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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
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.

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

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**Technical Information**

<table>
<thead>
<tr>
<th>Description</th>
<th>Technical Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICP-Monitor</td>
<td>Battery running time</td>
</tr>
<tr>
<td></td>
<td>-50 to +100 mmHg</td>
</tr>
<tr>
<td></td>
<td>+/-2 mmHg</td>
</tr>
<tr>
<td></td>
<td>Operation voltage</td>
</tr>
<tr>
<td></td>
<td>115-230 V, 50/60 Hz</td>
</tr>
<tr>
<td></td>
<td>Monitor output</td>
</tr>
<tr>
<td></td>
<td>5 µV/mmHg/V</td>
</tr>
</tbody>
</table>

**Parameters**

- **Weight measurement**: 1.5 kg
- **Battery running time**: up to 6 hours
- **Measurement range**: -50 to +100 mmHg
- **Accuracy**: +/-2 mmHg

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

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.
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.

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.

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.
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.

Technical Information

- **Material**: Polyurethane
- **Filling volume**: 0.05 - 0.1 cc
- **Outside diameter**: 2.3 mm
- **Inside diameter drainage**: 1 mm
- **Dual lumen length with radiopaque stripe**: 130 mm
- **Single lumen length (Drainage)**: 150 mm
- **Single lumen length (Air-System)**: 1370 mm
- **Depth marks**: 50 - 100 mm
- **Duration of use**: 3 years
- **Shelf life**: 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.
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.

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.

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<table>
<thead>
<tr>
<th>Description</th>
<th>Silverline® Intraventricular Probe 8F</th>
<th>Silverline® Intraventricular Probe 10F</th>
</tr>
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<tbody>
<tr>
<td>REF</td>
<td>SND13.1.14</td>
<td>SND13.1.15</td>
</tr>
</tbody>
</table>

**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 drainage tube**: 70 mm
- **Length of single lumen air tube**: 95 mm
- **Length of extension tube**: 1200 mm
- **Depth marks**: 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

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<table>
<thead>
<tr>
<th>Description</th>
<th>Silverline® Intraventricular Probe with Bolt 8F</th>
</tr>
</thead>
<tbody>
<tr>
<td>REF</td>
<td>SND13.1.14S</td>
</tr>
</tbody>
</table>

**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.

<table>
<thead>
<tr>
<th>Description</th>
<th>REF</th>
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</thead>
<tbody>
<tr>
<td>Tunneling Tool Kit for Probe 3</td>
<td>ZBH13.001.01/FV536R</td>
</tr>
<tr>
<td>Tube for Tunneling Tool Probe 3</td>
<td>ZBH13.002.01/FV537P</td>
</tr>
<tr>
<td>Tunneling Tool Kit for Probe 3XL</td>
<td>ZBH13.001.02/FV538R</td>
</tr>
<tr>
<td>Tube for Tunneling Tool Probe 3XL</td>
<td>ZBH13.002.02/FV539P</td>
</tr>
<tr>
<td>Tunneling Tool Kit for Probe 3PN</td>
<td>ZBH13.001.03</td>
</tr>
<tr>
<td>Tube for Tunneling Tool Probe 3PN</td>
<td>ZBH13.002.03</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Description</th>
<th>REF</th>
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</thead>
<tbody>
<tr>
<td>Pole Mount</td>
<td>ZBH26.001.01</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Description</th>
<th>REF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monitor Cables for HDM and CPP</td>
<td></td>
</tr>
<tr>
<td>Datex-Cardiocap</td>
<td>KBL13.007.00/FV608</td>
</tr>
<tr>
<td>Hellige 4./5. Generation</td>
<td>KBL13.003.00/FV609</td>
</tr>
<tr>
<td>Hewlett Packard/Philips</td>
<td>KBL13.004.00/FV610</td>
</tr>
<tr>
<td>Marquette/GE Carescare</td>
<td>KBL13.005.00/FV612</td>
</tr>
<tr>
<td>Propaq/Mennen</td>
<td>KBL13.009.00/FV617</td>
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<tr>
<td>Siemens/Draeger, 10-pins (Sirecust)</td>
<td>KBL13.002.00/FV620</td>
</tr>
<tr>
<td>Space-Labs</td>
<td>KBL13.006.00/FV622</td>
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</tbody>
</table>

Computer Cables RS 232 for HDM and CPP

<table>
<thead>
<tr>
<th>Description</th>
<th>REF</th>
</tr>
</thead>
<tbody>
<tr>
<td>IBM-AT, 9 pins, 1.5 m</td>
<td>KBL13.033.00/FV656</td>
</tr>
</tbody>
</table>

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

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