Introducing the INVOS™ 7100 regional oximetry system.

INVOS™ technology has set the clinical standard for regional oximetry, which is supported by more than 600 peer-reviewed publications. The new INVOS™ 7100 system integrates that technology to provide the same clinical performance of the INVOS™ 5100C system.

Reliable and validated characteristics include:

- Accurate value based on a good correlation with field saturation (75% venous to 25% arterial ratio)
- Optimal sensor spacing of 3 and 4 centimeters
- Wavelengths of 730 and 810 nanometers
- Clinically responsive algorithm

The INVOS™ 7100 system also shows trending performance comparable to that of the INVOS™ 5100C system. Based on this trending similarity, clinical data and studies collected from the INVOS™ 5100C system apply to the INVOS™ 7100 system.

Next-generation improvements include:

- Tablet-style touchscreen monitor that is lighter, smaller, and easy to move with the patient
- Intuitive interface for fast, easy data interpretation
- Smaller sensor footprint for co-use with the BIS™ monitoring system

The INVOS™ 7100 system uses fully validated INVOS™ technology to ensure the brain is measured with an accurate value sensitive to clinical changes. It provides the same trusted performance with improved workflow and ease of use across the continuum of care. Because seconds matter.

We updated the INVOS™ 7100 system using feedback from global customers who currently use the INVOS™ 5100C system. As the next step in the foundational INVOS™ system strategy, it offers a platform for innovation now and in the future.
VALIDATION OF THE INVOS™ VALUE AT DIFFERENT LEVELS OF OXYGENATION AND CARBON DIOXIDE


<table>
<thead>
<tr>
<th>Study design</th>
<th>Single-center</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arms</td>
<td>Comparison of the INVOS™ system value to field saturation of 75% venous and 25% arterial blood</td>
</tr>
<tr>
<td>Objective</td>
<td>To validate the accuracy of the INVOS™ system value by comparing it to field saturation of 75% venous and 25% arterial while changes in oxygenation and carbon dioxide were induced in subjects in a simulated clinical environment</td>
</tr>
<tr>
<td>N</td>
<td>42</td>
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<tr>
<td>Population</td>
<td>Healthy volunteer subjects ranging from 20 to 36 years old</td>
</tr>
<tr>
<td>Design</td>
<td>Adult INVOS™ sensors from the INVOS™ 4100 system were placed on the subjects’ right foreheads</td>
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<td></td>
<td>End tidal O₂ (PetO₂) was adjusted to five levels: 80, 45, 60, and 41 mm Hg and FIO₂ controlled at 50% during the blood draws for field saturation</td>
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<tr>
<td></td>
<td>A resting normal end tidal CO₂ was established in each subject (PetCO₂) and then elevated to 2 and 7 mm Hg above resting PetCO₂</td>
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<tr>
<td></td>
<td>A total of 410 points of field saturation measurements were compared</td>
</tr>
<tr>
<td>Results</td>
<td>The first graph represents 410 ‘static’ measurements,² or the individual points in time when the INVOS™ value was compared to the field saturation</td>
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<tr>
<td></td>
<td>The study found an r² value of 0.76 and a standard deviation of 5%</td>
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<td></td>
<td>A second graph combined 378 points of measurement to determine if the INVOS™ system accurately tracked changes in the field saturation when the oxygenation and carbon dioxide levels were altered²</td>
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<tr>
<td></td>
<td>Results showed an r² of 0.96, almost a perfect correlation between the blood draw for the field saturation and INVOS™ system values; the standard deviation was 2.8% and showed few outliers²</td>
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<tr>
<td>Conclusions</td>
<td>Good correlation was found between INVOS™ technology and field saturation. INVOS™ system values were statistically significant when compared to field saturation when static measurements were taken. The significance was even higher when examining whether the INVOS™ system value tracked with changes in oxygen and carbon dioxide levels.</td>
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</tbody>
</table>

![Graph 1](image1.png)

410 points

\[ r^2 = 0.76 \]

\[ SD = 5\% \]

![Graph 2](image2.png)

378 points

\[ r^2 = 0.96 \]

\[ SD = 2.8\% \]
### VALIDATION OF INVOS™ TECHNOLOGY SPACING


<table>
<thead>
<tr>
<th>Study design</th>
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</thead>
<tbody>
<tr>
<td>Arms</td>
<td>Comparison of different spacing with an INVOS™ sensor from 1 to 4.5 cm, testing each 0.5 cm</td>
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<tr>
<td>Objective</td>
<td>To test the correct distance between LED emitters and detectors in the INVOS™ device to ensure penetration of cerebral tissue</td>
</tr>
<tr>
<td>N</td>
<td>14</td>
</tr>
<tr>
<td>Population</td>
<td>Subjects ranging from 28 to 83 years old</td>
</tr>
<tr>
<td>Design</td>
<td>• Adult sensors were placed on each side of the subjects’ right and left foreheads. The left sensor had a detector spacing of 1.5, 2.5, 3.5, and 4.5 cm and the right sensor had a detector spacing of 1, 2, 3, and 4 cm • Indocyanine green dye was injected in separate tests into the internal and external carotid</td>
</tr>
<tr>
<td>Results</td>
<td>• When dye was injected into the <em>external</em> carotid, the intensity of the dye was detected similarly at all distances because the dye was in the scalp and bone • When dye was injected into the <em>internal</em> carotid, the more distant the detector was from the emitter the larger the intensity • Reliable detection of dye injected into the internal carotid first occurred at 2.5 cm</td>
</tr>
<tr>
<td>Conclusions</td>
<td>These findings show that the distances of 3 and 4 cm chosen for INVOS™ technology ensure that the outermost portion of the brain is interrogated.</td>
</tr>
</tbody>
</table>

[Diagram of LED emitter, Proximal detector, Distal detector, Left Side Sensor, Right Side Sensor distances]
### Study design
- Single-center, nonrandomized, prospective study conducted at Clinimark Laboratories in Louisville, CO

### Arms
- Comparison of monitors for the INVOS™ 5100c and INVOS™ 7100 systems

### Objective
- To ensure that the trending performance of the INVOS™ 7100 system is comparable to that of the INVOS™ 5100c system, with an rSO2 trending precision of less than or equal to 2.9% standard deviation measured by an INVOS™ 5100c system with an adult sensor at somatic and cerebral sites

### N
- 27

### Population
- Healthy volunteer subjects ranging from 19 to 48 years old with distribution across both genders. Range of skin pigmentation includes 67% light skin tone, 11% medium skin tones, and 22% dark skin tones.

### Design
- Adult INVOS™ sensors from the 5100c and 7100 monitors were placed cerebrally and somatically on the subjects’ foreheads and calves
- The hypoxia sequence was induced over the saturation range of ~70% to 100% SpO2 levels using Nellcor™ pulse oximetry and a Max-A sensor
- Subjects were given a mixture of oxygen and nitrogen to induce hypoxia to the targeted SpO2 level, which was maintained for 2 to 3 minutes
- Data was collected via the Medtronic raw data acquisition system (RDAS)

### Results
- Cerebral trending was 1.95%
- Somatic trending was 1.98%
- Standard acceptable criterion was less than 2.9% standard deviation between the INVOS™ 5100c and INVOS™ 7100 systems
- Both values were in the acceptable range of less than 2.9%

### Conclusions
- These results provide supporting evidence that the INVOS™ 7100 system with an adult sensor performs within acceptable trending precision compared to the INVOS™ 5100c system at cerebral and somatic sites. Based on the similar trending performance, clinical studies and data collected from the INVOS™ 5100c system also apply to the INVOS™ 7100 system. Both systems also demonstrated trending similarity in medium to dark skin subjects, which was how one-third of the subjects were classified.

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2. Based on internal report #18-PM-0051. Page 1, 3INE, 2INE, 4INE, 8INE. Page 5, 1INM. – Based on internal test report MDT17069MAPARE(RE00126834) – Comparison 5100c vs. PM7100 Clinical Study Report – Based on internal report #10125972 – PMSENS71-A drawing – Based on internal report #312552 SAFB-SM drawing – PM7100 Firmware (10153110) – 5100c Firmware (10005333)
5. Based on clinical study report, Comparison of 5100C versus PM7100.

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**Medtronic**

IMPORTANT: Please refer to the package insert for complete instructions, contraindications, warnings and precautions.

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