Spiegelberg:

Technology for brains

Intracranial Pressure Monitoring

Contents

ICP-Monitoring with Spiegelberg Air-Pouch Method

The Air-Pouch System

The Air-Pouch System consists of a hollow body connected to a pressure transducer by tubing. The pressure transducer, the electronic hardware, and the device for filling the Air-Pouch are integrated in the Brain-Pressure Monitor.

Position of Probe

For intraventricular or intraparenchymal pressure measurement the Air-Pouch is placed in the ventricle or in the parenchyma, respectively. For epidural pressure measurement the Air-Pouch is placed on the dura of the patient.

How it works

The intracranial pressure is transmitted across the thin pouch wall to the air volume in the pouch and transformed into an electric signal by the pressure transducer.

The Monitor

On the digital display, the mean pressure and the amplitude of the pressure wave are shown. At the monitor output, the pulsatile signal is available.

The ICP-Monitor can be connected to all intensive care unit bedside monitors through their pressure transducer input.

A voltage output allows the connection to chart recorders.

Through an RS 232 interface, a computer can be connected to read out the pressure signal.

The ICP-Monitor zeroes automatically once per hour. This automatic in-vivo zeroing is a unique feature of the Air-Pouch System.

Benefit of Spiegelberg ICP-Monitoring:

- Plug&Play technology
- Simultaneous ventriculostomy and ICP-Monitoring
- Automatic hourly calibration
- Probes MR Conditional
- Cost-efficient

Spiegelberg Air-Pouch Technology

Probe 3PS

ICP-Monitor | HDM26.1

Description	REF
ICP-Monitor 230 V	HDM26.1/FV500
ICP-Monitor 115 V	HDM26.1/FV503

Technical Information

Weight measurement	3,3 kg
Measurement range	-50 to +100 mmHg
Accurancy	+/-2 mmHg
Monitor output	5 µV/mmHg/V

The ICP-Monitor uses the Air-Pouch method for measuring intracranial pressure. It is compatible with the full range of Air-Pouch probes, with the CPP-Monitor and the Compliance-Monitor.

The digital display indicates mean ICP, systolic ICP and diastolic ICP. Additionally a mains power control light is visible.

ICP-Monitor | HDM29.1

Description	REF
ICP-Monitor with Batteries (indicate voltage)	HDM29.1

Technical Information

Weight measurement	3,4 kg
Battery running time	up to 4 hours
Measurement range	-50 to +100 mmHg
Accurancy	+/-2 mmHg
Monitor output	5 µV/mmHg/V

The ICP-Monitor uses the Air-Pouch method for measuring intracranial pressure. It is compatible with the full range of Air-Pouch probes, with the CPP-Monitor and the Compliance-Monitor.

The digital display indicates mean ICP, systolic ICP and diastolic ICP. Additionally a charge control light and a battery state indicator are visible.

The HDM29.1 is equipped with rechargeable batteries that allow more than three hours of independent operation.

ICP-Monitor | HDM29.2

Proven technology in a new design

Easy to use - precise results

Easier handling in clinical day-to-day life
More than 50% lighter than previous model.

Improved display through latest technology
Clear and distinct display of mean, systolic and diastolic ICP as well as indicator for battery level and battery charge.

Proven Plug&Play function for ease of use
Connect Spiegelberg air-pouch probe, switch on, automatic calibration - done.
Safe and comfortable method of zeroing between ICP-Monitor and bedside monitor with the →0←button.

Battery operation
The ICP-Monitor is equipped with rechargeable batteries. The monitor can be used up to 6 hours without power supply.

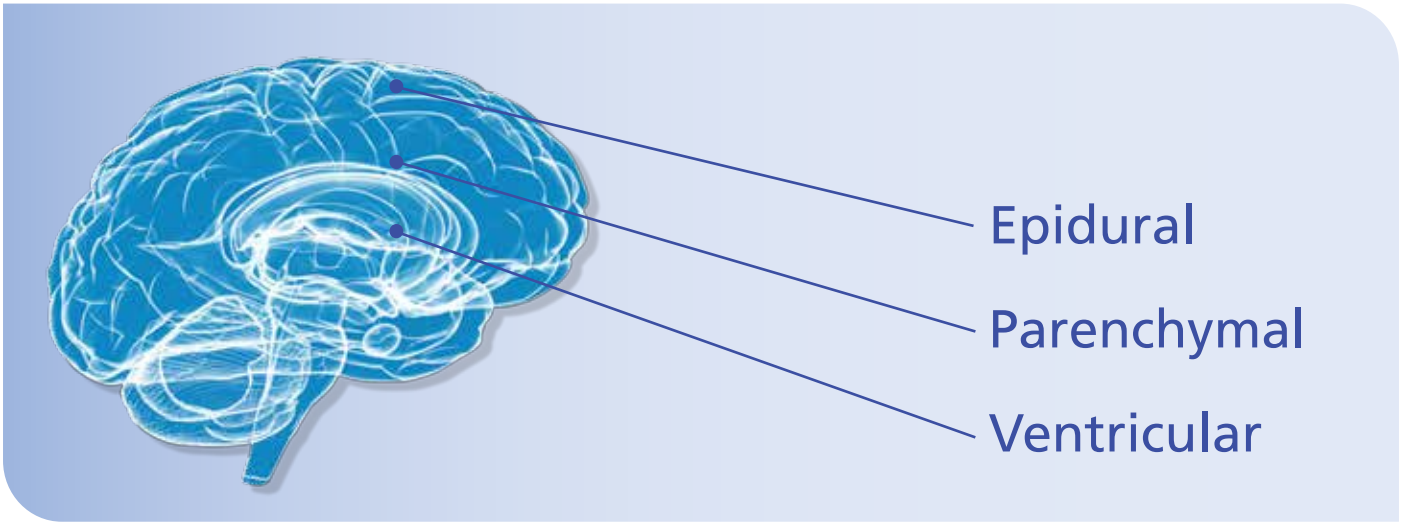
Connectivity options
Two sockets in the back allow connection to a patient bedside monitor and a computer.

Description	**REF**
ICP-Monitor	HDM29.2

Technical Information

Weight measurement	1.5 kg
Battery running time	up to 6 hours
Measurement range	-50 to +100 mmHg
Accurancy	+/-2 mmHg
Operation voltage	115-230 V, 50/60 Hz
Monitor output	5 µV/mmHg/V

Areas for monitoring



Epidural Probes

Probe 1

Probe 1 is placed concentrically on the dura. It is used when intracranial pressure monitoring with minimum risk of infection is desired.

A burr hole of 11 mm diameter is required. In adults this can be drilled with a standard trepan. For thin skull caps the use of a Martell Drill or hand drill is recommended.

Description	**REF**
Probe 1	SND13.1.11/FV530P
Technical Information	
Material	Polyurethane
Filling volume	0.05 - 0.1 cc
Outer diameter	2 mm
Length	1500 mm
Air-Pouch diameter	16 mm
Burr hole diameter	11 mm
Duration of use	Short term, not more than 30 days
Shelf life	3 years
Double packed	
EO sterile	
For single use	
Latex free	

Probe 2

Probe 2 is to be used postoperatively after large trepanation. It is placed under the bone flap.

After mobilization of a sufficiently large area of the dura, the probe can be inserted between the dura and the cranial bone through a burr hole.

Description	**REF**
Probe 2	SND13.1.12/FV531P
Technical Information	
Material	Polyurethane
Filling volume	0.05 - 0.1 cc
Outer diameter	2 mm
Length	1500 mm
Air-Pouch width	11 mm
Air-Pouch length	25 mm
Duration of use	Short term, not more than 30 days
Shelf life	3 years
Double packed	
EO sterile	
For single use	
Latex free	

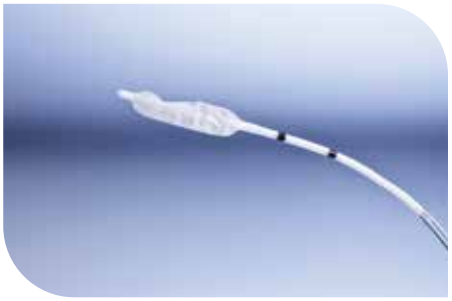
Parenchymal Probes

Probe 3PN

Probe 3PN measures intraparenchymal pressure.

Probe 3PN is placed in the parenchyma through a burr hole. Probe 3PN can be tunneled with the aid of the tunneling tool ZBH13.001.03.

Probe 3PN is fixed to the skin with a suturing flap.



Description	**REF**
Probe 3PN	SND13.1.53/FV534P
Technical Information	
Material	Polyurethane
Filling volume	0.05 - 0.1 cc
Diameter	1.3 mm
Length	1500 mm
Air tube	radiopaque
Depth marks	30mm 40mm
Duration of use	Short term, not more than 30 days
Shelf life	3 years
Double packed	
EO sterile	
For single use	
Latex free	

Probe 3PN with Trocar

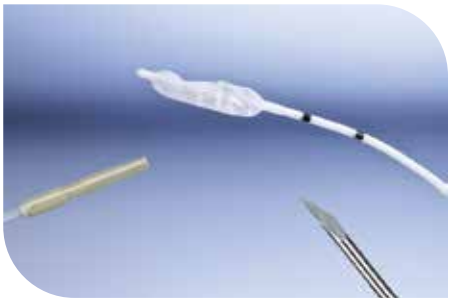
Probe 3PN with Trocar measures intraparenchymal pressure.

The Probe is placed in the parenchyma through a burr hole.

Probe 3PN with Trocar is tunneled by means of the trocar in a surgically correct fashion away from the burr hole. To facilitate the tunneling, the air tube is equipped with a connector that is taken up by the trocar.

After tunneling, the trocar is removed and the air tube is connected to the ICP-Monitor by means of the extension.

Probe 3PN is fixed to the skin with a suturing wing.



Description	**REF**
Probe 3PN with Trocar	SND13.1.54
Technical Information	
Material	Polyurethane
Filling volume	0.05 - 0.1 cc
Diameter	1.3 mm
Length	1500 mm
Air tube	radiopaque
Depth marks	30 mm 40 mm
Duration of use	Short term, not more than 30 days
Shelf life	3 years
Double packed	
EO sterile	
For single use	
Latex free	

Probe 3PS

Probe 3PS measures intraparenchymal pressure.

Probe 3PS is placed in the parenchyma through a bolt that is screwed into the cranial bone. A compression screw connection fixes the probe in the bolt and tightens it.

Description	**REF**
Probe 3PS	SND13.1.63/FV535P
Technical Information	
Material	Polyurethane
Filling volume	0.05 - 0.1 cc
Diameter	1.3 mm
Length	1500 mm
Air tube	radiopaque
Duration of use	Short term, not more than 30 days
Shelf life	3 years
Double packed	
EO sterile	
For single use	
Latex free	

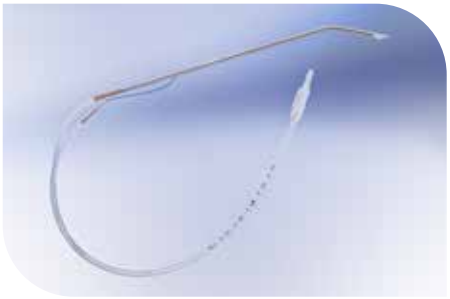
Ventricular Probes

Probe 3 / Probe 3XL

Probe 3 measures intraventricular pressure using an Air-Pouch mounted in the tip region of a dual lumen probe. One lumen transmits the pressure to the Brain-Pressure Monitor. The second lumen is used for drainage of CSF. The measurement of pressure in the parenchyma is also possible. There is no interference of drainage and pressure measurement.
As opposed to measurements via CSF coupled pressure transducers, ICP is still transmitted in the case of slit ventricles.
Probe 3XL has all the properties of Probe 3. Furthermore, it is equipped with a wider drainage lumen for use in conditions of blood in the CSF.

Description	Probe 3	Probe 3XL
REF	SND13.1.13/FV532P	SND13.1.13XL/FV533P
Technical Information		
Material	Polyurethane	Polyurethane
Filling volume	0.05 - 0.1 cc	0.05 - 0.1 cc
Outside diameter	2.3 mm	3 mm
Inside diameter drainage	1 mm	1.6 mm
Dual lumen length with radiopaque stripe	130 mm	130 mm
Single lumen length (Drainage)	150 mm	150 mm
Single lumen length (Air-System)	1370 mm	1370 mm
Depth marks	50 - 100 mm	50 - 100 mm
Duration of use	Short term, not more than 30 days	Short term, not more than 30 days
Shelf life	3 years	3 years
Double packed		
For single use		
EO sterile		
Latex free		

True Tunneling Intraventricular Probe 7F / 9F



Ventricular probes are tunneled by means of the dual trocar in a surgically correct fashion away from the burr hole. To facilitate the tunneling, the air tube is equipped with a connector, that is taken up by the trocar together with the drainage tube. After tunneling, the trocar is removed and the air tube is connected to the ICP-Monitor by means of the extension. The drainage tube is connected to a drainage kit with the Luer connector

Description	True Tunneling Intraventricular Probe 7F	True Tunneling Intraventricular Probe 9F
REF.	SND13.1.13TT	SND13.1.13XLTT
Technical Information		
Material	Polyurethane	Polyurethane
Filling volume	0.05 - 0.1 cc	0.05 - 0.1 cc
Outside diameter	2.3 mm	3 mm
Inside diameter drainage	1 mm	1.6 mm
Dual lumen length with radiopaque stripe	130 mm	130 mm
Single lumen length (Drainage)	150 mm	150 mm
Single lumen length (Air-System)	1370 mm	1370 mm
Depth marks	50 - 100 mm	50 - 100 mm
Duration of use	short term, not more than 30 days	short term, not more than 30 days
Shelf life	3 years	3 years
Double packed		
For single use		
EO sterile		
Latex free		

Silverline® Ventricular Probes

Silverline® Intraventricular Probe

Silverline ventricular probes are tunneled by means of the dual trocar in a surgically correct fashion away from the burr hole. To facilitate the tunneling, the air tube is equipped with a connector, that is taken up by the trocar together with the drainage tube. After tunneling, the trocar is removed and the air tube is connected to the ICP-Monitor by means of the extension. The drainage tube is connected to a drainage kit with the Luer connector.

Silverline probes incorporate a silver additive intended to reduce the possibility that the surfaces of the device become microbially compromised.

Description	Silverline® Intraventricular Probe 8F	Silverline® Intraventricular Probe 10F
REF	SND13.1.14	SND13.1.15
Technical Information		
Material	Silver impregnated radiopaque polyurethane	Silver impregnated radiopaque polyurethane
Filling volume	0.05 - .1 ml	0.05 - .1 ml
Outer diameter	2.7 mm	3.3 mm
Inner diameter drainage	1.5 mm	2 mm
Length of dual-lumen probe	200 mm	200 mm
Length of single lumen drainage tube	70 mm	70 mm
Length of single lumen air tube	95 mm	95 mm
Length of extension tube	1200 mm	1200 mm
Depth marks	50 - 100 mm 150 mm	50 - 100 mm 150 mm
Duration of use	short term, not more than 30 days	
Shelf life	3 years	
Double packed For single use EO sterile Latex free		

Silverline® Intraventricular Probe with Bolt

The Silverline ventricular probe with bolt is fixed in the bone by means of a bolt. After making a burr hole and opening the dura the probe is placed in the ventricle with the bolt in place in the upper region of the probe. Then the bolt is slid down to the burr hole and screwed into the bone. Finally the probe is fixed in the bolt with the clamping nut. The Luer-connector is placed in the drainage tube and connected to a drainage kit. The air tube is connected to the ICP-Monitor.

The tip of the probe is equipped with four rows of drainage holes, just like a ventricular catheter.
Silverline probes incorporate a silver additive intended to reduce the possibility that the surfaces of the device become microbially compromised.

Description	**REF**
Silverline® Intraventricular Probe with Bolt 8F	SND13.1.14S
Technical Information	
Material	Silver impregnated radiopaque polyurethane
Filling volume	0.05 - 0.1 ml
Outer diameter	2.7 mm
Inner diameter drainage	1.5 mm
Length of dual-lumen probe	200 mm
Length of single lumen air tube	1300 mm
Length of single lumen drainage tube	70 mm
depth marks	50 mm 60 mm 70 mm
Duration of use	short term, not more than 30 days
Shelf life	3 years
Double packed EO sterile For single use Latex-free	

Accessories

The Tunneling Tool

The Tunneling Tool is an accessory for the sterile placement of Probe 3, Probe 3XL, and Probe 3PN.

The Tunneling Tool consists of a metal trocar, a tapered splitable tube, and a guide wire.

Description	REF
Tunneling Tool Kit for Probe 3	ZBH13.001.01/FV536R
Tube for Tunneling Tool Probe 3	ZBH13.002.01/FV537P
Tunneling Tool Kit for Probe 3XL	ZBH13.001.02/FV538R
Tube for Tunneling Tool Probe 3XL	ZBH13.002.02/FV539P
Tunneling Tool Kit for Probe 3PN	ZBH13.001.03
Tube for Tunneling Tool Probe 3PN	ZBH13.002.03

Technical Information

Material trocar	Stainless steel
Material guide wire	Stainless steel
Material tube	Biocompatible plastic alloy
Length trocar	200 mm

The Pole Mount

With the Pole Mount an ICP-Monitor, CPP-Monitor or combinations thereof are securely held on a wall rail or on an IV-pole.

Description	REF
Pole Mount	ZBH26.001.01

Technical Information

For rail profile	10 mm x 25 mm
For IV-pole diameter	15 mm - 30 mm
Area	200 mm x 200 mm
Maximum load	7 kg

Connecting Cables

Description	REF
Monitor Cables for HDM and CPP	
Datex-Cardiocap	KBL13.007.00/FV608
Hellige 4./5. Generation	KBL13.003.00/FV609
Hewlett Packard/Philips	KBL13.004.00/FV610
Marquette/GE Carescare	KBL13.005.00/FV612
Propaq/Mennen	KBL13.009.00/FV617
Siemens/Draeger, 10-pins (Sirecust)	KBL13.002.00/FV620
Space-Labs	KBL13.006.00/FV622
Computer Cables RS 232 for HDM and CPP	
IBM-AT, 9 pins, 1.5 m	KBL13.033.00/FV656

Above cables are an extract of our product portfolio.
Your cable is not listed? Tell us what you need,
we will supply the solution.

ICP-Lab

Data Capture
The ICP Lab software has been written to allow data capture from the Spiegelberg ICP-Monitor, CPP-Monitor, and Compliance-Monitor (CMP) using data connection and a Windows XP up to Windows7 32bit computer.

ICP Lab captures up to five signals simultaneously:

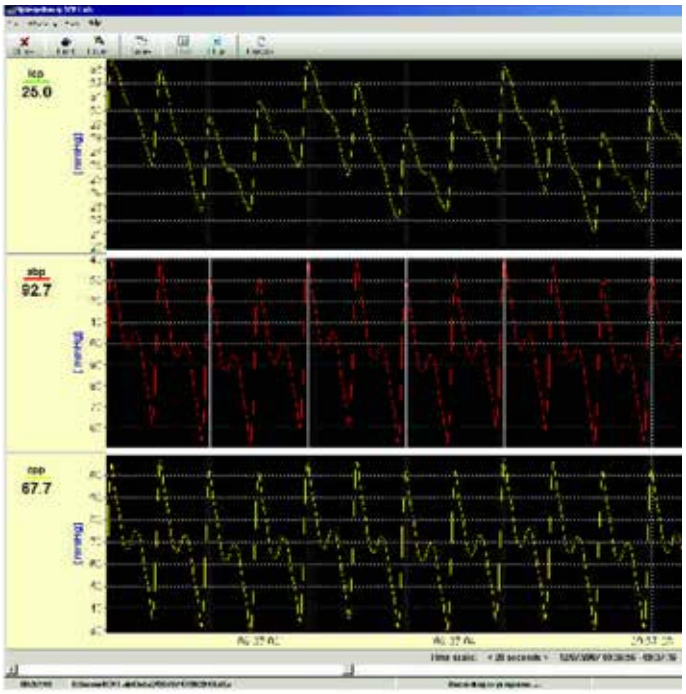
- ICP
- ABP
- CPP
- Compliance
- PVI

Sampling Frequency
The data collection can be made with sampling frequency of up to 100 Hz. The data is then stored in a file using ICM+ software raw signals format '.dta'.

Browsing
The ICP Lab software contains some basic tools for signal browsing. The time scale and pressure scale can be chosen individually. Printing of selected time intervals can be performed in black and white or full color on any of the standard printers of your computer.

Advanced Analysis
For more advanced analysis the data can be exported to a text file and then imported to a spreadsheet application like Excel.

However, for best results it should be analysed using specialised software for ICP waveforms analysis like ICM+.



Trial Version
The software will work for one month. After the trial period, you will need to register the software. To register you will need to obtain a license from your distributor. With the license you will get a license number.

Compatibility
ICP Lab uses the same data format as ICM+. It is fully upward compatible. All data files created with ICP Lab can be later analyzed by ICM+.

For more Information, please contact us.
Note: Not for clinical use.

MR Safety Information

Non-clinical testing has demonstrated that Spiegelberg Probes are MR-conditional at 1.5T and 3T. A patient with these devices may be safely scanned in an MR system provided that the MR safety information accompanying the product is followed.

Manufacturer

Spiegelberg GmbH & Co. KG
Tempowerkring 4
21079 Hamburg
Germany

Phone: **+49-40-790-178-0**
Fax: **+49-40-790-178-10**
Email: **info@spiegelberg.de**
Internet: **www.spiegelberg.de**

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