	30	10	0.6	
Inlet tubing	PUR** 200	200	200	200	1.0	
Outlet tubing	g PUR** 45	45	45	45	1.0	

* polyarylethersulfone ** polyurethane

THE 67 IV MICRODIALYSIS CATHETER is a sterile, single use device intended for intravenous monitoring through a standard peripheral vein catheter (PVC) for up to 72 hours.

The clean samples and possibility for frequent sampling make it ideal for research. Small substances diffuse into the catheter reflecting accurate concentrations in blood. The catheter should be perfused with a physiologic solution containing the anticoagulant dalteparin sodium to avoid clotting. The samples are collected in microvials and can be analyzed as often as every minute. The catheter forms a complete system together with the 106 or 107 Microdialysis Pump and a Microdialysis Analyzer. The catheter is also excellent for continuously monitoring the free concentrations of drugs in blood during pharmacokinetic and pharmacodynamic studies.



CAUTION: Investigational Device

Limited by United States Law to Investigational Use.

To be used only for Institutional Review Board (IRB) approved or, if applicable, FDA approved studies.

- * Continuous intravenous monitoring of substances in the blood for up to 3 days
- * Easy insertion using a standard peripheral venous catheter

70 Brain Microdialysis Catheter

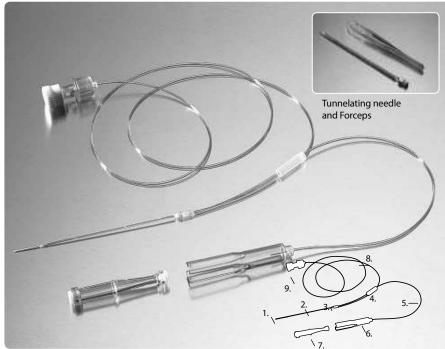
for use in brain tissue

Catheters

Ref No

THE sterile, single use 70 BRAIN MICRODIALYSIS CATHETER is a highly flexible catheter designed for implantation in brain tissue to follow brain metabolism. A selection of this model of catheters is available with different membrane and shaft lengths suitable for stereotaxic as well as manual implantation. When manually implanted in the brain, the 70 Microdialysis Catheter can be tunneled under the scalp and then inserted into the brain tissue through a hole drilled in the skull bone with the help of non-crushing forceps. The tip of the 70 Microdialysis Catheter has a gold thread, which makes it visible on a CT-scan to easily determine its position in vivo.

The catheter inlet tubing is connected to a Microdialysis Pump and the outlet ends in a microvial which collects the sample. The samples can be analyzed in the Microdialysis Analyzer for Glucose, Lactate, Pyruvate, Glycerol and Glutamate or sent to the laboratory for further analysis.



10mm membrane sizes are cleared for use in the USA as part of the neuromonitoring system. CAUTION: All other uses for that catheter and the others noted below (20 and 30 mm membranes) are not FDA cleared and therefore in the USA may only be used with IRB approval or with an IDE from the FDA.

* High biocompatibility * Designed to monitor metabolic changes
 * Gold tip for location by CT scan

ORDERING INFORMATION

70 Brain Microdialysis Catheter 4/pkg

	Ref. NO.
70 Brain Microdialysis Catheter	
60/10	P000049
70 Brain Microdialysis Catheter	
60/20	P000080
70 Brain Microdialysis Catheter	
60/30	P000081
70 Brain Microdialysis Catheter	
100/10	P000050
70 Brain Microdialysis Catheter	
90/20	P000051
70 Brain Microdialysis Catheter	
80/30	P000052

Accessories

Tunnelating needleP000055ForcepsP000056For product information on Microvials, Microvialracks, Syringes, Perfusion Fluid, Tunnelatingneedle and Forceps, see page 24-27.

Parts of the 70 Brain Microdialysis Catheter

1. Dialysis membrane	6. Vial holder
2. Shaft	7. Microvial
3. Liquid cross	8. Inlet tube
4. Stopper	9. Luer-Lock connection
5. Outlet tube	

TECHNICAL INFORMATION

Membrane cut-off: 20 000 Daltons

	Material		Length		Diamete
		(mm)	(mm)	(mm)	(mm)
		P000049	P000080	P000081	
Shaft	PUR**	60	60	60	0.9
Membrane	PA*	10	20	30	0.6
Inlet tubing	PUR**	600	600	600	1.0
Outlet tubing	PUR**	220	220	220	1.0
		P000050	P000051	P000052	
Shaft	PUR**	100	90	80	0.9
Membrane	PA*	10	20	30	0.6
Inlet tubing	PUR**	600	600	600	1.0
Outlet tubing	PUR**	220	220	220	1.0
* nolvamide					

polyamide ** polyurethane

9

70 Microdialysis Bolt Catheter

for use in brain tissue

ORDERING INFORMATION

70 Microdialysis Bolt Catheter 4/pkg

Ref. No.

P000131

70 Microdialysis Bolt Catheter 130/10

Accessories

For product information on Microvials, Microvial racks, Syringes and Perfusion Fluid, see page 24-25.

Parts of the 70 Microdialysis Bolt Catheter

1. Dialysis membrane	5. Vial holder
2. Shaft	6. Microvial
3. Liquid cross with	7. Inlet tube
Luer-Lock connection	8. Luer-Lock connection
4. Outlet tube	

TECHNICAL INFORMATION

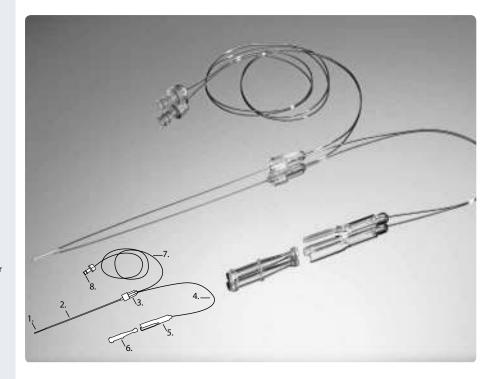
Membrane cut-off: 20 000 Daltons

	Material	Length (mm)	Diamete (mm)
Shaft	PUR**	130	0.9
Membrane	PA*	10	0.6
Inlet tubing	PUR**	600	1.0
Outlet tubing	PUR**	220	1.0

* polyamide ** polyurethane

THE sterile, single use 70 MICRODIALYSIS BOLT CATHETER is designed for implantation in brain tissue through an intracranial access device that has been fixed to the skull. The catheter's Luer-Lock fitting connects to a port on an intracranial access device from Integra. The catheter's steel reinforcement prevents flow obstruction when the compression screw of the bolt is tightened. The shaft length of the microdialysis catheter is 130 mm and the dialyzing membrane length is 10 mm.

The catheter inlet tubing is connected to a Microdialysis Pump and the outlet ends in a microvial which collects the sample. The samples can be analyzed in the Microdialysis Analyzer for Glucose, Lactate, Pyruvate, Glycerol and Glutamate or sent to the laboratory for further analysis. This catheter is FDA-cleared for use in humans as part of the Neuromonitoring System.



- * Implanted through a lumen in an intracranial access bolt from Integra
- * Gold tip for location by CT scan

71 High Cut-Off Brain Microdialysis Catheter

allows sampling of large molecules

THE sterile, single use 71 HIGH CUT-OFF BRAIN MICRODIALYSIS CATHETER is minimally invasive and designed for implantation in brain tissue through tunnelation. The large pore size of this catheter allows diffusion of large molecules such as cytokines and inflammatory markers. If ultrafiltration occurs we recommend perfusing the catheter with a fluid containing high molecular weight substances to balance colloidal osmosis (e.g. Dextran). The catheter inlet tubing is connected to a Microdialysis Pump and the outlet ends in a microvial which collects the sample.

ORDERING INFORMATION

71 High Cut-Off Brain Microdialysis Catheter 4/pkg



Accessories

For product information on Microvials, Microvial racks, Syringes, Tunnelating needle and Forceps, see page 24-27.

Parts of the 71 High Cut-Off Brain **Microdialysis Catheter**

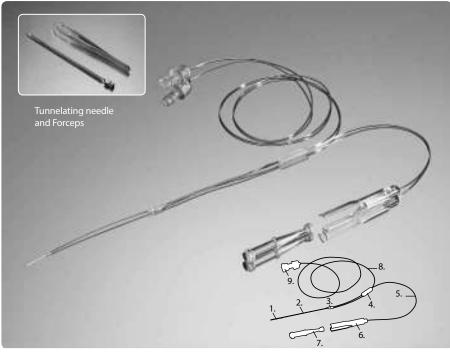
1. Dialysis membrane	6. Vial holder
2. Shaft	7. Microvial
3. Liquid cross	8. Inlet tube
4. Stopper	9. Luer-Lock connection
5. Outlet tube	J. Eder Eber connection

TECHNICAL INFORMATION

Membrane cut-off: 100 000 Daltons

	Mate (r	erial nm)	Len <u>c</u> (mm) (r	gth mm)	Diameter (mm)
		80	10320 80103	31 8010337	
Shaft	PUR**	60	60	60	0.9
Membrane	PAES*	10	20	30	0.5
Inlet tubing	PUR**	600	600	600	1.0
Outlet tubing	PUR**	220	220	220	1.0

* polyarylethersulfone ** polyurethane



CAUTION: Investigational Device Limited by United States Law to Investigational Use. To be used only for Institutional Review Board (IRB) approved or, if applicable, FDA approved studies.

* Designed for use together with the portable 106 and 107 Microdialysis Pump

* With gold tip, visible on CT * Used to recover large molecules such as cytokines

12 Catheters Custom Made Catheters

ORDERING INFORMATION

Custom Made Catheters

Ref. No. P000046

Custom Made Catheters

Prior to the acceptance of an order for custom catheters, the specifications must be submitted for approval.

CUSTOM MADE CATHETERS can be produced for many advanced Microdialysis applications. The approval process includes an assessment of sterility validation based on the proposed specifications of the custom made catheter. Custom made production takes 6-12 weeks from approval.



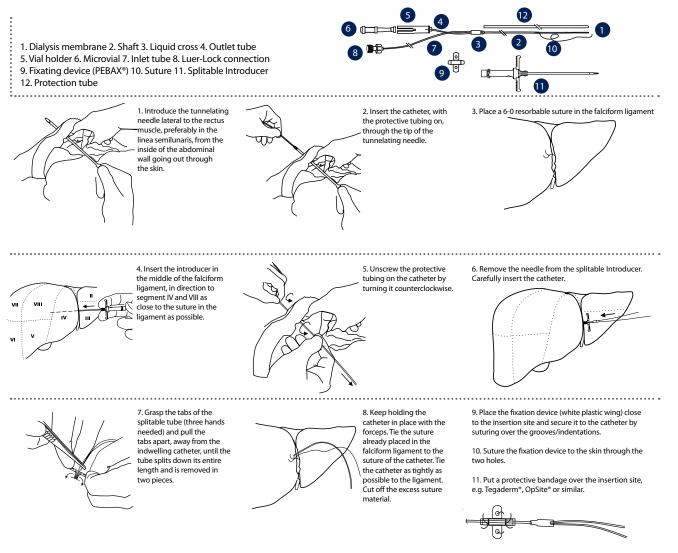
CAUTION: Investigational Device Limited by United States Law to Investigational Use. To be used only for Institutional Review Board (IRB) approved or, if applicable, FDA approved studies.



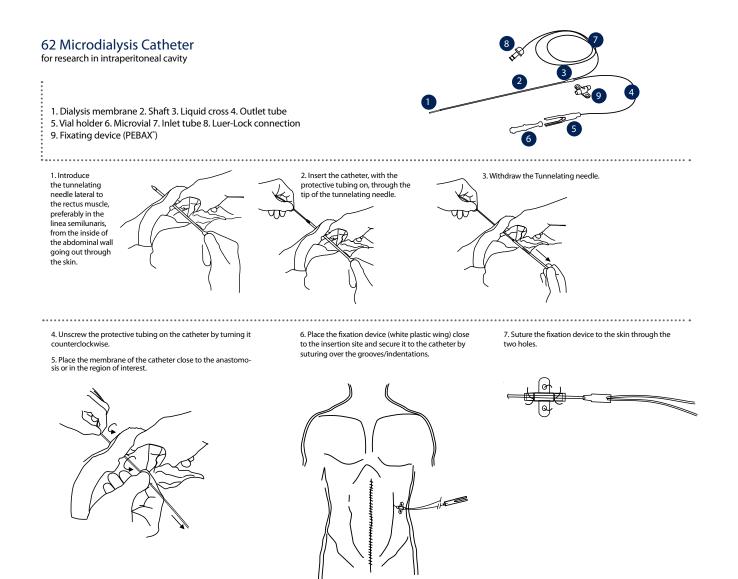
14

Implantation of catheters

61 Hepatic Microdialysis Catheter for metabolic research in liver tissue



Implantation of catheters



16

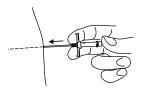
Implantation of catheters

63 Microdialysis Catheter for resting skeletal muscle, subcutaneous adipose tissue and research in liver during open surgery

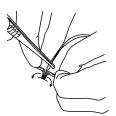
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- 1. Dialysis membrane 2. Shaft 3. Liquid cross 4. Outlet tube
- 5. Vial holder 6. Microvial 7. Inlet tube 8. Luer-Lock connection
- 9. Fixating device (PEBAX®) 10. Splitable Introducer

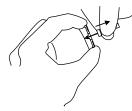
1. Break the handles of the Splitable Introducer before insertion to avoid damaging the tissue.



4. Carefully insert the Microdialysis Catheter into the splitable tube. Do not touch the white membrane of the catheter.



2. Insert the Introducer completely to the handle of the splitable tube into the tissue.



3. Remove the Introducer needle carefully while keeping the splitable tube in position. Do not reinsert the introducer needle after withdrawal.

5. Grasp the tabs of the splitable tube (three hands needed) and pull the tabs apart, away from the indwelling catheter, until the tube splits down its entire length.

6. If needed, carefully anchor the catheter. Please use the fixation devices included in the package.

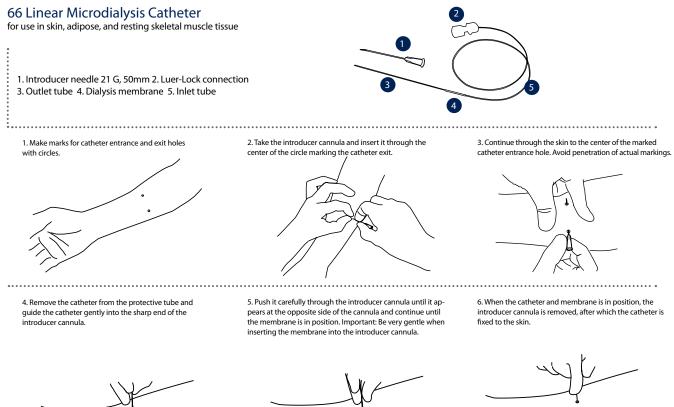


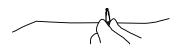
7. If needed the Microdialysis Catheter can also be fixated to the skin by sutures around the stopper on the catheter.

8. Cover the insertion site with a protective bandage.

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Implantation of catheters







Implantation of catheters

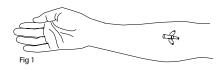
67 IV Microdialysis Catheter for peripheral blood monitoring

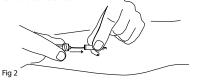
1. Dialysis membrane 2. Shaft 3. Liquid cross with Luer-Lock connector 4. Outlet tube 5. Vial holder 6. Microvial 7. Inlet tube 8. Luer-Lock connection 9. Peripheral Venous Catheter (PVC)

1. Connect the inlet tubing of the 67 IV MD catheter to the syringe and place it in a 106/107 Pump. Close the lid to start the pump.

• 2. Insert the peripheral venous catheter delivered with 67 IV Microdialysis catheter in a peripheral vein accoording to normal hospital routines

(Fig 1). Observe that the peripheral venous catheter (PVC) delivered with the 67 IV Microdialysis catheter must be used. Flush the PVC with a saline solution.





3. Unscrew the protective tubing and remove it from the 67 IV Microdialysis catheter. Insert 67 IV Microdialysis catheter through the peripheral venous catheter (Fig 2) and fixate it by attaching the luer-lock of the 67 IV Microdialysis catheter to the luer-lock of the peripheral venous catheter (Fig 3).

6



4.Connect the catheter to the pump. Attach the pump to the patient by a bandage or similar

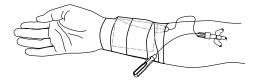
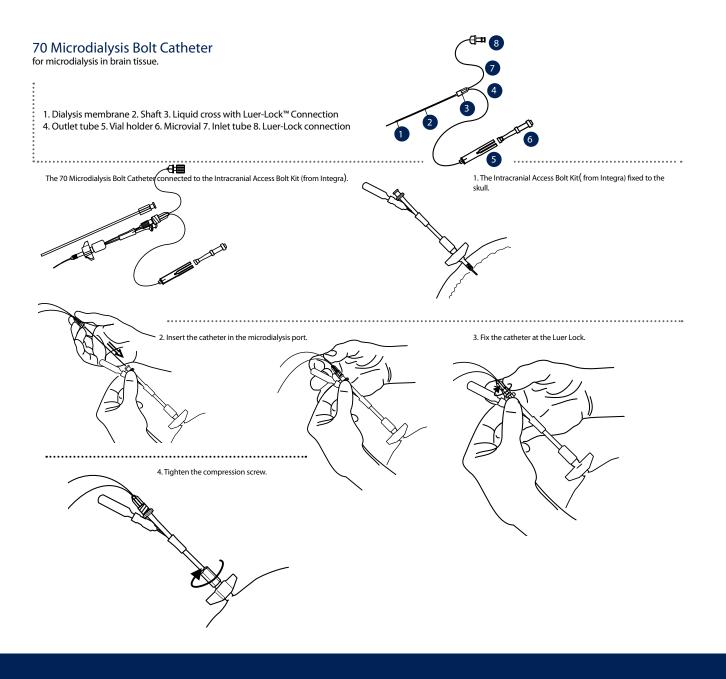


Fig 4

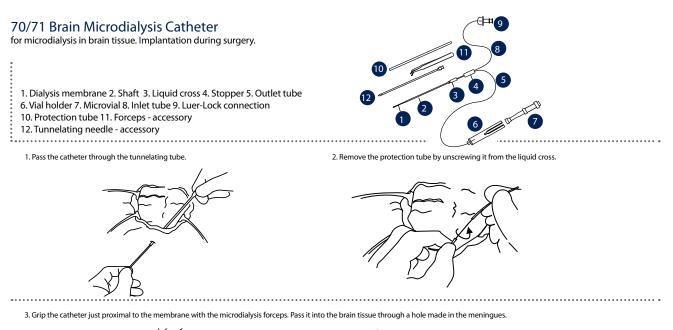
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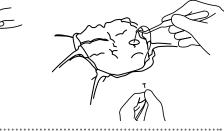
Implantation of catheters



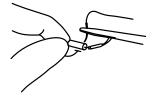
Implantation of catheters



A B



4. Stretch the catheter and fix it firmly to the scalp by suturing around the stopper.



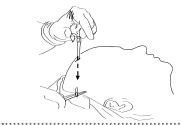
21

Implantation of catheters

70/71 Brain Microdialysis Catheter for microdialysis in brain tissue. Percutaneous Implantation. 1. Dialysis membrane 2. Shaft 3. Liquid cross 4. Stopper 5. Outlet tube 6. Vial holder 7. Microvial 8. Inlet tube 9. Luer-Lock connection 10. Protection tube 11. Forceps - accessory 12. Tunnelating needle - accessory 2. Perforate the meninges (including the Pia Mater). 1. Drill a small hole.



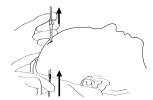
3. Create a tunnel under the skin using the tunnelating needle.



5. Unscrew the protection tube from the catheter.



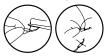
4. Insert the 70 Brain Microdialysis catheter into the beveled end of the tunnelating needle, then remove the tunnelating needle.

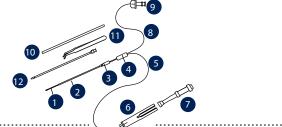


6. Insert the catheter with the forceps through the hole made in the meninges.



7. Stretch the catheter inlet and outlet tubing to externalize the excess and fix it firmly to the scalp by suturing around the stopper.







Pumps

106 Microdialysis Pump

a portable, fixed-flow, battery-operated pump

ORDERING INFORMATION

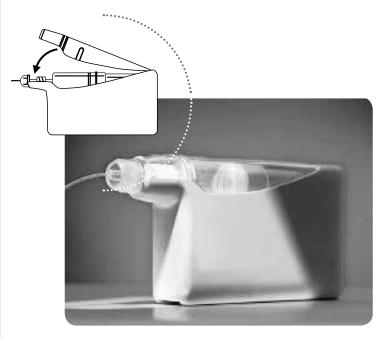
106 Microdialysis Pump

	Ref. No.
106 Microdialysis Pump	P000003

Accessories

MD Pump Kit, Peripheral Tissue	8003790
MD Pump Kit, Brain Tissue	8003791
Syringe, 20/pkg	8010191
Battery, 2x3 V	8001788
Perfusion Fluid, T1, 5 mL, 10/pkg	P000034
Perfusion Fluid, CNS, 5 mL, 10/pkg	P000151

THE 106 MICRODIALYSIS PUMP has been developed to function together with Microdialysis Catheters. Portable and battery-driven, this small lightweight microprocessor-controlled syringe pump is very easy to use. The syringe, filled with 2.5 mL of a sterile perfusion fluid and connected to a catheter, is placed in the carriage of the pump. When the lid is closed, the pump automatically starts a flush sequence (15 μ L/min) for the first 5 minutes to fill the lines. Thereafter the flow rate decreases automatically to 0.3 μ L/min. Colored LEDs indicate function, enabling the user to easily oversee the operation.



TECHNICAL INFORMATION

Normal Flow rate: Fixed, 0.3 µL/min Flush flow: 15 µL/min Dimension: 90 x 50 x 20 mm Weight: 70g (incl. Battery) Battery: 6V Silver oxide Casing: ABS plastic, splash proof Operating temperature: +5 to +40°C Alarms: Error, Low battery

* Portable, small and lightweight
 * Easy to handle
 * Self-controlled with LED function signals
 * Splash proof

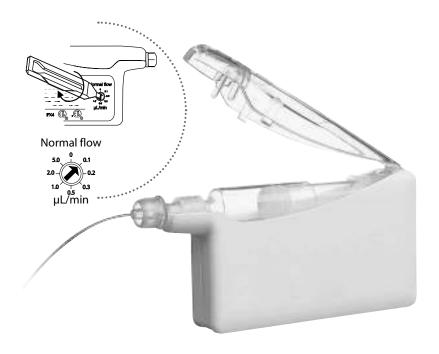
Pumps

107 Microdialysis Pump

a portable, adjustable flow, battery-operated pump

THE 107 MICRODIALYSIS PUMP is a unique 2.5 mL syringe pump with flexibility in flow rate that enables the user to change the flow for different purposes: low flow rate for high recovery of low molecular weight substances in a tissue, or high flow rate for blood flow measurements and for more frequent sampling intervals. The operating flow is adjustable to eight different settings: 0, 0.1, 0.2, 0.3, 0.5, 1.0, 2.0 and 5.0 μ L/min.

The 107 Microdialysis Pump is a portable battery-driven pump and very easy to use. The syringe is filled with 2.5 mL of sterile perfusion fluid, connected to the microdialysis catheter and then placed in the pump. When the pump lid is closed, a 5-minute flush cycle begins and is followed by an automatic decrease to the pre-set operating rate.



CAUTION: Investigational Device Limited by United States Law to Investigational Use. To be used only for Institutional Review Board (IRB) approved or, if applicable, FDA approved studies.

* Portable, small and lightweight
 * Easy to handle
 * Self-controlled with LED function signals
 * Splash proof
 * Variable flow

ORDERING INFORMATION

107 Microdialysis Pump

	Ref. No.
07 Microdialysis Pump	P000127
Accessories	

MD Pump Kit, Peripheral Tissue	8003790
MD Pump Kit, Brain Tissue	8003791
Syringe, 20/pkg	8010191
Battery, 2 x 3V	8001788
Perfusion Fluid, T1, 5 mL,10/pkg	P000034
Perfusion Fluid, CNS, 5 mL,10/pkg	P000151

TECHNICAL INFORMATION

Normal Flow: Variable, 0.1-5 μ L/min, 8 settings Flush flow: 15 μ L/min Dimension: 90 x 50 x 20 mm Weight: 70g (incl. battery) Battery: 6V Silver oxide Casing: ABS plastic, splash proof Operating temperature: +5 to +40°C Alarms: Error, Low battery

Accessories

Microvials and Microvial Racks

ORDERING INFORMATION

Microvials

		Ref. No.
Microvials	250/pkg	P000001
Microvial R	acks	
		Ref. No.
Microvial Rack, 12	/pkg	P000028
Microvial R	acks, Sterile	
		Ref. No.
Microvials in a rac	k, 12 x 4	P000154

MICROVIALS are designed to collect micro-volume samples and minimize evaporation. Each vial holds 200 µL. If needed sterile microvials are packed and sold in racks for use under sterile conditions.

MICROVIAL RACKS. To minimize evaporation, samples in microvials can be placed in a Microvial Rack prior to storage in the refrigerator or freezer. The rack can store and close 12 microvials and facilitate the logistics of sample handling.



Accessories

Syringe and Perfusion Fluid

of Perfusion Fluid.

THE SYRINGE is specially designed for the 106 and 107 Microdialysis Pumps. The syringe holds 2.5 mL

PERFUSION FLUID is an isotonic sterile solution developed specifically for microdialysis probe and catheter perfusion. Perfusion Fluids are available for use in both the central nervous system (CNS) and peripheral tissue (T1). The fluid is conveniently packaged in glass ampoules, 5 mL each, sterile and ready to use.



ORDERING INFORMATION

Syringe	2	
		Ref. No.
Syringe 20/pkg		8010191
Perfusi	on Fluid	
		Ref. No.
Perfusion F 10/pkg, 5 n	luid T1 nL glass ampoule	P000034 s
Contents: NaCl 1- KCl 4 CaCl, 2 Total chlori 155.6 mmo	mmol/L .3 mmol/L de content:	
Perfusion F 10/pkg, 5 m	luid CNS nL glass ampoule	P00015
Contents: NaCl 1-	17 mmol/l	
KCI 2	.7 mmol/L	
	2 mmol/L	
0.0 1	.85 mmol/L	

Accessories

Microdialysis Pump Kit

ORDERING INFORMATION

MD Pump Kit, Peripheral Tissue

	Ref. No.
ID Pump Kit, Peripheral Tissue 106/107 Syringe, 1 battery,	8003790
Perfusion Fluid T1	

8003791

MD Pump Kit, Brain Tissue

MD Pump Kit, Brain Tissue 1 106/107 Syringe, 1 battery, 1 Perfusion Fluid CNS

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1 11 MICRODIALYSIS PUMP KIT, Peripheral Tissue

This Pump Kit includes the accessories needed for single patient microdialysis monitoring in peripheral tissue. The kit contains a syringe, a battery and a T1 perfusion fluid ampoule.

MICRODIALYSIS PUMP KIT, Brain Tissue

This Pump Kit includes the accessories needed for single patient microdialysis monitoring in brain tissue. The kit contains a syringe, a battery and a CNS perfusion fluid ampoule.



Accessories

Splitable Introducer, Tunnelating Needle and Forceps

THE SPLITABLE INTRODUCER is intended for easy insertion of the 61 Hepatic Microdialysis Catheter and the 63 Microdialysis Catheter

ORDERING INFORMATION

Splitable Introducer SI-2 4/pkg

Ref. No.

Splitable Introducer SI-2

8010343

TECHNICAL INFORMATION

	Material	Length	ID (OD)
Solitable tube	HDPE*	(mm) 74	(mm) 1.0 (1.5)
Cannula	Stainless Steel	77	(1.0)

* High-density polyethylene

Tunnelating Needle & Forceps

Ref. No.

Tunnelating Needle, 1/pkg P000055 Forceps, 1/pkg P000056

TECHNICAL INFORMATION

	Material	Length	ID (OD)
Tunnelating Needle	Stainless Steel	(mm) 139	(mm) 3,0 (3,5)
Forceps	Stainless Steel	118	



TUNNELATING NEEDLE AND FORCEPS. A tunnelating needle and a special forceps simplify the insertion when using the Brain Microdialysis Catheters. The tunnelating needle is also used to introduce the catheter through the abdominal wall during Gastro Intestinal and Transplant Surgery.



ISCUS^{flex} Microdialysis Analyzer

for point-of-care and advanced research

ORDERING INFORMATION

ISCUS^{fex} Microdialysis Analyzer

	Ref. No.
ISCUS ^{IIII} Microdialysis Analyzer	8003295
ISCUS ^{tec} Microdialysis Analyzer, Resear For research use only	ch 8003296

Includes: KUpilot[™] Software

NOTE: This product may not be approved by your national regulatory authorities. Please contact your local representative for further information

TECHNICAL INFORMATION

Weight: 29 lbs/13 kg Voltage: 100-240 V-, 50/60 Hz Power consumption: 100 WA Dimensions: 430 (H) x 350 (W) x 270 (D) mm Type of protection: Class 1, Type B Measurement principle: Kinetic enzymatic analyzer Vials: Microvials, 300uL glass vials Samples: Microdialysates Sample volume used: 0.2 - 2 µL/analysis (depending on analyte) Min, sample volume: Sum of sample volumes per analyte + 2 µL Reagent consumption: <15 µL/analysis (depending on analyte) Pipetting imprecision: < 2 % (0.5 µL) rel. standard deviation Calibration : Automatic (every 6 hrs) Wwm-up time: 10 minutes Measuring time: 30 seconds Time per test: 60 - 90 seconds Throughput: 30 measurements per hour Detector type: Single beam filter photometer Light source: Class 1M LED Wavelengths: 375 and 530 nm Detector cell temperature: 99°F/37°C Detector cell: Capillary flow cell 10 mm, 2 µL Assay imprecision: <4 % rel. standard deviation for Control Sample Normal Assay inaccuracy: <10 % for Control Sample Normal ISCUSth is a Microdialysis Analyzer for point-of-care and advanced research. This analyzer uses enzymatic reagents and colorimetric measurements to monitor tissue chemistry from within microdialysis samples taken from virtually any tissue or organ in the body.

The analyzer is easy to operate by medical professionals and researchers alike. Up to six different reagents (glucose, lactate, pyruvate, glycerol, glutamate, and urea) provide unique opportunities for early detection of metabolic crisis and ischemia and to guide therapeutic interventions. The analysis results are displayed as trend curves for easy and fast interpretation. For comparison with other monitoring data, the unique ICUpilot[™] software is included for installation on a separate computer.

ISCUS^{IIII} combines reliability and flexibility. It offers the opportunity to monitor several subjects at a time and with a capacity of 16 vials, the ISCUS^{IIII} offers batch analysis for advanced research. The throughput of the analyzer is 30 measurements per hour.



- * Easy to operate graphical user interface * Quick one-button 2 minute analysis * Batch capacity of 16 samples * Less than 2 µL of sample required per analysis
- * Automatic calibration and controls

ISCUS^{flex} Microdialysis Analyzer

for point-of-care and advanced research

ORDERING INFORMATION



Ref. No.Reagent Set A, Incl.8002163Reagent Glucose 1 x 6 mL8002163Reagent Lactate 1 x 6 mLReagent Glycerol 1 x 6 mLCalibrator A 1 x 6 mL8002164Reagent Glucose 1 x 6 mL8002164Reagent Set B, Incl.8002164Reagent Glycerol 1 x 6 mL8002164Reagent Glycerol 1 x 6 mL8002165Reagent Glucose 1 x 6 mL8002165Reagent Lactate 1 x 6 mL8000011Reagent Kit, Incl.9000011Reagent Glucose 1 x 6 mL8010361Reagent Lactate 1 x 6 mL8010361Reagent Lactate 1 x 6 mL8010361Reagent Lactate 1 x 6 mL8010361Glucose Reagent, 6 mL, 5/pkg900023Lactate Reagent, 6 mL, 5/pkg900024Pyruvate Reagent, 6 mL, 5/pkg900025Glutamate Reagent, 6 mL, 5/pkg900026Calibrator A 6 mL, 10/pkg900057Control Samples 5 mL,80103062 levels 2 x 5/pkg8010306Control Samples 5 ro US 5 mL,8002171Winsing Fluid for Analyzer, 8 x 0,5 L8002171 </th <th>Accessories</th> <th></th>	Accessories	
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Rinsing Fluid for Analyzer, 8 x 0.5 L 8002171		0010500
		9002171
Waste Bottles, 0.5L 8/pkg 8002161		
Thermal Print Paper roll, 4/pkg 8002162		
Sample Cannula 8001721		
Secure Digital Memory Card 8002360		
Vial Glass 300µL* 7431007	•	
Vial Adapter P000114		
ISCUS Vial Cassette 8003409		
ISCUS Maintenance kit 8002792	ISCUS Maintenance kit	8002792

* Needs to be bought by CMA Microdialysis AB For product information on Reagents, see page 30-31 For product information on LABpilot™ and ICUpilot™, see page 32

Reagents

Glucose

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Glucose oxidase method for analysis of microdialysates

Measuring principle

Glucose is enzymatically oxidized by glucose oxidase (GOD). The hydrogen peroxide formed reacts with phenol and 4-amino-antipyrine. This reaction is catalyzed by peroxidase (POD) and yields the red-violet colored quinoneimine. The rate of formation is measured photometrically at 530 nm and is proportional to the Glucose concentration.

D-Glucose + O₂ $\xrightarrow{\text{GOD}}$ luconolactone + H₂O₂ 2 H₂O₂ + phenol + 4-amino-antipyrine $\xrightarrow{\text{POD}}$ quinoneimine + 4 H₂O

Lactate

Lactate oxidase method for analysis of microdialysates

Measuring principle

Lactate is enzymatically oxidized by lactate oxidase. The hydrogen peroxide formed reacts with 4-chlorophenol and 4-amino-antipyrine. This reaction is catalyzed by peroxidase (POD) and yields the red-violet colored quinoneimine. The rate of formation is measured photometrically at 530 nm and is proportional to the Lactate concentration. $\begin{array}{l} L\text{-Lactate} + O_2 \quad \stackrel{\text{LOD}}{\longrightarrow} pyruvate + H_2O_2 \\ H_2O_2 + 4\text{-chloro-phenol} + 4\text{-amino-antipyrine} \\ \stackrel{\text{POD}}{\longrightarrow} \quad quinoneimine + 2 \ H_2O + HCI \end{array}$

Pyruvate

Pyruvate oxidase method for analysis of microdialysates

Measuring principle

Pyruvate is enzymatically oxidized by pyruvate oxidase (PyrOx). The hydrogen peroxide formed reacts with N-ethyl-N-(2-hydroxy-3-sulfopropyl)-m-toluidine (TOOS) and 4-amino-antipyrine. This reaction is catalyzed by peroxidase (POD) and yields the red-violet colored quinonediimine. The rate of formation is measured photometrically at 530 nm and is proportional to the Pyruvate concentration.

Pyruvate + O_2 + inorganic phosphatePyrOxacetylphosphate + CO_2 + H_2O_2 H_2O_2 + TOOS + 4-amino-antipyrinequinonediimine + 4 H_2O

Glycerol

Glycerol colorimetric method for analysis of microdialysates

Measuring principle

Glycerol is phosphorylated by adenosine triphosphate (ATP) and glycerol kinase (GK) to glycerol-3-phosphate, which is subsequently oxidized in the presence of glycerol-3-phosphate oxidase (GPO). The hydrogen peroxide formed reacts with 3,5-dichloro-2-hydroxy-benzene sulphonic acid (DCHBS) and 4-amino-antipyrine. This reaction is catalyzed by peroxidase (POD) and yields the red-violet colored quinoneimine. The rate of formation is measured photometrically at 530 nm and is proportional to the Glycerol concentration.

Glycerol + ATP \xrightarrow{GK} Glycerol-3-phosphate + ADP Glycerol-3-phosphate + O₂ \xrightarrow{GPO} dihydroxyacetone phosphate + H₂O₂ H₂O₂+ DCHBS + 4-amino-antipyrine \longrightarrow ACBS + 2 H₂O + HCl

Reagents

Glutamate

Glutamate oxidase method for analysis of microdialysates

Measuring principle

Glutamate is enzymatically oxidized by glutamate oxidase (GltOx). The hydrogen peroxide formed reacts with N-ethyl-N-(2-hydroxy-3-sulfopropyl)-m-toluidine (TOOS) and 4-aminoantipyrine. This reaction is catalyzed by peroxidase (POD) and yields the red-violet colored guinonediimine. The rate of formation is measured photometrically at 530 nm and is proportional to the Glutamate concentration.

Urea

Urea UV-method for analysis of microdialysates

Measuring principle

Urea is hydrolyzed in the presence of urease to ammonium ions and carbon dioxide. The ammonium ions react with 2-oxoglutarate in the presence of glutamate dehydrogenase (GIDH) and NADH to form glutamate and NAD⁺. The rate of utilization of NADH is measured photometrically at 370 nm and is proportional to the Urea concentration.

Calibrator A

For calibration of Glucose Reagent, Lactate Reagent, Pyruvate Reagent

Glycerol Reagent, Glutamate Reagent and Urea Reagent

The Microdialysis Analyzers use enzymatic reagents that are commonly used in clinical chemistry.

At present reagents for glucose, lactate, pyruvate, glycerol, glutamate and urea are available. The assays are based on kinetic measurements in order to get the analytical results as quickly as possible instead of waiting for the enzymatic reaction to reach completion, which might take several minutes. The absorbance change during the first 30 s of the reaction is monitored and the maximal reaction rate during this time is used for quantification.

A single multicomponent calibrator, containing known concentrations of the different analytes is used for calibrating the assays. Since the reaction rate is proportional to the analyte concentration, quantification is done by comparing the calculated slope of the obtained absorbance versus time curve with that obtained from measuring the calibrator solution with its known analyte concentrations.

Glutamate + $O_2 \xrightarrow{GltOx} 2$ -oxoglutarate $+ H_{2}O_{2} + NH_{3}$ POD H₂O₂ + TOOS + 4-amino-antipyrine quinonediimine + 4 H₂O

Analyte Concentration

Glucose	5.55 mmol/L	
Lactate	2.5 mmol/L	
Pyruvate	250 µmol/L	
Glycerol	475 µmol/L	
Glutamate 25 µmol/l	-	
Urea	13.3 mmol/L	

L-glutamate + NAD⁺ + H₂O

Urea + H_2O	$\stackrel{\text{Urease}}{\longrightarrow} 2 \text{ NH}_3 + \text{CO}_2$	
2-oxoglutara	ate + NH_4^+ + NADH	GIDH

LABpilot[™] and ICUpilot[™] Software

data navigation in the laboratory

ORDERING INFORMATION

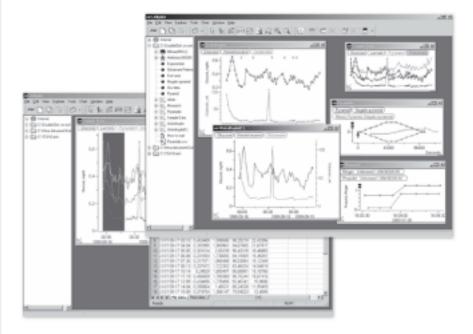
LABpilot[™] Software and ICUpilot[™]Software

	Ref. No.
LABpilot** Software	P000157
ICUpilot [™] Software	8001027

These two computer programs are designed to handle microdialysis and other data collected over time. The programs' graphic interfaces allow integration and synchronization of microdialysis data from several subjects for faster data interpretation.

Simply copy MS Excel files and paste or drag directly onto the LABpilot[™] or ICUpilot[™] window to instantaneously generate graphs. Just one click can transform data from real time to elapsed time, from absolute values to percent values, view data as regression plots, display means, medians, SEM or SD.

The ICUpilot[™] software enables connection with other patient monitors and automatic collection of multimodal monitoring data.



Designed to work using a graphical interface.

The software facilitates processing a large number of data using graphs – not numbers. Display, compare, comment and interpret the data.

Easy to handle graphic interface # Display, compare, comment and interpret graphs # Allows for faster data interpretation # Allows for easy collaboration and communication

Vial Adapter for MD Analyzers

THE ISCUS^{flex} MICRODIALYSIS ANALYZER was originally developed to handle samples collected in Microvials (P000001). However, with the Vial Adapter for MD Analyzers, it is possible to use the ISCUS^{flex} for analysis of samples collected in 300 μL glass vials.



ORDERING INFORMATION

Vial Adapter for MD Analyzers

Ref. No.

Includes:	P000114
35 Vial Adapters	
Used with glass vials from CMA	Microdialysis AB.

ISCUS^{flex} Normal Linear Range

REAGENT	LINEAR INTERVAL	SAMPLE VOLUME μ L	REAGENT VOLUME μL
Glucose	0.1 - 25 mmol/L	0.5	14.5
Lactate	0.1 - 12 mmol/L	0.2	14.8
Pyruvate*	10 - 1500 µmol/L	0.5	14.5
Glycerol	10 - 1500 µmol/L	0.5	14.5
Glutamate	1 - 150 μmol/L	1.5	7.5
Urea	0.5 - 25 mmol/L	0.5	14.5



* Pyruvate default linear range is low linear range

Methods for lower sample concentration

In basic research, samples are generally acquired at higher flow rates (1 - 5 μ L/min) which results in lower analyte recoveries. In order to facilitate the analysis of these samples, the ISCUS^{flex} Microdialysis Analyzer can be configured to use more sensitive methods for the following analytes:

ISCUS^{flex} Low Linear Range

REAGENT	LINEAR INTERVAL	SAMPLE VOLUME μ L	REAGENT VOLUME μ L
Glucose	0.02 - 6.0 mmol/L	2.0	13.0
Lactate	0.02 - 2.5 mmol/L	0.8	14.2
Pyruvate*	2 - 900 µmol/L	2.0	13.0
Glycerol	2 - 500 µmol/L	2.0	13.0

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General Information



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Customer Support General Information

Customer Support

Support and Technical Service

Head Office

For general information about the technique and for more information regarding our products you are welcome to contact us or the local distributor in your area.

We have a skilled staff available to solve your technical problems if an equipment oriented problem should arise.

Obtain a return authorization number from either your local Representative or Service before you return any products for repair.

A detailed description will help minimize cost and turnaround time.

Visit www.mdialysis.com for the latest technical support and service information.

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US Office

Phone: (866) 868 9236 Fax: (978) 251 1960 Email: usa@mdialysis.com service.usa@mdialysis.com



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Contact Us

Contact Us

Head Office (Sweden)

The head office of M Dialysis is located in Stockholm, Sweden not far from the Karolinska Institute. The branch office in Boston is responsible for the US, Canada and South America. Distributors in other countries can be found at www.mdialysis.com

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³⁹ Notes

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